

Zantac 150 1ct Sachet/Pouch

09.27.18

ZAN_150_1ct_Pouch_Mexico_0100658-01_FDA_2018_FNL4



Sanofi Regulatory Specifications		Verified Date: 09/27/18
Drug Facts Info		
Drug Facts (Title)	Font name:	NA point type
Drug Facts (continued)	Font name:	NA point type
Headings	Font name: Helvetica Neue 77 Bold Condensed	4.4 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	4.4 point type
Body Text	Font name: Helvetica Neue 57 Condensed	4.4 point type
Bullets	Font name: Helvetica Neue 57 Condensed	4.4 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		N/A
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	4 pt.	Maximum Characters/Inch: 50
Barlines:	N/A pt.	Hairlines: N/A pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.0324 in
PDP dimensions (in millimeters)		H 50mm W 75mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 6 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 32 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 1ct Sachet/Pouch

09.27.18

ZAN_150_1ct_Pouch_Spain_0100660-01_FDA_2018_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/27/18
Drug Facts Info		
Drug Facts (Title)	Font name:	NA point type
Drug Facts (continued)	Font name:	NA point type
Headings	Font name: Helvetica Neue 77 Bold Condensed	4.4 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	4.4 point type
Body Text	Font name: Helvetica Neue 57 Condensed	4.4 point type
Bullets	Font name: Helvetica Neue 57 Condensed	4.4 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		N/A
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	4 pt.	Maximum Characters/Inch: 50
Barlines:	N/A pt.	Hairlines: N/A pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.0324 in
PDP dimensions (in millimeters)		H 50mm W 75mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 6 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 32 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 3ct Carton

09.27.18

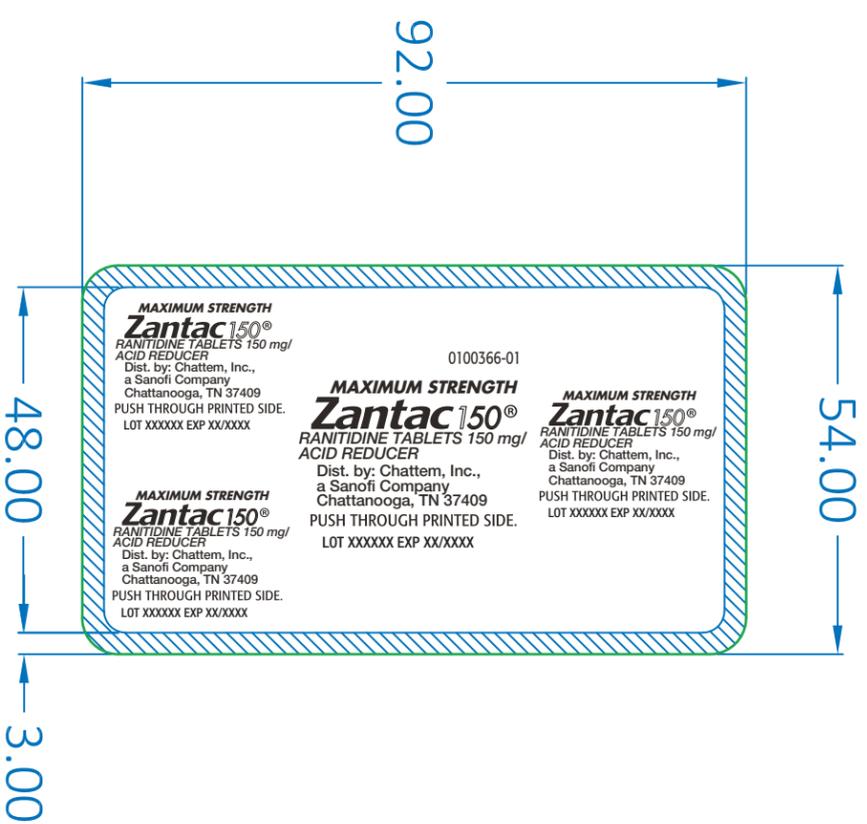
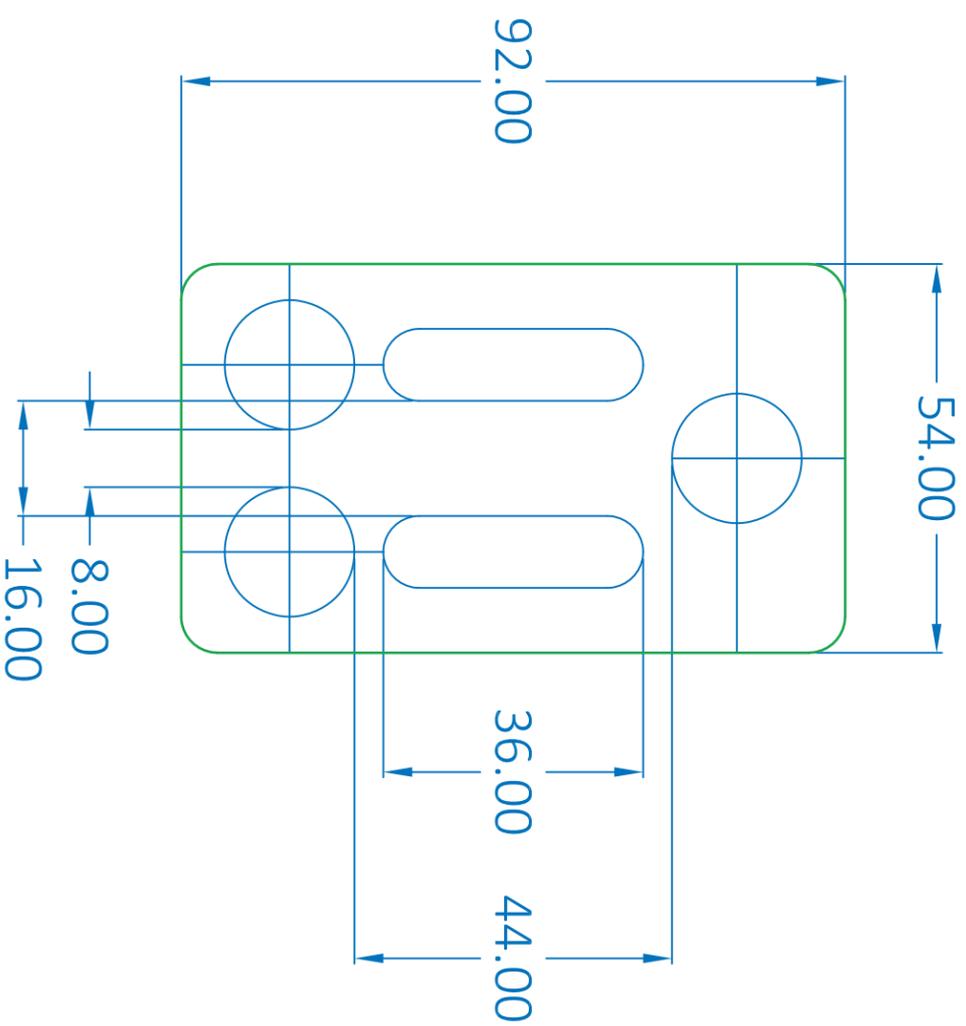
ZAN_150_3ct_CTN_0100641-01_MEX_FDA_2018_FNL2



Sanofi Regulatory Specifications		Verified Date: 09/27/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 62mm W 97mm
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 9.25 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 65 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150mg 3ct Blister Layout

(b) (4)

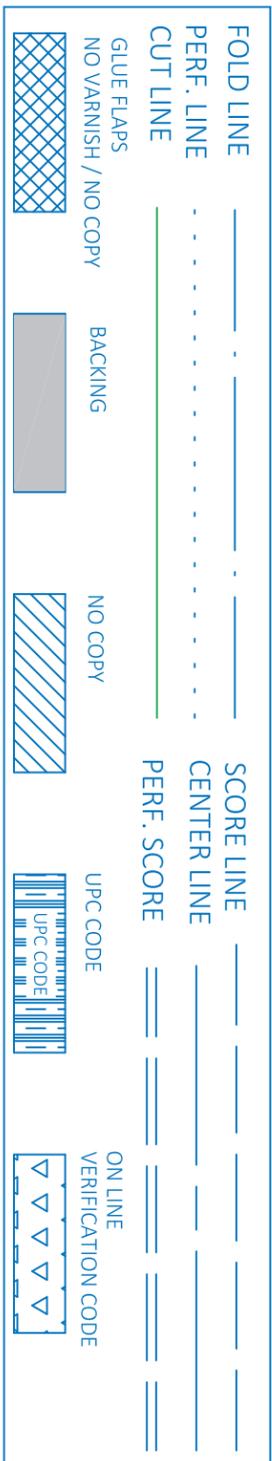


(b) (4)

BLISTER LAYOUT

COPY AREA LAYOUT

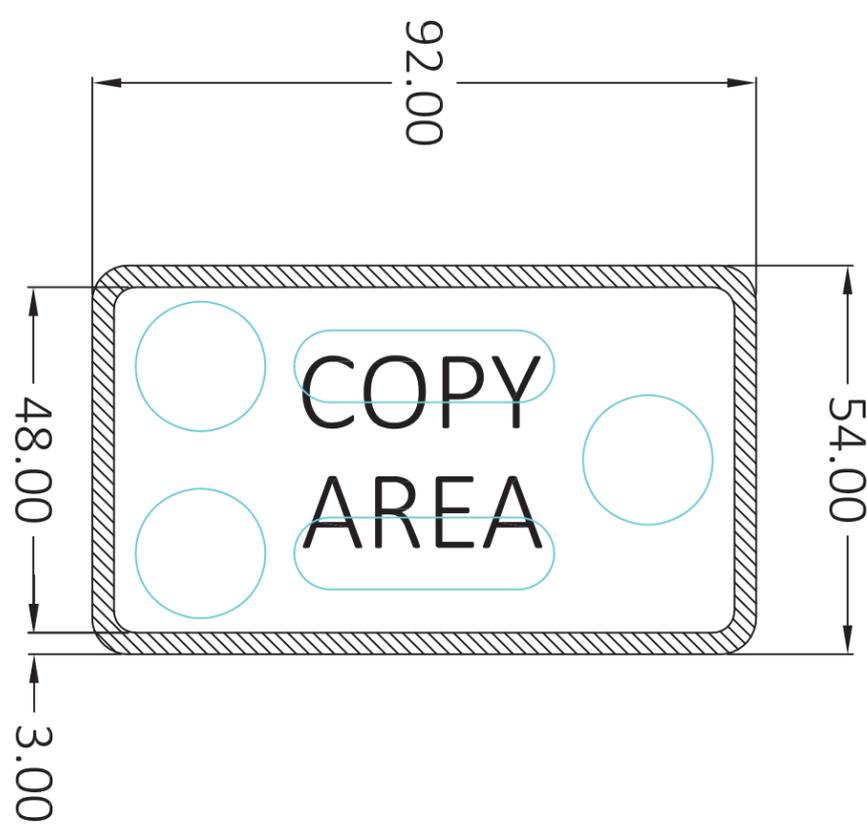
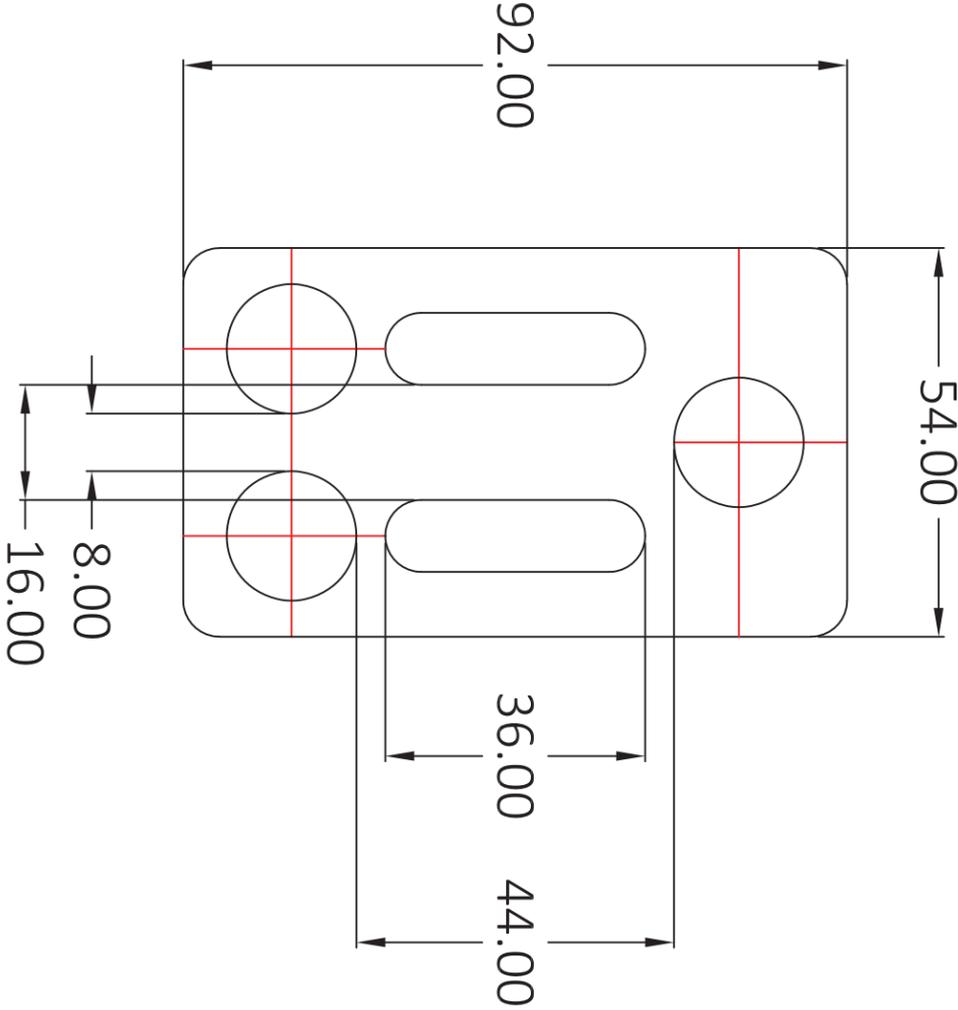
TEST COPY



(b) (4)

Zantac 150mg 3ct Blister Layout

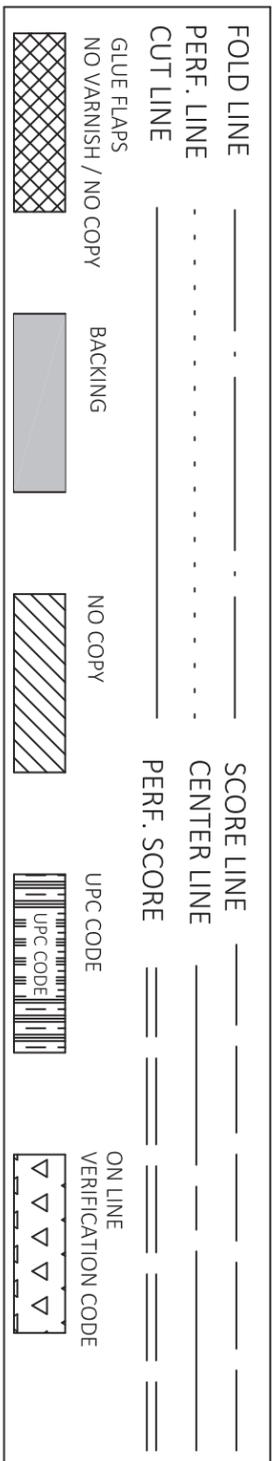
(b) (4)



BLISTER LAYOUT

COPY AREA LAYOUT

TEST COPY



(b) (4)

Zantac 150 8ct Carton

09.26.18

ZAN_150_8ct_CTN_0100642-01_MEX_FDA_2018_FNL2



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 8ct Carton
09.26.18

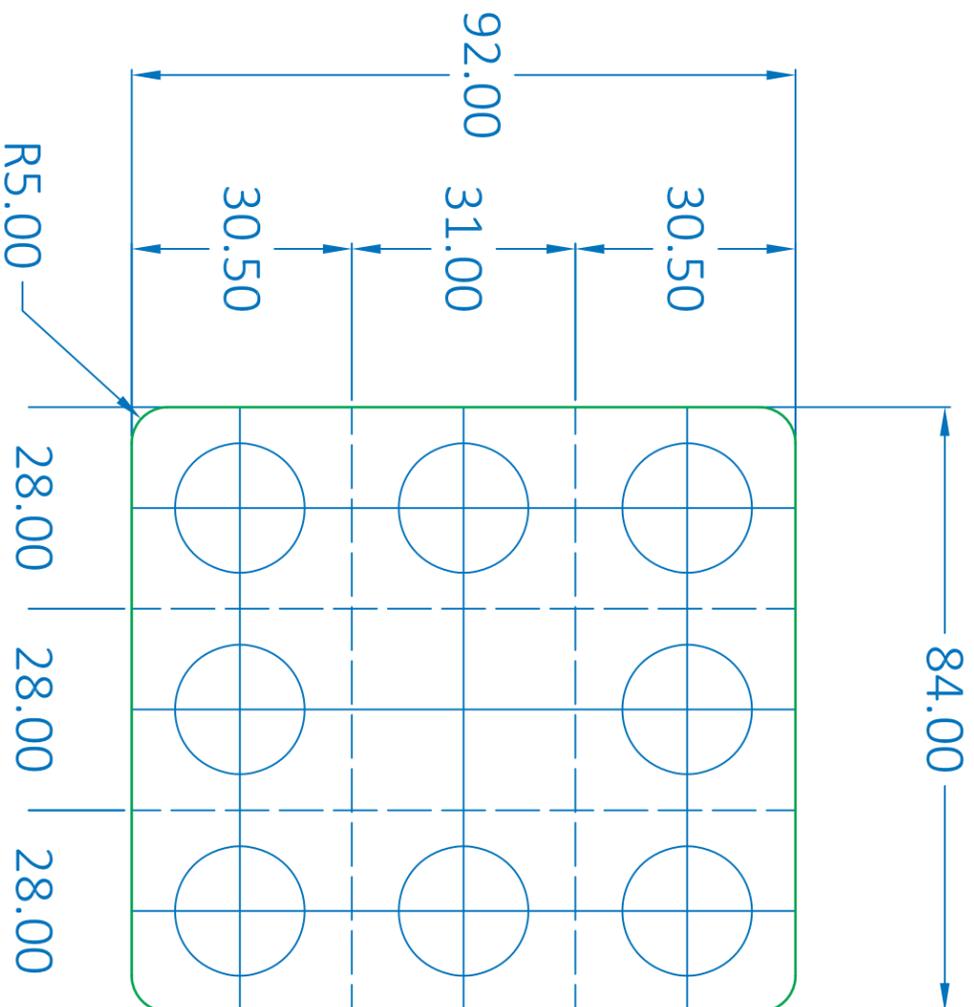
ZAN_150_8ct_CTN_0100650-01_Spain_FDA_2018_FNL3



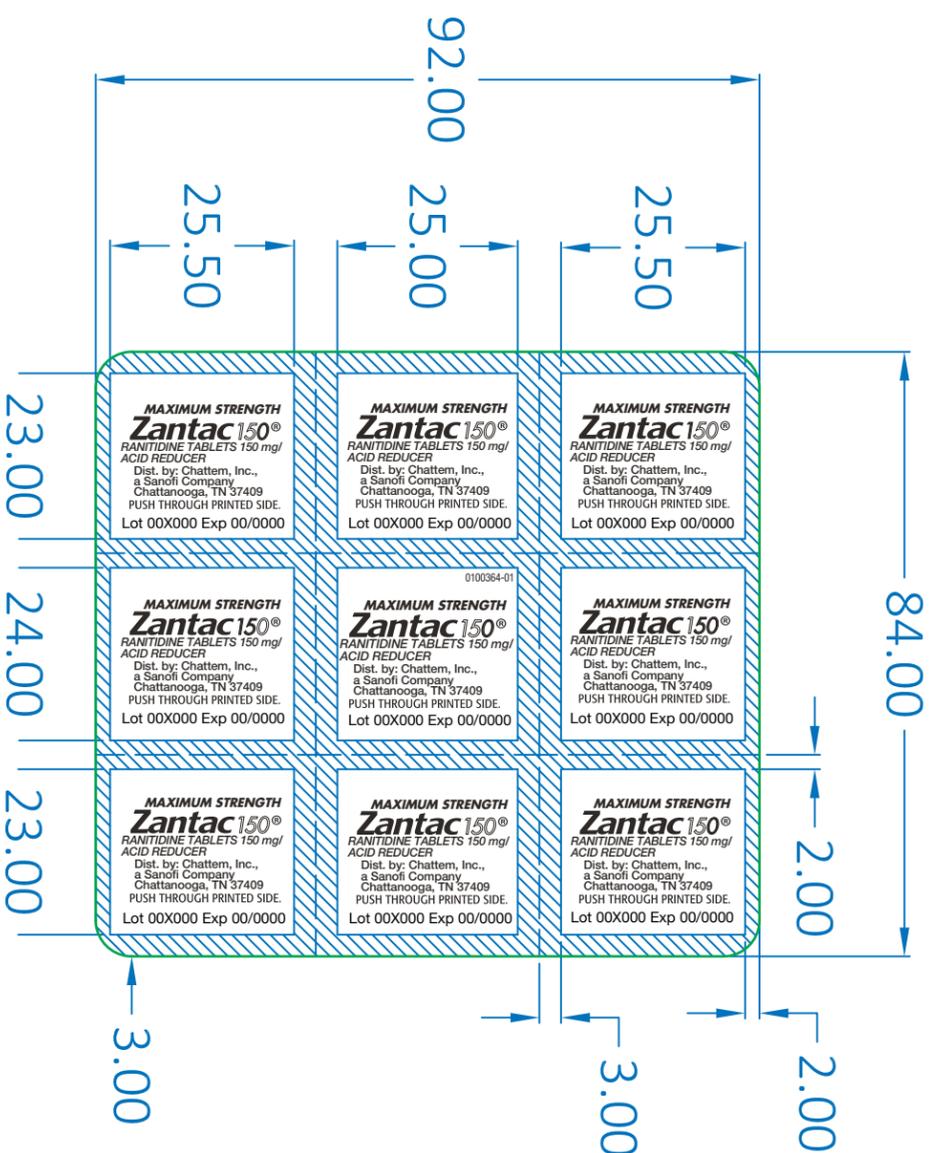
Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150mg & 150mg Cool Mint 8ct Blister Layout

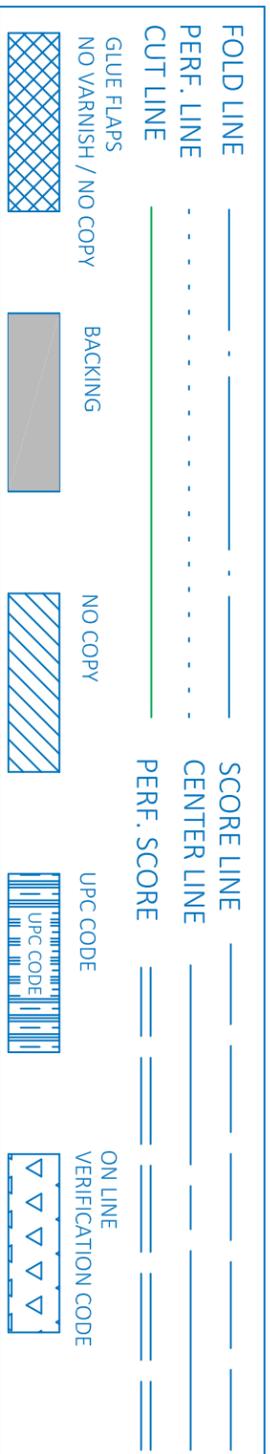
(b) (4)



BLISTER LAYOUT



COPY AREA LAYOUT



(b) (4)

(b) (4)

Zantac 150 24ct Carton

09.28.18

ZAN_150_24ct_CTN_0100643-01_MEX_FDA_2018_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/28/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines; end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt. Maximum Characters/inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 24ct Carton

09.28.18

ZAN_150_24ct_CTN_0100651-01_Spain_FDA_2018_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/28/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 32ct Bonus (24 plus 8)

09.29.18

ZAN_150_32ct_Bonus_Mexico_CTN_0100620-01_2018_FDA_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/29/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique / Helvetica Neue 57 Condensed	8 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	6.25 pt.	Maximum Characters/Inch: 30
Barlines:	2.5 pt.	Hairlines: .5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		.1204 in
PDP dimensions (in inches)		H 6.75 in W 7.75 in
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 80 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 32ct Bonus (24 plus 8)

09.29.18

ZAN_150_32ct_Bonus_Spain_CTN_0100619-01_2018_FDA_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/29/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique / Helvetica Neue 57 Condensed	8 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	6.25 pt.	Maximum Characters/Inch: 30
Barlines:	2.5 pt.	Hairlines: .5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		.1204 in
PDP dimensions (in inches)		H 6.75 in W 7.75 in
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 80 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):		6.0 pt. Maximum Characters/Inch:
		40
Barlines:		2.5 pt. Hairlines:
		0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) Divided by Largest Logo Copy (pt.)		V 15% H 0%



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt.	Maximum Characters/Inch: 40
Barlines:	2.5 pt.	Hairlines: 0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by Largest Logo Copy (pt.))		V 15% H 0%

Zantac 150 50ct Carton
09.26.18

ZAN_150_50ct_CTN_0100597-01_MEX_FDA_2018_FNL2



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		V 15% H 0%
Statement of Identity (pt.) (Divided by Largest Logo Copy (pt.))		V 15% H 0%

Zantac 150 50ct Carton
09.26.18

ZAN_150_50ct_CTN_0100627-01_SPAIN_FDA_2018_FNL2



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt.	Maximum Characters/Inch: 40
Barlines:	2.5 pt.	Hairlines: 0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)	0.088 in	
PDP dimensions (in millimeters)	H 89mm W 97mm	
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")	V 11.5 pt. H 0.00 pt.	
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")	V 82 pt. H 0.00 pt.	
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) / Divided by Largest Logo Copy (pt.)	V 15% H 0%	



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		
Tracking: 0 to 8 pt.		Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts): 6.0 pt.		Maximum Characters/Inch: 40
Barlines: 2.5 pt.		Hairlines: 0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by Largest Logo Copy (pt.))		V 15% H 0%



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt.	Maximum Characters/Inch: 40
Barlines:	2.5 pt.	Hairlines: 0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) / Divided by / Largest Logo Copy (pt.)		V 15% H 0%

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P.O. Box 2219, Chatham, TN 37409-0219

SANOFI

Read the directions, consumer information
leaflet and warnings before use.
Keep the carton.
It contains important information.

Drug Facts (continued)
or visit www.zantac.com

Questions? call 1-800-633-1610

Drug Facts

Active ingredient (in each tablet)
Ranitidine 150 mg (as ranitidine hydrochloride 156 mg) acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings

- Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- if you have other acid reducers
- with other acid reducers

Ask a doctor before use if you have

- headburn over 3 months. This may be a sign of a more serious condition.
- headburn with **lightheadness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- chest pain
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- chest pain
- stomach pain
- kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug, acid reducers may interact with certain prescription drugs.

- nasal or vomiting
- stomach pain
- kidney disease

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over:
- to relieve symptoms, swallow 1 tablet with a glass of water
- to prevent symptoms, swallow 1 tablet with a glass of water
- 30 to 60 minutes before eating food or drinking beverages that cause heartburn
- can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- children under 12 years: ask a doctor

Other information

- do not use if printed foil under bottle cap is open or torn
- store at 20°-25°C (68°-77°F)
- this product is sodium and sugar free
- avoid excessive heat or humidity

Inactive ingredients
titanium dioxide, tracetin
hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, hydroxypropyl methylcellulose

6 81421 03134 **9**

MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/Acid Reducer
150

BONUS! 13 FREE TABLETS

BONUS! 13 FREE TABLETS

MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/Acid Reducer
150

**PREVENTS & RELIEVES
HEARTBURN** associated with
acid indigestion and sour stomach

78 ~~65~~ TABLETS
(78 DOSES)

Drug Facts (continued)
or visit www.zantac.com

Questions? call 1-800-633-1610

6 81421 03134 **9**

Drug Facts

Active ingredient (in each tablet)
Ranitidine 150 mg (as ranitidine hydrochloride 156 mg) acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings

- Do not use if you are allergic to ranitidine or other acid reducers
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers
- with other acid reducers

Ask a doctor before use if you have

- headburn over 3 months. This may be a sign of a more serious condition.
- headburn with **lightheadness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- chest pain
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- chest pain
- stomach pain
- kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug, acid reducers may interact with certain prescription drugs.

- nasal or vomiting
- stomach pain
- kidney disease

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and over:
- to relieve symptoms, swallow 1 tablet with a glass of water
- to prevent symptoms, swallow 1 tablet with a glass of water
- 30 to 60 minutes before eating food or drinking beverages that cause heartburn
- can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- children under 12 years: ask a doctor

Other information

- do not use if printed foil under bottle cap is open or torn
- store at 20°-25°C (68°-77°F)
- this product is sodium and sugar free
- avoid excessive heat or humidity

Inactive ingredients
titanium dioxide, tracetin
hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, hydroxypropyl methylcellulose

6 81421 03134 **9**

MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/Acid Reducer
150

BONUS! 13 FREE TABLETS

BONUS! 13 FREE TABLETS

MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/Acid Reducer
150

**PREVENTS & RELIEVES
HEARTBURN** associated with
acid indigestion and sour stomach

78 ~~65~~ TABLETS
(78 DOSES)

Drug Facts (continued)
or visit www.zantac.com

Questions? call 1-800-633-1610

6 81421 03134 **9**

Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		V 15% H 0%
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Sanofi Regulatory Specifications		Verified Date: 09/25/18
Drug Facts Info		
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Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
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Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same line: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box - i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking	0 to 9 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts)	6.5 pt. Maximum Characters/Inch:	30
Barlines	2.5 pt. Hairlines:	.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		.0933 in
PDF dimensions (in inches)		H 4.00 in. W 4.75 in
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 13 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 94 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		V 15% H 0%
Statement of Identity (s) (Divided by) Largest Logo Copy (s)		V 15% H 0%

MAXIMUM STRENGTH Zantac 150
 Ranitidine Tablets 150 mg/Acid Reducer

Drug Facts	Purpose
Active ingredient (in each tablet) Ranitidine 150 mg (as ranitidine hydrochloride) 168 mg.	Acid reducer
Uses • relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages	
Warnings Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers.	
Do not use • if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. • with other acid reducers	
Ask a doctor before use if you have • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with lightheadedness, sweating or dizziness • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness • frequent chest pain • frequent sneezing, particularly with heartburn • unexplained weight loss • trouble or difficulty swallowing • stomach pain • kidney disease	
Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.	
Stop use and ask a doctor if • your heartburn continues or worsens • you need to take this product for more than 14 days	
If pregnant or breast-feeding, ask a health professional before use. • you need to take this product for more than 14 days	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions • Adults and children 12 years and over: • to relieve symptoms, swallow 1 tablet with a glass of water • to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn. • can be used up to twice daily (do not take more than 2 tablets in 24 hours) • children under 12 years: ask a doctor.	
Other information • do not use if individual foil pouch is open or torn • store at 20°-25°C (68°-77°F) • this product is sodium and sugar free	
Inactive ingredients hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, hydroxypropyl methylcellulose	
Questions? call 1-800-433-1618 or visit www.zantac.com for Tips for Managing Heartburn	

Sanofi



Do not discard this carton.
 It contains important consumer information.

80 POUCHES
 1 TABLET (1 DOSE)

PUSH IN TAB AND PULL OUT TO OPEN

What you should know about Zantac 150
 Ranitidine Tablets 150 mg/Acid Reducer

What is MAXIMUM STRENGTH Zantac 150?
 MAXIMUM STRENGTH Zantac 150 contains 150 mg of ranitidine hydrochloride (168 mg), a medicine that doctors have prescribed more than 200 million times worldwide. The ingredient in MAXIMUM STRENGTH Zantac 150, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 has been shown safely with many frequently prescribed medications.

What symptoms does MAXIMUM STRENGTH Zantac 150 relieve and prevent?
 • relieves symptoms, swallow 1 tablet with a glass of water.
 • to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn.
 • can be used up to twice daily (do not take more than 2 tablets in 24 hours).
 • children under 12 years: ask a doctor.

How should I take MAXIMUM STRENGTH Zantac 150?
 • to relieve symptoms, swallow 1 tablet with a glass of water.
 • to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn.
 • can be used up to twice daily (do not take more than 2 tablets in 24 hours).
 • children under 12 years: ask a doctor.

Other information
 • do not use if individual foil pouch is open or torn.
 • store at 20°-25°C (68°-77°F).
 • this product is sodium and sugar free.

Inactive ingredients hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, hydroxypropyl methylcellulose.

Questions? call 1-800-433-1618 or visit www.zantac.com for Tips for Managing Heartburn.

Do not use if individual foil pouch is open or torn.



How does MAXIMUM STRENGTH Zantac 150 work?
 MAXIMUM STRENGTH Zantac 150 reduces the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

Tips for managing heartburn
 • Do not lie flat or bend over soon after eating.
 • Do not eat an apple or just before bedtime.
 • Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables.
 • Eat slowly and do not eat big meals.
 • If you are overweight, lose weight.
 • If you smoke, quit smoking.
 • Elevate the head of your bed.
 • Wear loose fitting clothing around your stomach.

When should I see a doctor?
 • Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 • with other acid reducers.
 • Ask a doctor before use if you have:
 • had heartburn over 3 months. This may be a sign of a more serious condition.
 • heartburn with **lightheadedness, sweating or dizziness**
 • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness.
 • frequent chest pain.
 • frequent sneezing, particularly with heartburn.
 • unexplained weight loss.
 • trouble or difficulty swallowing.
 • stomach pain.
 • kidney disease.
 • Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.
 • Stop use and ask a doctor if:
 • your heartburn continues or worsens.
 • you need to take this product for more than 14 days.
 • If pregnant or breast-feeding, ask a health professional before use.
 • you need to take this product for more than 14 days.
 • MAXIMUM STRENGTH Zantac 150 should not be given to children under 12 years old unless directed by a doctor.
 • Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers.



Sanofi Regulatory Specifications		Verified Date: 09/25/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same line: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box - i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 9 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.5 pt. Maximum Characters/Inch:	30
Barlines:	2.5 pt. Hairlines:	.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		.0933 in
PDF dimensions (in inches)		H 4.00 in. W 4.75 in
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 13 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 94 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		V 15% H 0%
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/Acid Reducer **150**

Drug Facts	Purpose
Active ingredient (in each tablet) Ranitidine 150 mg (as ranitidine hydrochloride) 168 mg.	Acid reducer
Uses • relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages	
Warnings Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers.	
Do not use • if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. • with other acid reducers.	
Ask a doctor before use if you have • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with lightheadedness, sweating or dizziness . • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness. • frequent chest pain. • frequent sneezing, particularly with heartburn. • unexplained weight loss. • nausea or vomiting. • stomach pain. • kidney disease.	
Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.	
Stop use and ask a doctor if • your heartburn continues or worsens. • you need to take this product for more than 14 days.	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions • Adults and children 12 years and over: • to relieve symptoms, swallow 1 tablet with a glass of water. • to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn. • can be used up to twice daily (do not take more than 2 tablets in 24 hours). • children under 12 years: ask a doctor.	
Other information • do not use if individual foil pouch is open or torn. • store at 20°-25°C (68°-77°F). • avoid exposure to heat or humidity.	
Inactive ingredients hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, hydroxypropyl methylcellulose.	
Questions? call 1-800-433-1618 or visit www.zantac.com for Tips for Managing Heartburn.	

Sanofi



Do not discard this carton.
It contains important consumer information.

80 POUCHES
1 TABLET (1 DOSE)

PUSH IN TAB AND PULL OUT
TO OPEN

What you should know about **MAXIMUM STRENGTH Zantac 150**
Ranitidine Tablets 150 mg/Acid Reducer

What is MAXIMUM STRENGTH Zantac 150?
MAXIMUM STRENGTH Zantac 150 contains 150 mg of ranitidine hydrochloride (168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

What symptoms does MAXIMUM STRENGTH Zantac 150 relieve and prevent?
• relieves symptoms associated with acid indigestion and sour stomach.
• prevents heartburn associated with acid indigestion and sour stomach.

How should I take MAXIMUM STRENGTH Zantac 150?
• To relieve symptoms, swallow 1 tablet with a glass of water.
• To prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn.

What are the risks of using MAXIMUM STRENGTH Zantac 150?
• Do not use if individual foil pouch is open or torn.
• Avoid exposure to heat or humidity.

Other information
• Do not use if individual foil pouch is open or torn.
• Store at 20°-25°C (68°-77°F).
• Avoid exposure to heat or humidity.

Questions? call 1-800-433-1618 or visit www.zantac.com for Tips for Managing Heartburn.



How does MAXIMUM STRENGTH Zantac 150 work?
MAXIMUM STRENGTH Zantac 150 reduces the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

Tips for managing heartburn
• Do not lie flat or bend over soon after eating.
• Do not eat an meal or just before bedtime.
• Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables.
• Eat slowly and do not eat big meals.
• If you are overweight, lose weight.
• If you smoke, quit smoking.
• Elevate the head of your bed.
• Wear loose fitting clothing around your stomach.

When should I see a doctor?
• If you have trouble or pain swallowing food, vomiting with blood or bloody or black stools, these may be signs of a serious condition. See your doctor.
• With other acid reducers.
• Ask a doctor before use if you have:
• had heartburn over 3 months. This may be a sign of a more serious condition.
• heartburn with **lightheadedness, sweating or dizziness**.
• chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness.
• frequent chest pain.
• frequent sneezing, particularly with heartburn.
• unexplained weight loss.
• nausea or vomiting.
• stomach pain.
• kidney disease.
• Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.
• Stop use and ask a doctor if:
• your heartburn continues or worsens.
• you need to take this product for more than 14 days.
• If pregnant or breast-feeding, ask a health professional before use.
• MAXIMUM STRENGTH Zantac 150 should not be given to children under 12 years old unless directed by a doctor.
• Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers.



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9.1 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.0 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%



Sanofi Regulatory Specifications		Verified Date: 09/26/18
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Ratio of Statement of Identity to Logo/Largest Copy on PDP	V 15% H 0%	
Statement of Identity to Logo/Largest Copy (pt.)	V 15% H 0%	

Zantac 150 Insert for Blister Cartons

09.25.18

ZAN_150_BlisterCTN_Insert_0100655-01_FDA_2018_FNL2

FRONT

BACK

SANOFI 

What you should know about

MAXIMUM STRENGTH Zantac

RANITIDINE TABLETS 150 mg
ACID REDUCER **150**[®]

(Please read all of this information before taking MAXIMUM STRENGTH Zantac 150. Save this leaflet for future reference.)

**What is
MAXIMUM STRENGTH
Zantac 150?**

• MAXIMUM STRENGTH Zantac 150 contains 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

**Excellent Safety
Record**

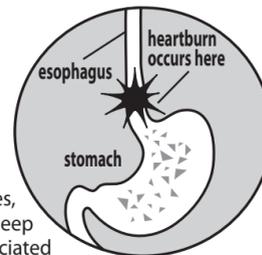
• The ingredient in MAXIMUM STRENGTH Zantac 150, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 has been taken safely with many frequently prescribed medications.

• MAXIMUM STRENGTH Zantac 150 tablets are sodium and sugar free.

**What symptoms does
MAXIMUM STRENGTH
Zantac 150 relieve
and prevent?**

• MAXIMUM STRENGTH Zantac 150 relieves and prevents heartburn associated with acid indigestion and sour stomach.

• Certain foods or beverages, and even lying down to sleep can cause heartburn associated with acid indigestion and sour stomach. It is normal for the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause burning pain and discomfort.



**How should I take
MAXIMUM STRENGTH
Zantac 150?**

• To **relieve** symptoms, swallow 1 tablet with a glass of water.

• To **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn.

• This medicine can be used up to twice daily (do not take more than 2 tablets in 24 hours).

• MAXIMUM STRENGTH Zantac 150 should not be given to children under 12 years old unless directed by a doctor.

• **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers.



**How does
MAXIMUM STRENGTH
Zantac 150 work?**

MAXIMUM STRENGTH Zantac 150 reduces the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

**Tips for managing
heartburn**

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

**When should
I see a doctor?**

- **Do not use**
 - if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 - with other acid reducers

• **Ask a doctor before use if you have**

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

• **Ask a doctor or pharmacist before use if you are**

- taking a prescription drug. Acid reducers may interact with certain prescription drugs.

• **Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days

• **If pregnant or breast-feeding,** ask a health professional before use.

• **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Questions? call 1-800-633-1610 or visit www.zantacotc.com

BOTTLES: Bottle is sealed with printed foil under cap. Do not use if printed foil is open or torn.

BLISTERS: Do not use if the individual blister unit is open or torn.

FOIL PACKET: Do not use if the individual foil packet is open or torn.

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Zantac 150 Insert for Bottle Cartons
09.25.18
ZAN_150_BottleCTN_Insert_0100609-01_FDA_2018_FNL2

FRONT

BACK

SANOFI 

What you should know about
MAXIMUM STRENGTH
Zantac
RANITIDINE TABLETS 150 mg **150**[®]
ACID REDUCER

(Please read all of this information before taking MAXIMUM STRENGTH Zantac 150. Save this leaflet for future reference.)

What is MAXIMUM STRENGTH Zantac 150?

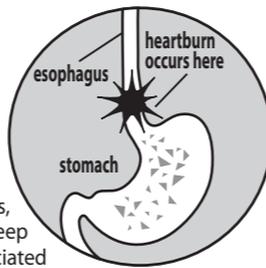
- MAXIMUM STRENGTH Zantac 150 contains 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

Excellent Safety Record

- The ingredient in MAXIMUM STRENGTH Zantac 150, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 has been taken safely with many frequently prescribed medications.
- MAXIMUM STRENGTH Zantac 150 tablets are sodium and sugar free.

What symptoms does MAXIMUM STRENGTH Zantac 150 relieve and prevent?

- MAXIMUM STRENGTH Zantac 150 relieves and prevents heartburn associated with acid indigestion and sour stomach.
- Certain foods or beverages, and even lying down to sleep can cause heartburn associated with acid indigestion and sour stomach. It is normal for the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause burning pain and discomfort.



How should I take MAXIMUM STRENGTH Zantac 150?

- To **relieve** symptoms, swallow 1 tablet with a glass of water.
- To **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn.
- This medicine can be used up to twice daily (do not take more than 2 tablets in 24 hours).
- MAXIMUM STRENGTH Zantac 150 should not be given to children under 12 years old unless directed by a doctor.
- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers.

MAXIMUM STRENGTH Zantac 150
RANITIDINE TABLETS 150 mg **150**[®]
ACID REDUCER

0100609-01

How does MAXIMUM STRENGTH Zantac 150 work?

MAXIMUM STRENGTH Zantac 150 reduces the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

Tips for managing heartburn

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

When should I see a doctor?

- **Do not use**
 - if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 - with other acid reducers
- **Ask a doctor before use if you have**
 - had heartburn over 3 months. This may be a sign of a more serious condition.
 - heartburn with **lightheadedness, sweating or dizziness**
 - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 - frequent **chest pain**
 - frequent wheezing, particularly with heartburn
 - unexplained weight loss
 - nausea or vomiting
 - stomach pain
 - kidney disease
- **Ask a doctor or pharmacist before use if you are**
 - taking a prescription drug. Acid reducers may interact with certain prescription drugs.
- **Stop use and ask a doctor if**
 - your heartburn continues or worsens
 - you need to take this product for more than 14 days
- **If pregnant or breast-feeding**, ask a health professional before use.
- **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Questions? call 1-800-633-1610 or visit www.zantacotc.com

BOTTLES: Bottle is sealed with printed foil under cap. Do not use if printed foil is open or torn.

BLISTERS: Do not use if the individual blister unit is open or torn.

FOIL PACKET: Do not use if the individual foil packet is open or torn.

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Zantac 150 Cool Mint 8ct Carton

09.26.18

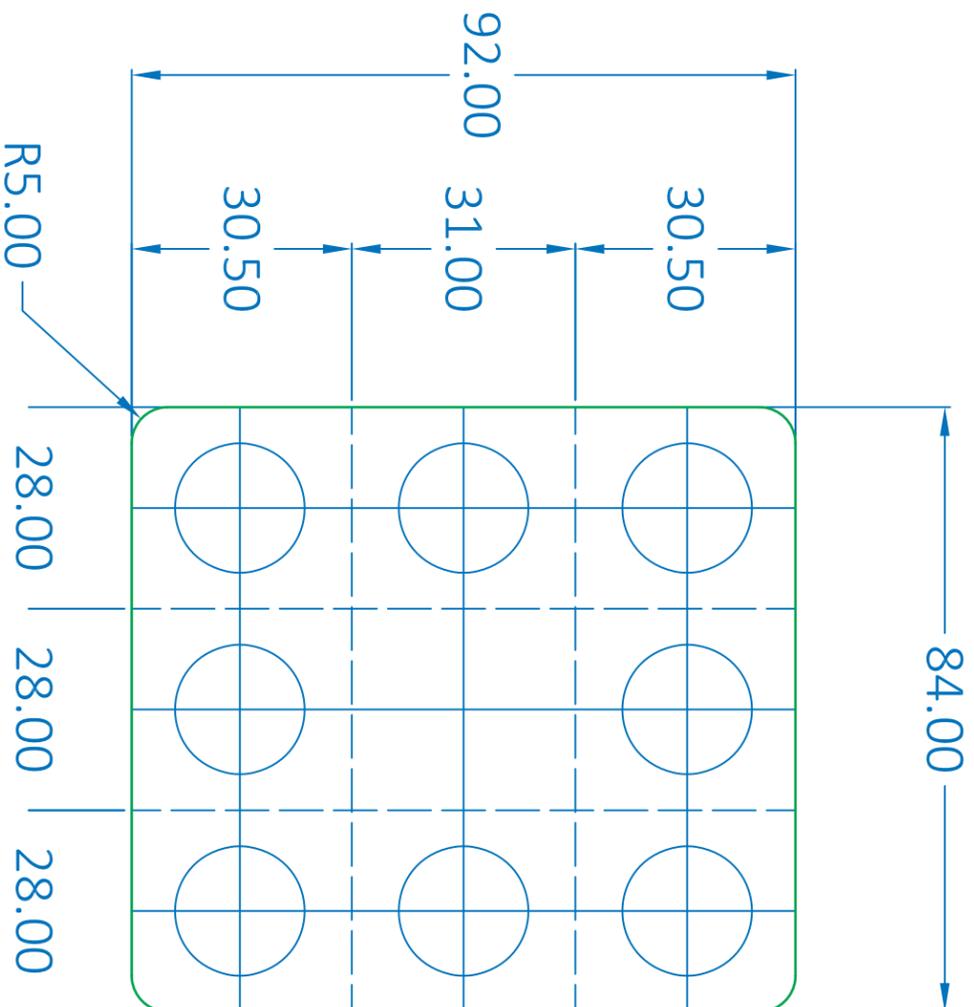
ZAN_150_CoolMint_8ct_Mex_CTN_0100644-01_FDA_2018_FNL2



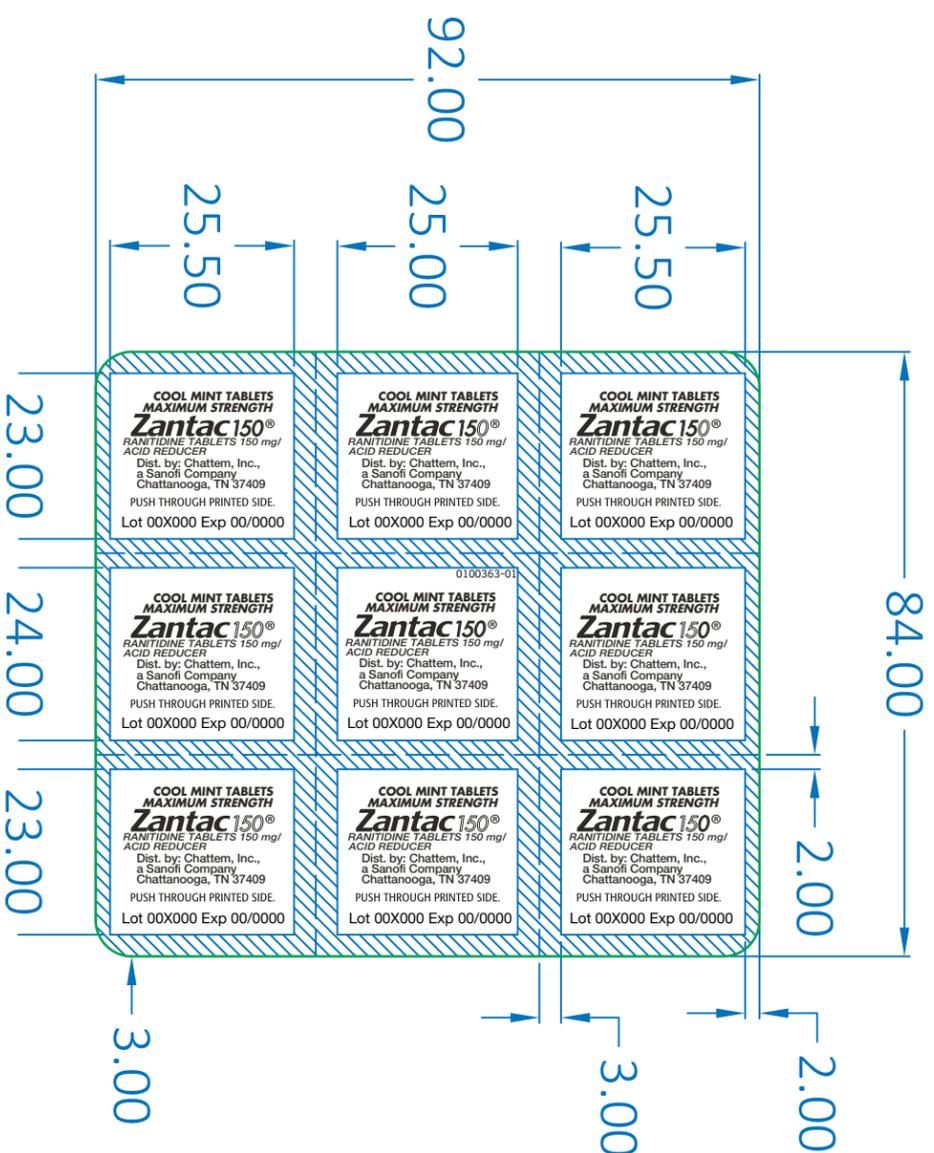
Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	5.9 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150mg & 150mg Cool Mint 8ct Blister Layout

(b) (4)

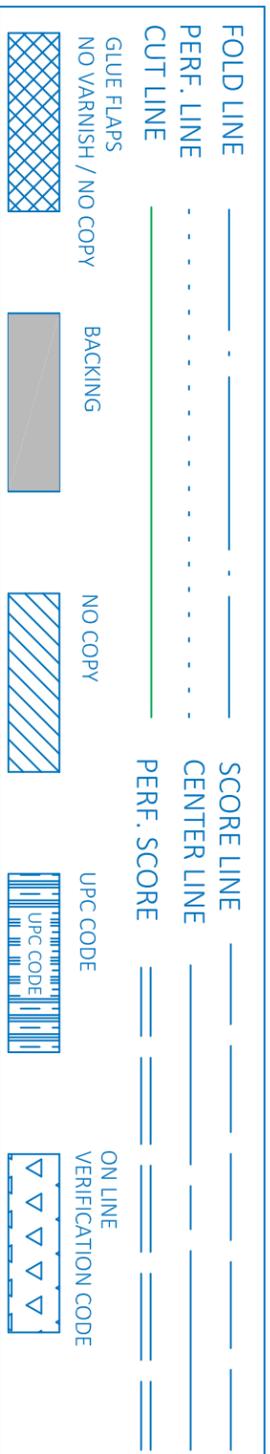


BLISTER LAYOUT



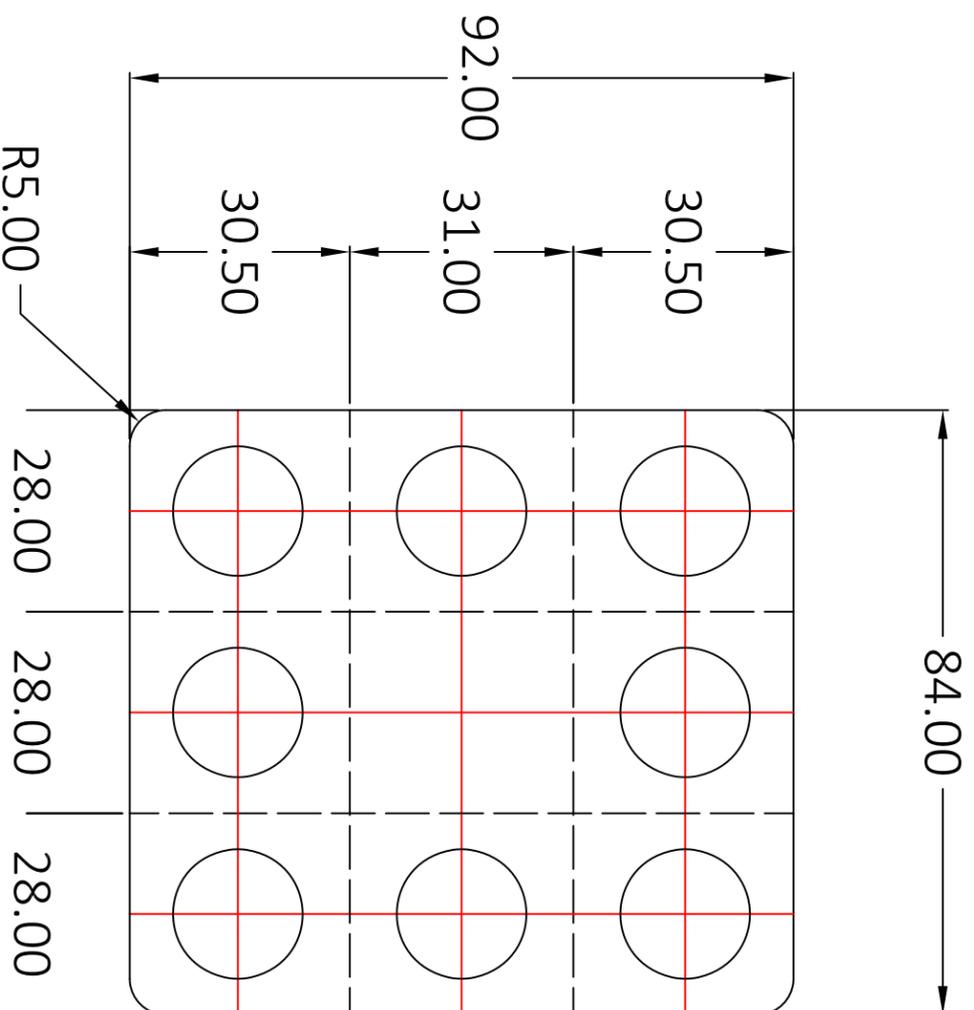
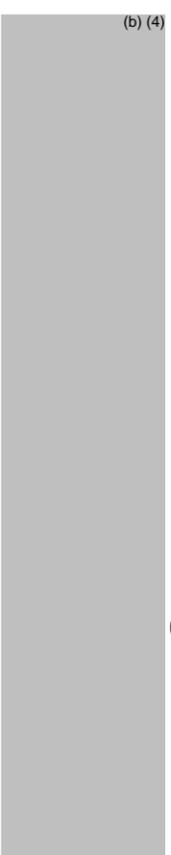
COPY AREA LAYOUT

(b) (4)

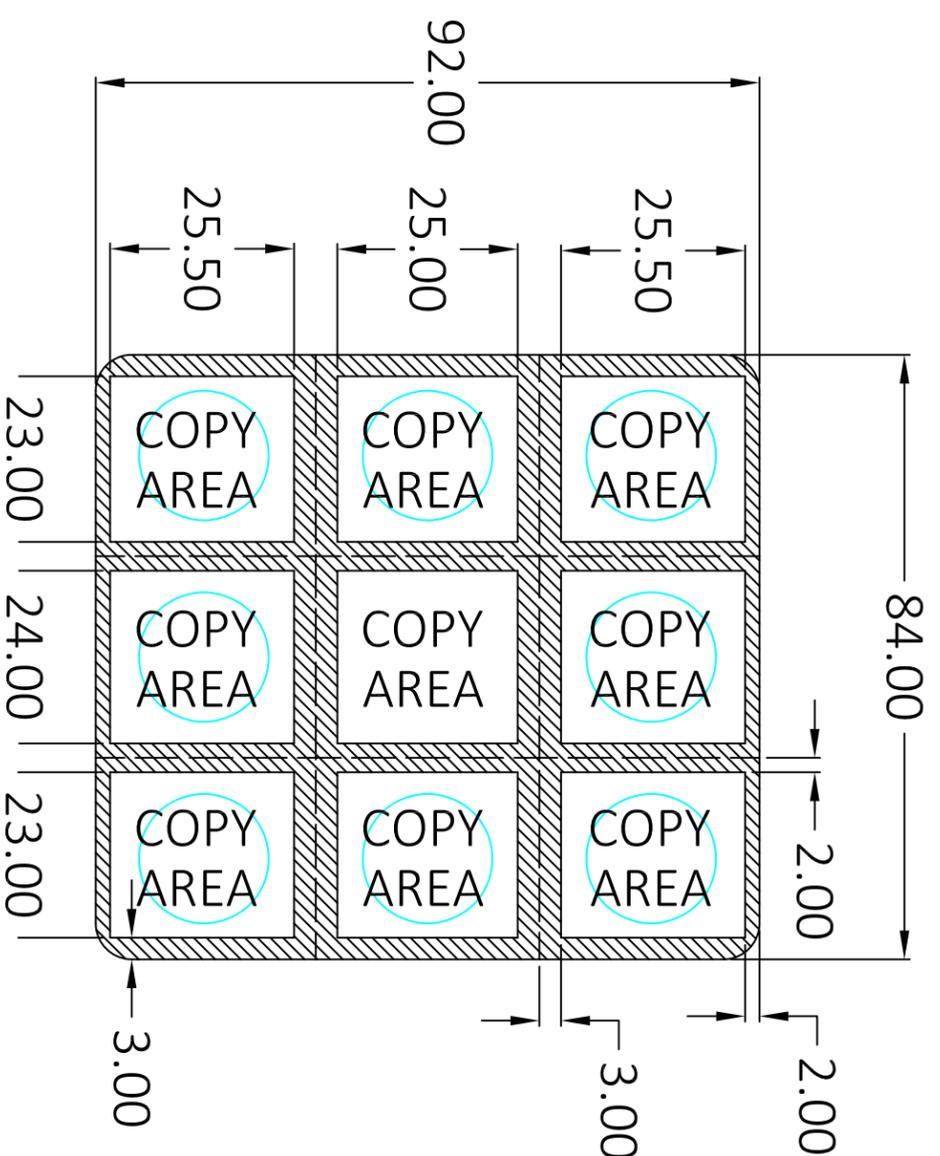


(b) (4)

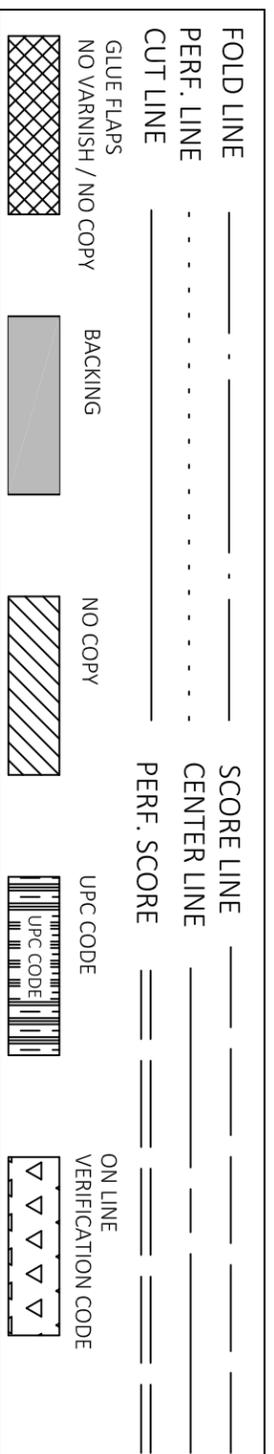
Zantac 150mg & 150mg Cool Mint 8ct Blister Layout



BLISTER LAYOUT



COPY AREA LAYOUT



Zantac 150 Cool Mint 24ct Carton

09.26.18

ZAN_150_CoolMint_24ct_CTN_0100645-01_Mex_FDA_2018_FNL2



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	5.9 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 Cool Mint 32ct Bonus (24 plus 8)

09.26.18

ZAN_150_CoolMint_32ct_Bonus_Mexico_CTN_0100623-01_2018_FDA_FNL1



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique / Helvetica Neue 57 Condensed	8 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	6.25 pt. Maximum Characters/Inch:	30
Barlines:	2.5 pt. Hairlines:	.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		.1204 in
PDP dimensions (in inches)		H 6.75 in W 7.75 in
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 80 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 Cool Mint 40ct Carton

09.26.18

ZAN_150_CoolMint_40ct_CTN_0100601-01_FDA_2018_FNL2



Sanofi Regulatory Specifications Verified Date: 09/26/18

Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	5.9 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)	0.088 in	
PDP dimensions (in millimeters)	H 89mm W 97mm	
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")	V 11.5 pt. H 0.00 pt.	
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")	V 82 pt. H 0.00 pt.	
Font size of Statement of Identity (Largest Copy on PDP)	V 15% H 0%	
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)	V 15% H 0%	

Zantac 150 CoolMint 40ct Label

09.19.18

ZAN_150_CoolMint_40ct_LBL_0100588-01_FDA_2018_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/19/18
Drug Facts Info		
Drug Facts (Title)	Font name:	NA point type
Drug Facts (continued)	Font name:	NA point type
Headings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	4.6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		N/A
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	N/A pt.	Maximum Characters/Inch: 48
Barlines:	N/A pt.	Hairlines: N/A pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.059 in
PDP dimensions (in millimeters)		H 41mm W 27mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 6 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 20 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 Cool Mint 50ct Carton

09.26.18

ZAN_150_CoolMint_50ct_CTN_0100602-01_Mex_FDA_2018_FNL2

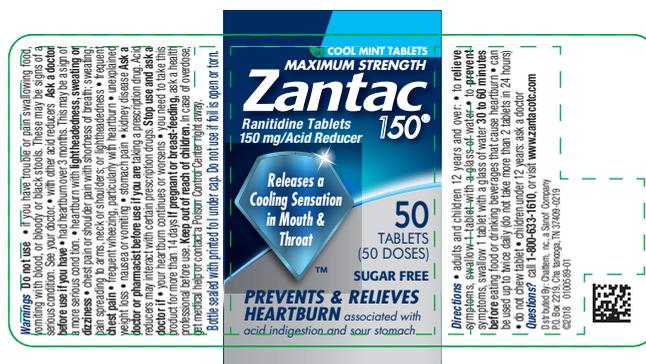


Sanofi Regulatory Specifications		Verified Date: 09/26/18
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Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):	5.9 pt. Maximum Characters/Inch:	40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)	0.088 in	
PDP dimensions (in millimeters)	H 89mm W 97mm	
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")	V 11.5 pt. H 0.00 pt.	
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")	V 82 pt. H 0.00 pt.	
Ratio of Statement of Identity to Logo/Largest Copy on PDP	V 15% H 0%	
Statement of Identity (pt.) / Largest Logo Copy (pt.)	V 15% H 0%	

Zantac 150 CoolMint 50ct Label

09.19.18

ZAN_150_CoolMint_50ct_LBL_0100589-01_FDA_2018_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/19/18
Drug Facts Info		
Drug Facts (Title)	Font name:	NA point type
Drug Facts (continued)	Font name:	NA point type
Headings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	4.6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		N/A
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	N/A pt.	Maximum Characters/Inch: 48
Barlines:	N/A pt.	Hairlines: N/A pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.059 in
PDP dimensions (in millimeters)		H 41mm W 27mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 6 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 20 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 Cool Mint 65ct Carton

09.26.18

ZAN_150_CoolMint_65ct_CTN_0100603-01_FDA_2018_FNL2



Sanofi Regulatory Specifications Verified Date: 09/26/18

Drug Facts Info	
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique 10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique 9 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique 8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed 6 point type
Body Text	Font name: Helvetica Neue 57 Condensed 6 point type
Bullets	Font name: Helvetica Neue 57 Condensed 5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems	YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box	YES
Tracking:	0 to 8 pt. Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	5.9 pt. Maximum Characters/Inch: 40
Barlines:	2.5 pt. Hairlines: 0.5 pt.
Principal Display Panel Info	
Font size of Net Quantity of Contents (Smallest character height in inches)	0.088 in
PDP dimensions (in millimeters)	H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")	V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")	V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Largest Copy on PDP	
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)	V 15% H 0%

Reference ID: A41574

Zantac 150 CoolMint 65ct Label

09.19.18

ZAN_150_CoolMint_65ct_LBL_0100590-01_FDA_2018_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/19/18
Drug Facts Info		
Drug Facts (Title)	Font name:	NA point type
Drug Facts (continued)	Font name:	NA point type
Headings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	4.6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		N/A
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	N/A pt.	Maximum Characters/Inch: 48
Barlines:	N/A pt.	Hairlines: N/A pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.059 in
PDP dimensions (in millimeters)		H 41mm W 27mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 6 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 20 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 Cool Mint 78ct Carton

09.26.18

ZAN_150_CoolMint_78ct_Bonus_CTN_0100604-01_FDA_2018_FNL2

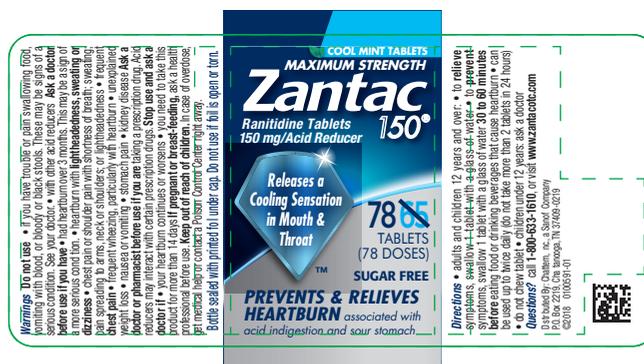


Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):		5.9 pt. Maximum Characters/Inch:
Barlines:		2.5 pt. Hairlines:
Barlines:		0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		V 15% H 0%
Reference ID: 4413742		

Zantac 150 CoolMint 78ct Label

09.26.18

ZAN_150_CoolMint_78ct_LBL_0100591-01_FDA_2018_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name:	NA point type
Drug Facts (continued)	Font name:	NA point type
Headings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	4.6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		N/A
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	N/A pt.	Maximum Characters/Inch: 48
Barlines:	N/A pt.	Hairlines: N/A pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.059 in
PDP dimensions (in millimeters)		H 41mm W 27mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 6 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 20 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name: Helvetica Neue 77 Bold Condensed Oblique	10 point type
Drug Facts (continued)	Font name: Helvetica Neue 77 Bold Condensed Oblique	9 point type
Headings	Font name: Helvetica Neue 77 Bold Condensed Oblique	8 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5.66 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		YES
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		YES
Tracking:	0 to 8 pt. Horizontal Scale:	97%-102%
Leading (Minimum space in body of Drug Facts):		40
Barlines:	2.5 pt. Hairlines:	0.5 pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.088 in
PDP dimensions (in millimeters)		H 89mm W 97mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 11.5 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 82 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		V 15% H 0%
Statement of Identity (pt.) (Unfilled by Largest Logo Copy (pt.))		

Zantac 150 CoolMint 90ct Label

09.26.18

ZAN_150_CoolMint_90ct_LBL_0100592-01_FDA_2018_FNL3



Sanofi Regulatory Specifications		Verified Date: 09/26/18
Drug Facts Info		
Drug Facts (Title)	Font name:	NA point type
Drug Facts (continued)	Font name:	NA point type
Headings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Subheadings	Font name: Helvetica Neue 77 Bold Condensed	4.6 point type
Body Text	Font name: Helvetica Neue 57 Condensed	4.6 point type
Bullets	Font name: Helvetica Neue 57 Condensed	5 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hairlines from edge of box – i.e. Minimum of 1 space either side of Drug Facts Box		N/A
Tracking:	0 to 8 pt.	Horizontal Scale: 97%-102%
Leading (Minimum space in body of Drug Facts):	N/A pt.	Maximum Characters/Inch: 48
Barlines:	N/A pt.	Hairlines: N/A pt.
Principal Display Panel Info		
Font size of Net Quantity of Contents (Smallest character height in inches)		0.059 in
PDP dimensions (in millimeters)		H 41mm W 27mm
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V 6 pt. H 0.00 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V 20 pt. H 0.00 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V 15% H 0%

Zantac 150 Cool Mint Insert for Bottle Cartons

09.26.18

ZAN_150_CoolMint_BottleCTN_Insert_0100610-01_FDA_2018_FNL2

FRONT

BACK

SANOFI 

What you should know about
COOL MINT TABLETS
MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/
Acid Reducer
150[®]

(Please read all of this information before taking MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets. Save this leaflet for future reference.)

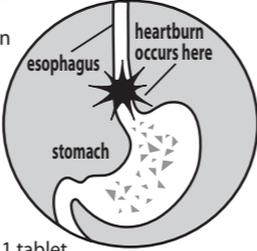
What are MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets?

- MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets contain 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.
- When swallowed, MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets release a cooling sensation in the mouth and throat.
- The ingredient in MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets has been taken safely with many frequently prescribed medications.
- MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets are sodium and sugar free.
- MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets relieve and prevent heartburn associated with acid indigestion and sour stomach.

Excellent Safety Record

What symptoms does MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets relieve and prevent?

Eating or drinking certain foods or beverages, and even lying down to sleep, can cause heartburn associated with acid indigestion and sour stomach. It is normal for the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause burning pain and discomfort.



How should I take MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets?

- To **relieve** symptoms, swallow 1 tablet with a glass of water.
- To **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn.

This medicine can be used up to twice daily (do not take more than 2 tablets in 24 hours).

- Do not chew tablet.
- MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets should not be given to children under 12 years old unless directed by a doctor.
- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers.

COOL MINT TABLETS
MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/
Acid Reducer
150
0100610-01

How do MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets work?

MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets reduce the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

Tips for managing heartburn

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

When should I see a doctor?

- **Do not use**
 - if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 - with other acid reducers
- **Ask a doctor before use if you have**
 - had heartburn over 3 months. This may be a sign of a more serious condition.
 - heartburn with **lightheadedness, sweating or dizziness**
 - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 - frequent **chest pain**
 - frequent wheezing, particularly with heartburn
 - unexplained weight loss
 - nausea or vomiting
 - stomach pain
 - kidney disease
- **Ask a doctor or pharmacist before use if you are**
 - taking a prescription drug. Acid reducers may interact with certain prescription drugs.
- **Stop use and ask a doctor if**
 - your heartburn continues or worsens
 - you need to take this product for more than 14 days
- **If pregnant or breast-feeding**, ask a health professional before use.
- **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Questions? call 1-800-633-1610
or visit www.zantacotc.com

BOTTLES: Bottle is sealed with printed foil under cap. Do not use if printed foil is open or torn.

BLISTERS: Do not use if the individual blister unit is open or torn.

FOIL PACKET: Do not use if the individual foil packet is open or torn.

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Zantac 150 Cool Mint Insert for Blister Cartons

09.26.18

ZAN_150_CoolMint_BlisterCTN_Insert_0100656-01_FDA_2018_FNL2

SANOFI 

What you should know about COOL MINT TABLETS MAXIMUM STRENGTH

Zantac

Ranitidine Tablets 150 mg/
Acid Reducer **150**[®]

(Please read all of this information before taking MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets. Save this leaflet for future reference.)

**What are
MAXIMUM STRENGTH
Zantac 150 Cool Mint
Tablets?**

• MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets contain 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

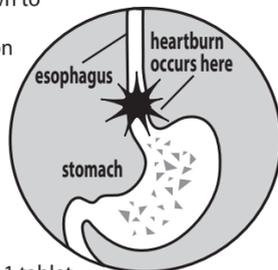
**Excellent Safety
Record**

• When swallowed, MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets release a cooling sensation in the mouth and throat.
• The ingredient in MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets has been taken safely with many frequently prescribed medications.

**What symptoms does
MAXIMUM STRENGTH
Zantac 150 Cool Mint
Tablets relieve and
prevent?**

• MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets are sodium and sugar free.
• MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets relieve and prevent heartburn associated with acid indigestion and sour stomach.

Eating or drinking certain foods or beverages, and even lying down to sleep, can cause heartburn associated with acid indigestion and sour stomach. It is normal for the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause burning pain and discomfort.



**How should I take
MAXIMUM STRENGTH
Zantac 150 Cool Mint
Tablets?**

• To **relieve** symptoms, swallow 1 tablet with a glass of water.
• To **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn.
This medicine can be used up to twice daily (do not take more than 2 tablets in 24 hours).
• Do not chew tablet.
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• **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers.

GLUE
PANEL

150[®]
Zantac
MAXIMUM STRENGTH
COOL MINT TABLETS
Ranitidine Tablets 150 mg/
Acid Reducer

COOL MINT TABLETS
MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/
Acid Reducer **150**[®]

0100656-01

GLUE
PANEL

**How do
MAXIMUM STRENGTH
Zantac 150 Cool Mint
Tablets work?**

**Tips for managing
heartburn**

MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets reduce the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

Ask a doctor or pharmacist before use if you are

- taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

• **If pregnant or breast-feeding**, ask a health professional before use.

• **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Questions? call 1-800-633-1610 or visit www.zantacotc.com

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**When should
I see a doctor?**

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

VALERIE S PRATT
04/04/2019 04:23:32 PM