

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-891

LABELING

March 30,
2006

**ATTACH LEGEND ON ALL
DIGITAL MECHANICALS**

STANDARD FORMAT

Helvetica Condensed
Variable horizontal scale adheres to 39 characters
per inch

Drug Facts - 9 pt Helvetica Cnd, Bold Italic

Drug Facts (continued)

Drug Facts - 8 pt Helvetica Cnd, Bold Italic
(continued) - 8 pt Helvetica Cnd.

Headings - 8 pt Helvetica Cnd, Bold Italic

Sub Heads - 6 pt Helvetica Cnd, Bold

Text - 6 pt Helvetica Cnd, minimum leading 6.5

Square Bullets - 3.5 pt Zaph Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule

Headline - 5 pt rule

Certified by: _____

29012008



No Varnish

Glue

No Varnish

© 1997, 2005, 2006 (1) BAYER AG, BAYER U.S. INC.
All rights reserved. Do not use for other purposes.

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients.
Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.
When using this product do not take more than directed. Taking more than directed may cause drowsiness.
Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.
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.

Other Information
phenylephrine: contains phenylephrine 1.4 mg per tablet
■ safety sealed: do not use if the individual blister unit imprinted with Children's Claritin® is open or torn
■ store between 20° to 25°C (68° to 77°F)

Directions
adults and children
6 years and over
children 2 to under
6 years of age
children under
2 years of age
chew 2 tablets daily, not more
than 2 tablets in 24 hours
chew 1 tablet daily, not more
than 1 tablet in 24 hours
ask a doctor
ask a doctor
consults with liver
or kidney disease

Drug Facts
Active ingredient (in each tablet)
Loratadine 5 mg, fexofenadine
antihistamine
Purpose
temporarily relieves these symptoms due to
hay fever or other upper respiratory allergies:
■ runny nose
■ sneezing
■ itching of the nose or throat
Warnings
Do not use if you have ever had an allergic reaction to
this product or any of its ingredients.
Ask a doctor before use if you have liver or kidney
disease. Your doctor should determine if you need a
different dose.
When using this product do not take more than
directed. Taking more than directed may cause
drowsiness.
Stop use and ask a doctor if an allergic reaction to
this product occurs. Seek medical help right away.
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.

No Varnish



29012008

**Children's
Claritin**
Allergy

**Grape
Flavored
Chewables** 5 CHEWABLE
TABLETS

NDC 11523-71-98-2

**Children's
Claritin**
Allergy

**Children's
Claritin**
Allergy
Non-Drowsy*
24 Hour Relief of:
• Sneezing
• Runny Nose
• Itchy, Watery Eyes
• Itchy Throat or Nose

Isoactive tablets 5 mg fexofenadine

5 CHEWABLE TABLETS

5 CHEWABLE TABLETS

*When taken as directed. See Drug Facts for details.

**Grape
Flavored
Chewables**
Actual
Size

Code Area
No Varnish
No Ink

**Children's
Claritin**
Allergy

STANDARD FORMAT
 Helvetica Condensed
 Variable horizontal scale adheres to 39 characters
 per inch

Drug Facts - 9 pt Helvetica Cond. Bold Italic

Drug Facts (continued)

Drug Facts - 8 pt Helvetica Cond. Bold Italic
 (continued) - 8 pt Helvetica Cond.

Headings - 8 pt Helvetica Cond. Bold Italic

Sub Headings - 5 pt Helvetica Cond. Bold

Text - 6 pt Helvetica Cond. minimum leading 6.5

Square Bullets - 3.5 pt Zapf Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule _____

Headline - 5 pt rule _____

29012105



NO VARNISH

[illegible]

NO VARNISH



29012105

Children's
Claritin
Allergy
10 CHEWABLE TABLETS

**Children's
Claritin[®]
Allergy**

Grade
Flavored
Chewables 10 CHEWABLE
TABLETS

WDC 11523-7198-1

Children's Claritin®

Non-Drowsy*
24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

loratadine tablets 5 mg/antihistamine

10 CHEWABLE TABLETS

Grape
Flavored
Chemables
Actual Size

Code Area
No Varnish
No Ink

Children's **Claritin** Allergy

Children's
Claritin
Allergy

The prescription form from Claritin for children is available at www.claritin.com or 800-441-2211.

© Octapharma U.S. Inc. All rights reserved. 200609-002201210E
Hoechst-Roussel Pharmaceuticals Inc., Kenilworth, NJ, USA



0"-41100"82067"

**ATTACH LEGEND ON ALL
DIGITAL MECHANICALS**

STANDARD FORMAT
Helvetica Condensed
Variable horizontal scale adheres to 39 characters
per inch

Drug Facts - 9 pt Helvetica Cnd. Bold Italic

Drug Facts (continued)

Drug Facts - 8 pt Helvetica Cnd. Bold Italic
(continued) - 8 pt Helvetica Cnd.

Headings - 8 pt Helvetica Cnd. Bold Italic

Sub Heads - 6 pt Helvetica Cnd. Bold

Text - 6 pt Helvetica Cnd, minimum leading 6.5

Square Bullets - 3.5 pt Zaph Dingbats no compression

Border - 1 pt rule, 3/64" gap all around

Barline - 1 pt rule _____

Hairline - .5 pt rule _____

Certified by: _____

BACK

Drug Facts (continued)

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

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.

Directions

adults and children 6 years and over	chew 2 tablets daily; not more than 2 tablets in 24 hours
children 2 to under 6 years of age	chew 1 tablet daily; not more than 1 tablet in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease:	ask a doctor

Drug Facts (continued)

Other information

- phenylephrine: contains phenylephrine 14 mg per tablet
- safety sealed: do not use if the individual blister unit imprinted with Children's Claritin® is open or torn
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

aspartame, citric acid anhydrous, colloidal silicon dioxide, D&C red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions or comments?

1-800-CLARITIN (1-800-252-7484) or www.claritin.com

© Copyright 2001 Schering-Plough HealthCare Products, Inc., Kenilworth, NJ 07033 USA All Rights Reserved 27739-00

Sample - Not for Sale

Children's
Claritin
Allergy

Non-Drowsy*
24 Hour Relief of:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

2 CHEWABLE TABLETS

Grape-Flavored
Chewables

*When taken as Directed. See Drug Facts Panel.

Drug Facts

Active Ingredient Purpose
(In each tablet)
Loratadine 5 mg.....Antihistamine

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings
Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

FRONT

© Copyright & Distributed by Scheer-Pfough Healthcare Products, Inc., Memphis, TN 38151 USA. All rights reserved. The graphics on this product constitute trademarks of Scheer-Pfough Corporation.

[illegible]

Claritin®

**SAMPLE &
COUPON ENCLOSED**

age 2

Children's

Claritin®

Allergy

loratadine tablets 5 mg/antihistamine

2 CHEWABLE TABLETS

***When taken as directed. See Drug Facts Panel.**

Non-Drowsy*

24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

Grape
Flavored
Chewables

PRODUCT SAMPLE - NOT FOR RETAIL SALE

OUTSIDE

Code Area
Lot & Exp

© Copyright & Distributed by Solvay-Frough Healthcare Products, Inc., Memphis, TN 38151 USA. All rights reserved.
The graphics on this product constitute trademarks of Solvay-Frough Corporation.

Drug Facts	
Active ingredient (in each tablet)	Loratadine 5 mg, Antihistamine
Uses	temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, runny nose, itchy, watery eyes, itching of the nose or throat
Warnings	Do not use if you have ever had an allergic reaction to this product or any of its ingredients. Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose. When using this product do not take more than directed. Taking more than directed may cause drowsiness. Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away. 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.
Directions	
adults and children	
chew 2 tablets daily, not more than 2 tablets in 24 hours	
children 2 to under 6 years of age	
chew 1 tablet daily, not more than 1 tablet in 24 hours	
children under 2 years of age	
ask a doctor	
consumers with liver or kidney disease	
ask a doctor	
Other information	
phenylephrine HCl, contains phenylephrine 1.4 mg per tablet	
safety sealed, do not use if the individual blister unit is printed with Children's Claritin [®] is open or torn	
store between 20° to 25°C (68° to 77°F)	
Inactive ingredients	
aspartame, citric acid anhydrous, colloidal silicon dioxide, D&C red No. 27 aluminum lake, FD&C blue No. 2 aluminum lake, flavor, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid	
Questions or comments?	
1-800-CLARITIN (1-800-252-7484) or www.claritin.com	

2 CHEWABLE TABLETS

Claritin

Children's Claritin[®] Allergy

loratadine tablets 5 mg/antihistamine

2 CHEWABLE TABLETS

*When taken as directed. See Drug Facts Panel.

Non-Drowsy*
24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

**Grape
Flavored
Chewables**

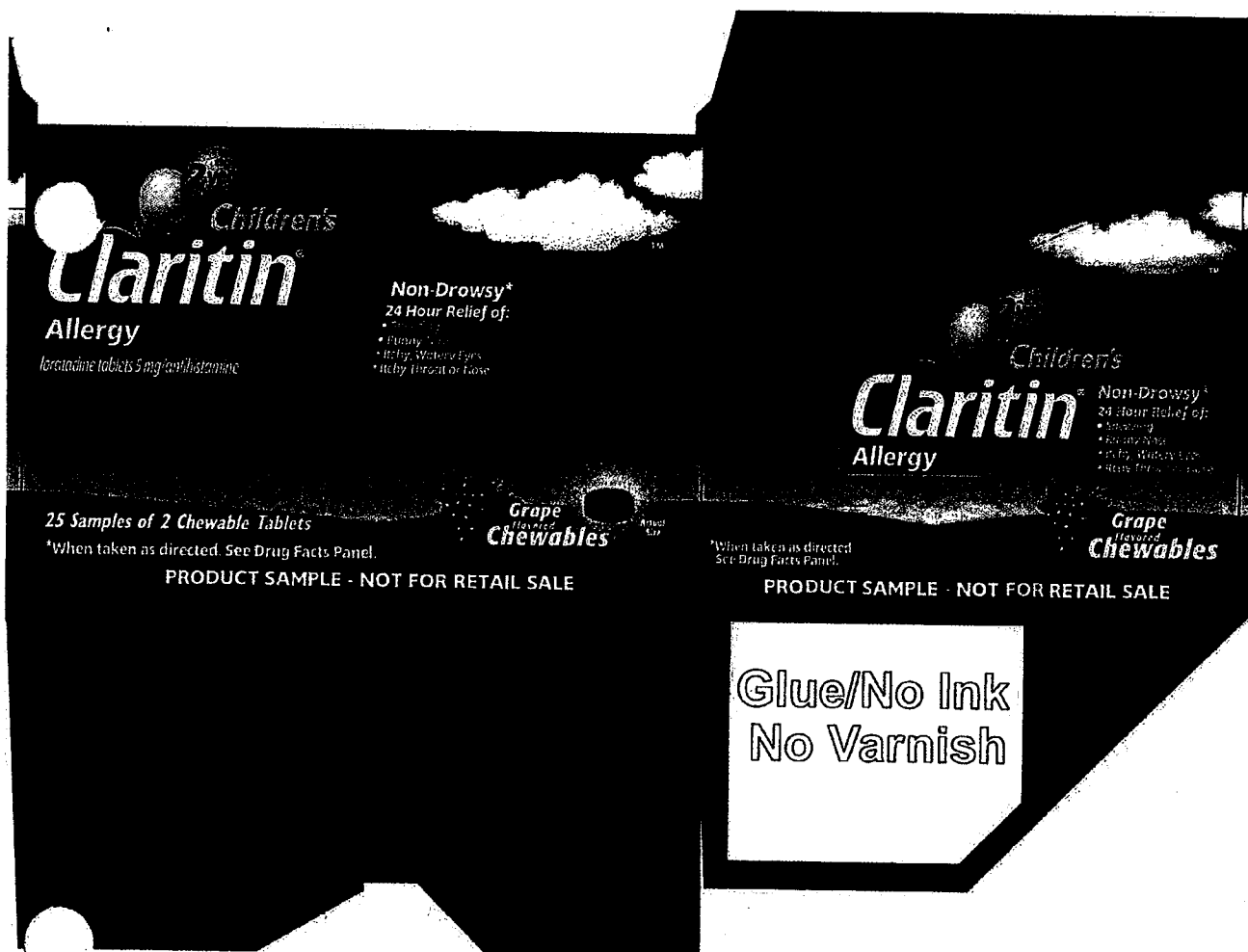
PRODUCT SAMPLE - NOT FOR RETAIL SALE

OUTSIDE

**ATTACH LEGEND ON ALL
DIGITAL MECHANICALS**

STANDARD FORMAT
 Helvetica Condensed
 Variable horizontal scale adheres to 30 characters
 per inch
 Drug Facts - 9 pt Helvetica Cond. Bold Italic
 Drug Facts (continued)
 Drug Facts - 8 pt Helvetica Cond. Bold Italic
 (continued) - 8 pt Helvetica Cond.
 Headings - 8 pt Helvetica Cond. Bold Italic
 Sub-Headings - 6 pt Helvetica Cond. Bold
 Text - 6 pt Helvetica Cond. minimum leading 6.5
 Square Bullets - 3.5 pt Zaph. Ologoths no compression
 Border - 1 pt rule, 3/64" gap all around
 Barline - 1 pt rule
 Flattine - .5 pt rule

Certified by: _____



Schering Plough
S16155CR1.EPS
Print Side Up
Sharp Corporation
21-Mar-2006

Glue/No Ink No Varnish

[illegible]

© Copyright & Distributed by Schering-Plough HealthCare Products, Inc.
Kenilworth, NJ 07033 USA. All Rights Reserved. 27780-00

Children's

Claritin

Allergy

Non-Drowsy!
24 Hour Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat, Nose

Non-Drowsy!
An Hour Relief of:

- Headaches
- Runny Nose
- Sore Throat/ Cough
- Itchy/ Watery Eyes

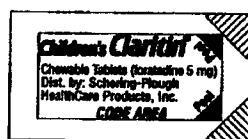
Grape
Flavored
Chewable

^aWhen taken as directed.
See Drug Facts Panel.

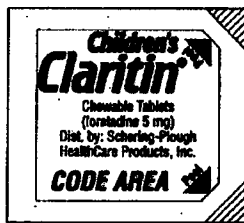
PRODUCT SAMPLE · NOT FOR RETAIL SALE

Glue/No Ink
No Varnish

Aug. 2, 2005



NDA 21-891, S-000
1.14.1 Draft Labeling
1.14.1.1 Blister Version 1



NDA 21-891, S-000
1.14.1 Draft Labeling
1.14.1.1 Blister Version 2