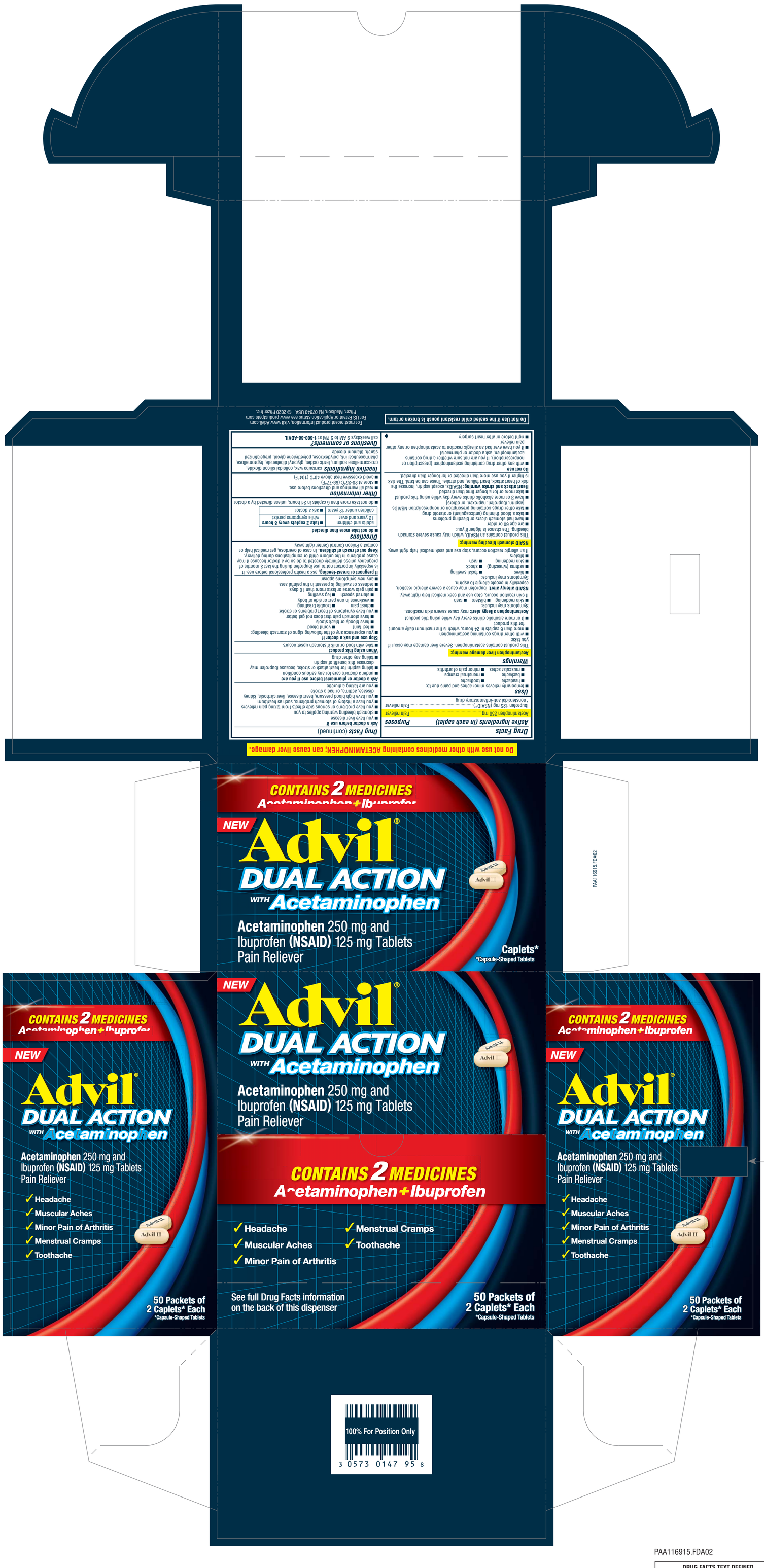
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211733Orig1s000

LABELING



PAA116915.FDA02

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• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

090177e192d8b9b7d\Final\Final On: 15-Feb-2020 02:55 (GMT)
Reference ID: 4568022

Reference ID: 4568022

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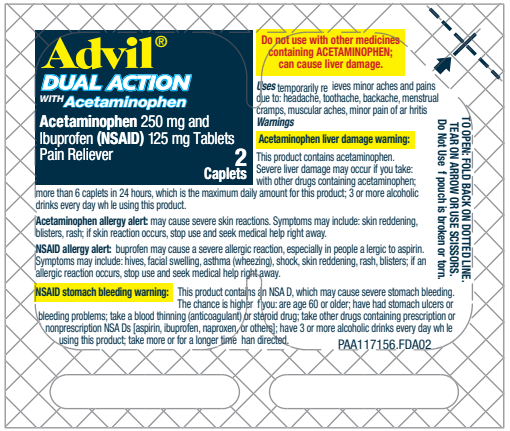

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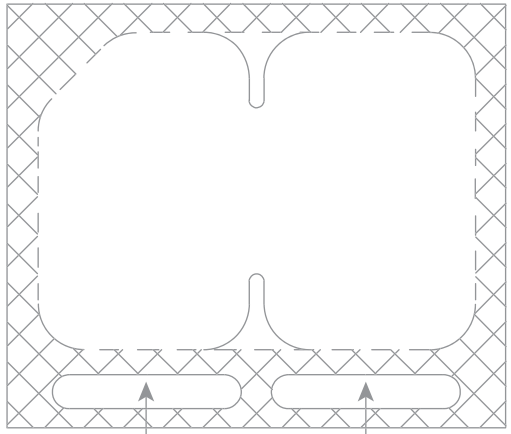

BACK

AREA FOR LOT AND EXP
TO BE PRINTED IN DARK COLOR

PAA117156.FDA02

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Reference ID: 4568022

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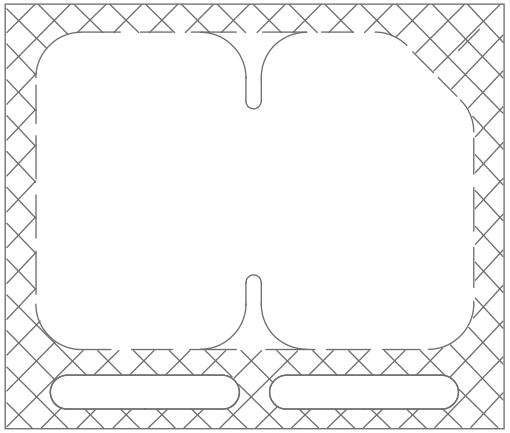

BACK

AREA FOR LOT AND EXP
TO BE PRINTED IN DARK COLOR
26 mm x 5.5 mm

PAA117157.FDA02

MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADINGS/BODY TEXT	4.5 pt
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• BULLETS	N/A
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PAA117160.FDA02

NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
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• BULLETS	N/A
• SPACE BEFORE BULLET	N/A
• BARLINES, HAIRLINES	1pt
• SPACE BETWEEN HAIRLINES AND BOX END	N/A

LIFT HERE

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage.

Drug Facts

Active ingredients (in each caplet)	Purposes
Acetaminophen 250 mg	Pain reliever
Ibuprofen 125 mg (NSAID*)	Pain reliever

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
- headache
- toothache
- backache
- menstrual cramps
- muscular aches
- minor pain of arthritis

PAA118118.FDA02

PANEL 1

Drug Facts (continued)

Warnings

Acetaminophen liver damage warning:

This product contains acetaminophen.
Severe liver damage may occur if you take:

- with other drugs containing acetaminophen
- more than 6 caplets in 24 hours, which is the maximum daily amount for this product
- 3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert: may cause severe skin reactions.
Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

Drug Facts (continued)

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.
Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

NSAID stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems

PANEL 2

Drug Facts (continued)

- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription).

Drug Facts (continued)

If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

- if you have ever had an allergic reaction to acetaminophen or any other pain reliever
- right before or after heart surgery

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

PANEL 3

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better

Drug Facts (continued)

- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

PANEL 4

Drug Facts (continued)

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

Directions

- **do not take more than directed**

adults and children 12 years and over	**take 2 caplets every 8 hours while symptoms persist**
children under 12 years	ask a doctor

- do not take more than 6 caplets in 24 hours, unless directed by a doctor

Other information

- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, ferric oxides, glyceryl dibehenate, hypromellose, pharmaceutical ink, polydextrose, polyethylene glycol, pregelatinized starch, titanium dioxide

Questions or comments?

call weekdays 9 AM to 5 PM at **1-800-88-ADVIL**

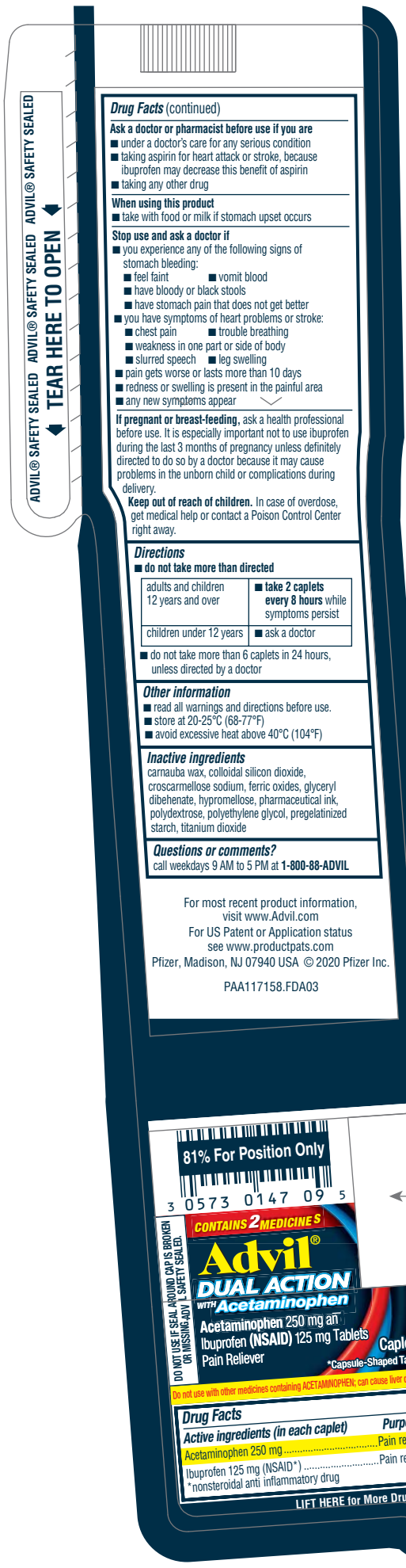
BASE PANEL

PAA118118.FDA02

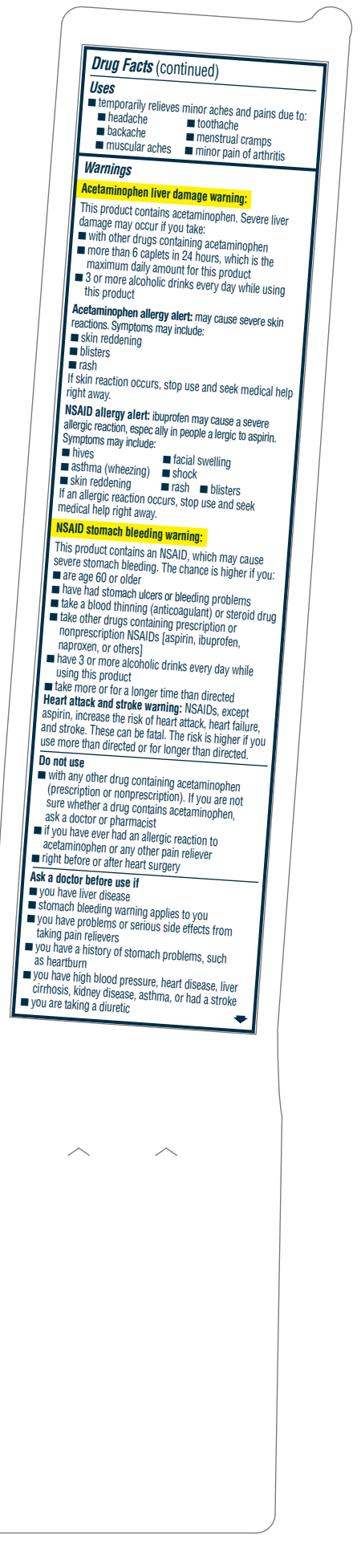
NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	8 pt
• DRUG FACTS CONTINUED	7 pt
• HEADINGS	7 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Reference ID: 4568022

Reference ID: 4568022



UNVARNISHED AREA
FOR LOT & EXP. DATE



PAA117158.FDA03

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• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
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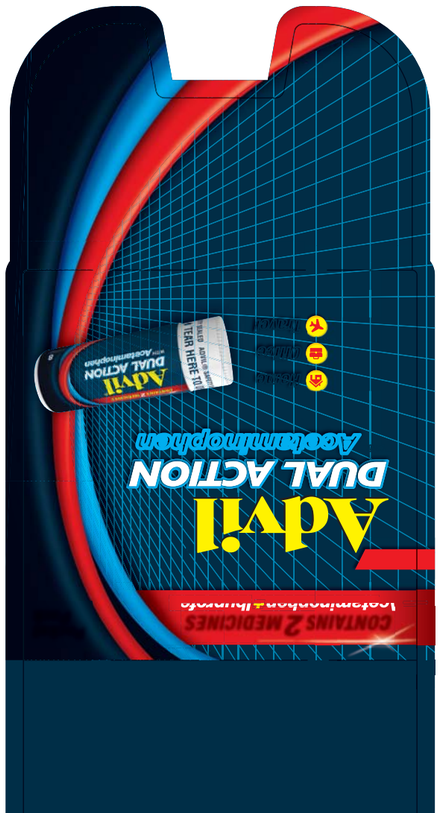
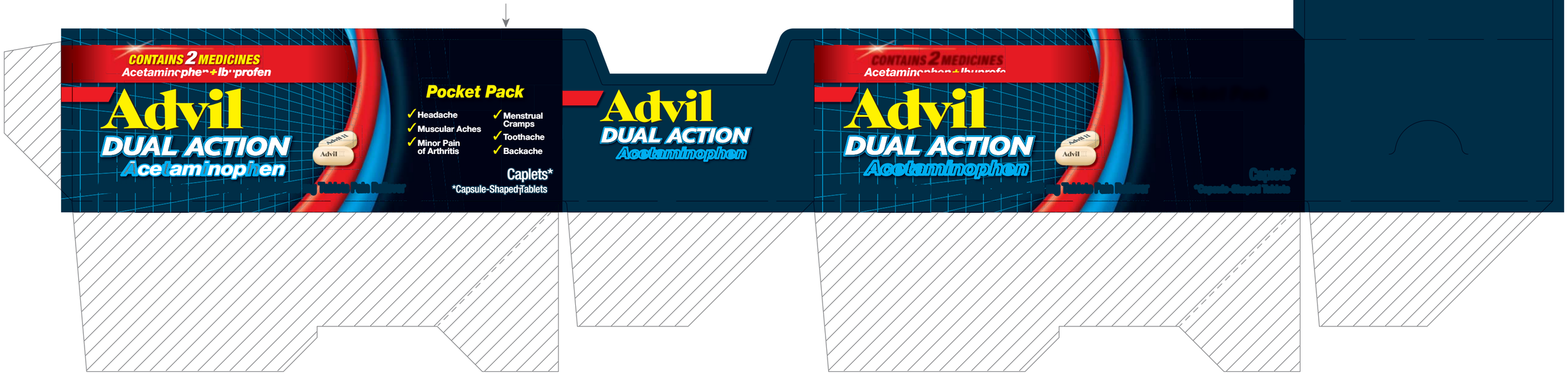
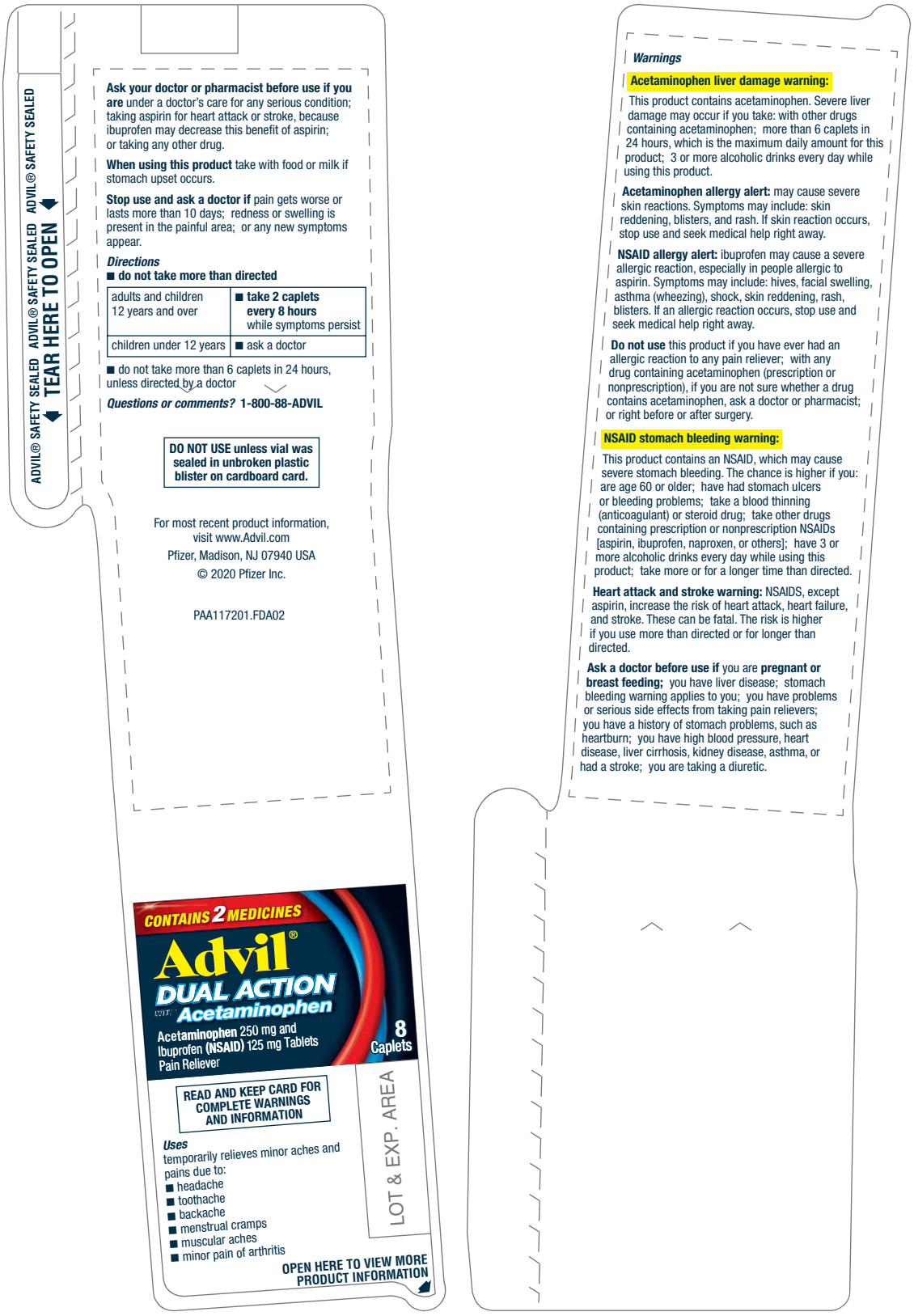




PAA118117.FDA02



PAA117201.FDA02

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• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	.5 pt

TOP (BACK)

Warnings

Acetaminophen liver damage warning:

This product contains acetaminophen. Severe liver damage may occur if you take: with other drugs containing acetaminophen; more than 6 caplets in 24 hours, which is the maximum daily amount for this product; 3 or more alcoholic drinks every day while using this product.

Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include: skin reddening, blisters, and rash. If skin reaction occurs, stop use and seek medical help right away.

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especia ly in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Do not use this product if you have ever had an allergic reaction to any pain reliever; w th any drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist; or right before or after surgery.

NSAID stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older; have had stomach ulcers or bleeding problems; take a blood thinning (anticoagulant) or steroid drug; take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]; have 3 or more alcoholic drinks every day while using this product; take more or for a longer time than directed.

BASE

Heart attack and stroke warning: NSAIDS, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Ask a doctor before use if you are **pregnant or breast feeding;** you have liver disease; stomach bleeding warning applies to you; you have problems or serious side effects from taking pain relievers; you have a history of stomach problems, such as heartburn; you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke; you are taking a diuretic.

Ask your doctor or pharmacist before use if you are under a doctor's care for any serious condition; taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin; or taking any other drug.

When using this product take with food or milk if stomach upset occurs.

Stop use and ask a doctor if pain gets worse or lasts more than 10 days; redness or swelling is present in the painful area; or any new symptoms appear.

Directions **do not take more than directed;** adults and children 12 years and over: **take 2 caplets every 8 hours** wh le symptoms persist; do not take more than 6 caplets in 24 hours, unless directed by a doctor; children under 12 years: ask a doctor.

Questions or comments? **1-800-88-ADVIL**

DO NOT USE unless vial was sealed in unbroken plastic blister on cardboard card.

For most recent product information, visit www.Advil.com
Pfizer, Madison, NJ 07940 USA © 2020 Pfizer Inc.

PAA116916.FDA02

TOP (FACE)

PAA116916.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	6 pt
• SUBHEADINGS/BODY TEXT	6 pt
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• BULLETS	5 pt
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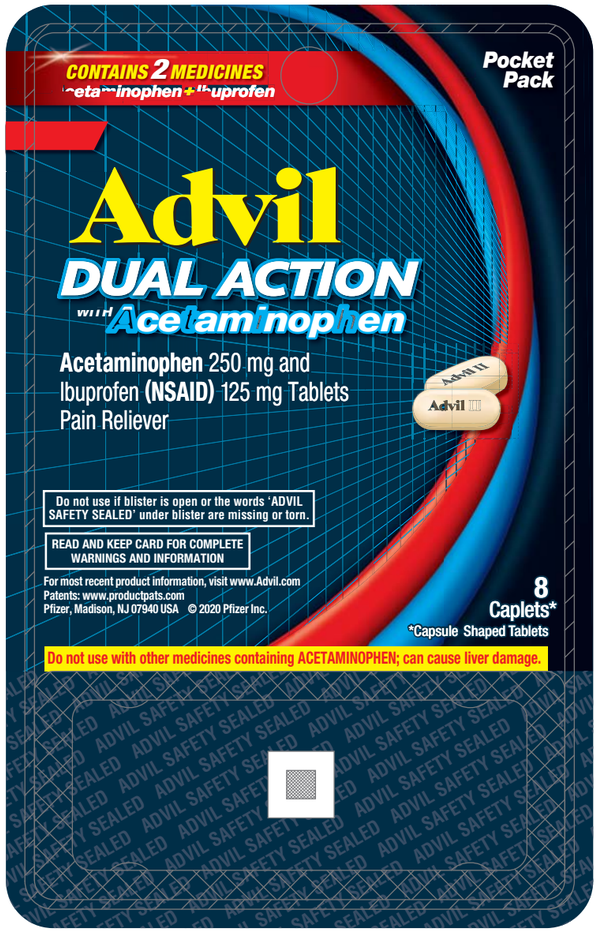
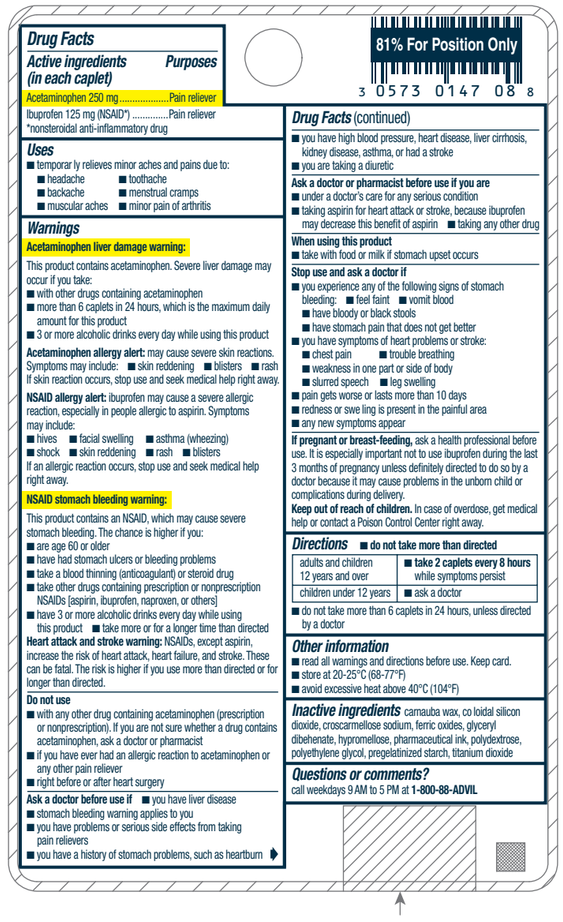
• WARNING BOX LINE	.5 pt





PAA117202.FDA02

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• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
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• BARLINES, HAIRLINES	1.5 pt, .5 pt
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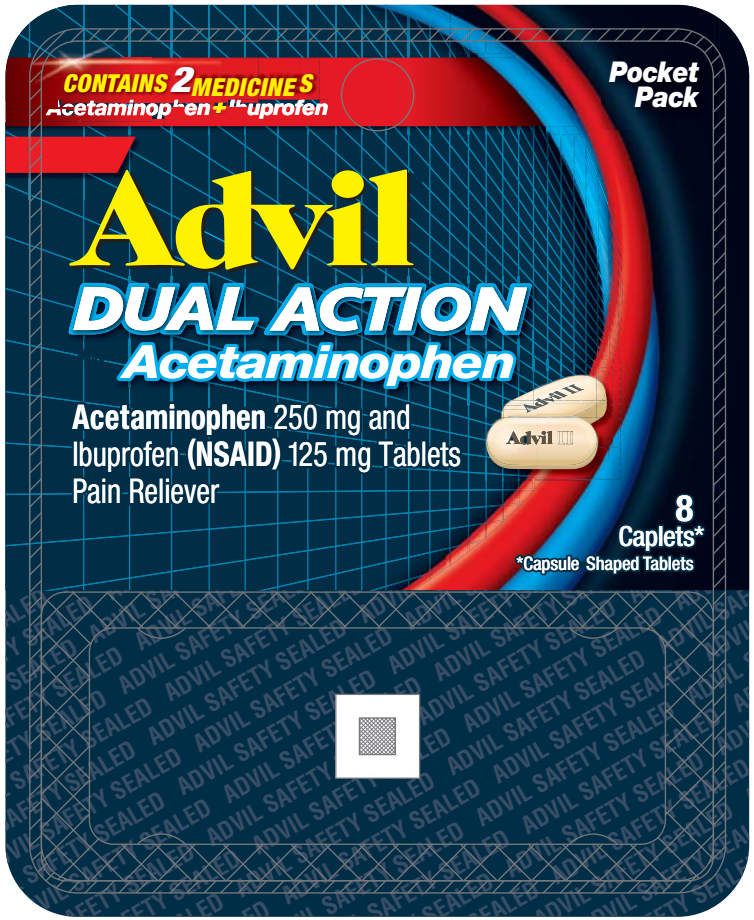

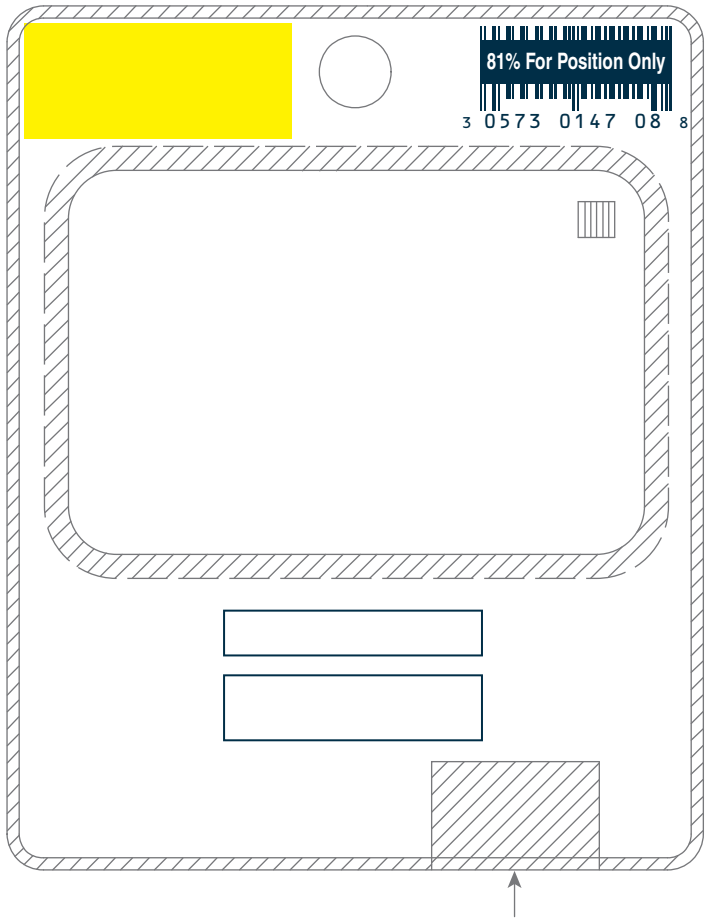

PAA117009.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
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Reference ID: 4568022

PANEL 2

Drug Facts (continued)

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

NSAID stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

Drug Facts (continued)

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

PANEL 3

Drug Facts (continued)

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- if you have ever had an allergic reaction to acetaminophen or any other pain reliever
- right before or after heart surgery

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers
- you have a history of stomach problems, such as heartburn

Drug Facts (continued)

- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

PANEL 4

Drug Facts (continued)

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
  - chest pain
  - trouble breathing
  - weakness in one part or side of body
  - slurred speech
  - leg swelling
- pain gets worse or lasts more than 10 days

Drug Facts (continued)

- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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

PANEL 1

Drug Facts

Active ingredients (in each caplet) ***Purposes***

Acetaminophen 250 mg ..... Pain reliever

Ibuprofen 125 mg (NSAID*) ..... Pain reliever

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
  - headache
  - toothache
  - backache
  - menstrual cramps
  - muscular aches
  - minor pain of arthritis

Drug Facts (continued)

Warnings

Acetaminophen liver damage warning:

This product contains acetaminophen. Severe liver damage may occur if you take:

- with other drugs containing acetaminophen
- more than 6 caplets in 24 hours, which is the maximum daily amount for this product
- 3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

LIFT HERE

Drug Facts (continued)

Directions

- **do not take more than directed**

adults and children 12 years and over	■ **take 2 caplets every 8 hours** while symptoms persist
children under 12 years	■ ask a doctor

- do not take more than 6 caplets in 24 hours, unless directed by a doctor

Other information

- read all warnings and directions before use.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, ferric oxides, glyceryl dibehenate, hypromellose, pharmaceutical ink, polydextrose, polyethylene glycol, pregelatinized starch, titanium dioxide

Questions or comments? call weekdays 9 AM to 5 PM at **1-800-88-ADVIL**

PAA118119.FDA02

BASE PANEL

PAA118119.FDA02

NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
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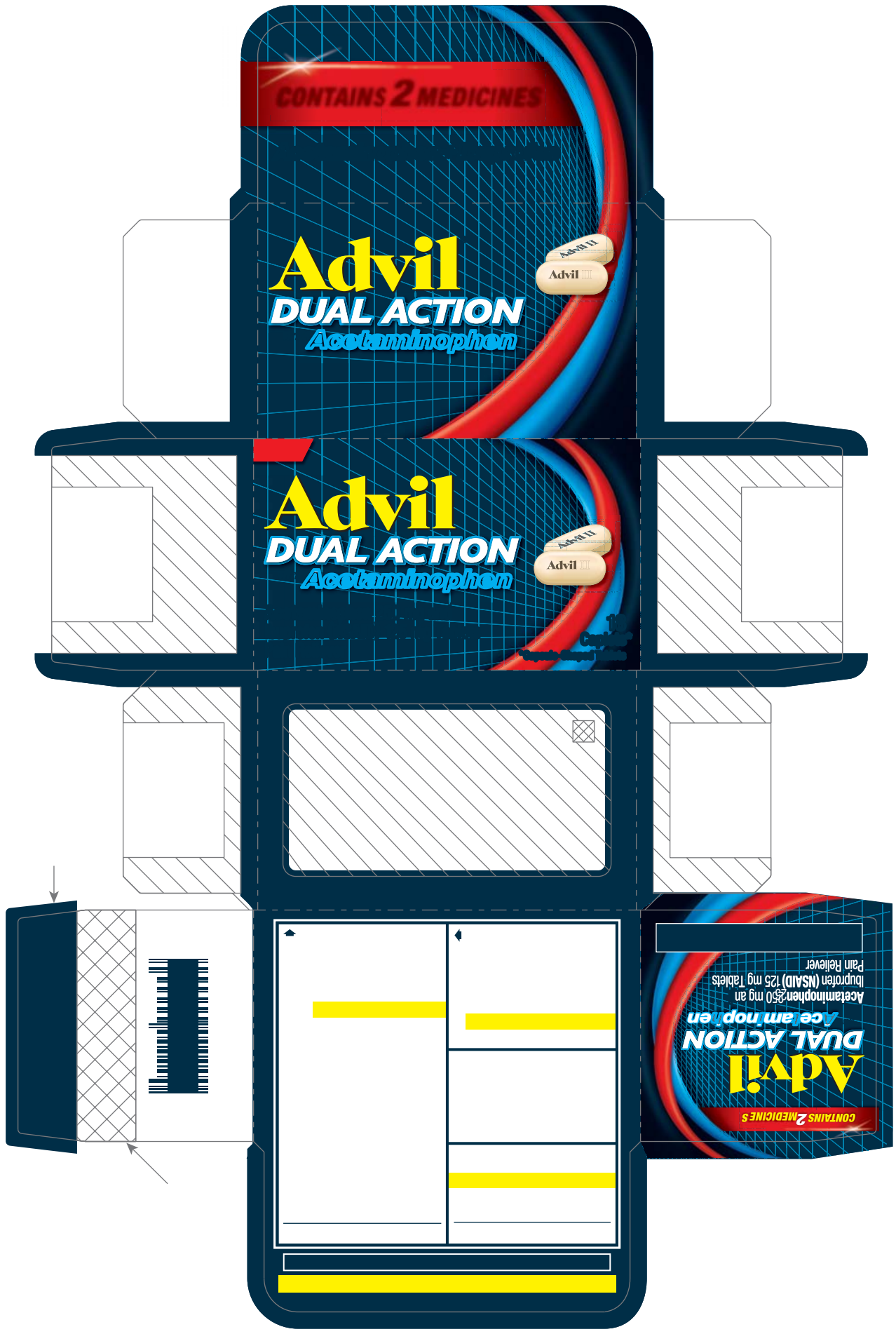
• HEADINGS	7 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces



PAA116859.FDA02

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• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
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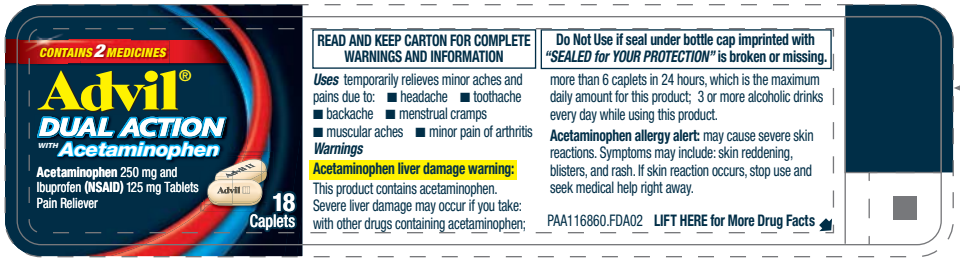
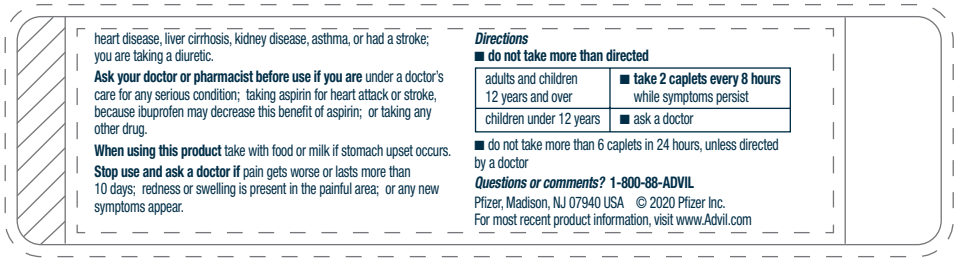
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

TOP (FACE)
PANEL 1

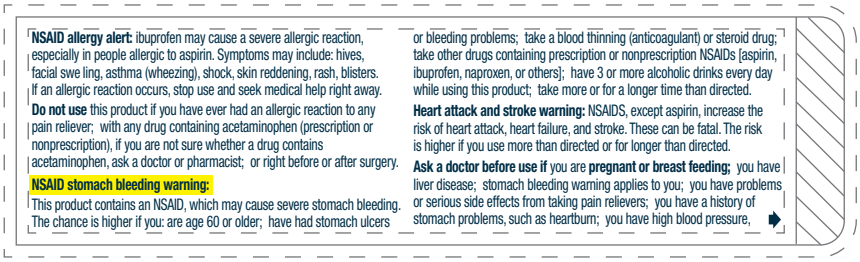


FOR LOT & EXPIRATION AREA, UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE.

BASE
PANEL 3



TOP (BACK)
PANEL 2



PAA116860.FDA02

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PAA116918.FDA02

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• BULLETS	5 pt
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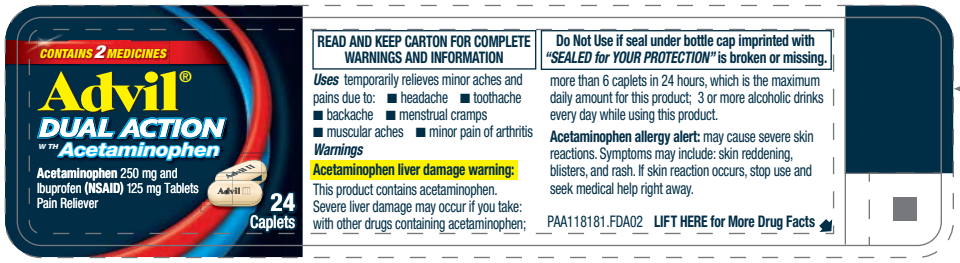
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

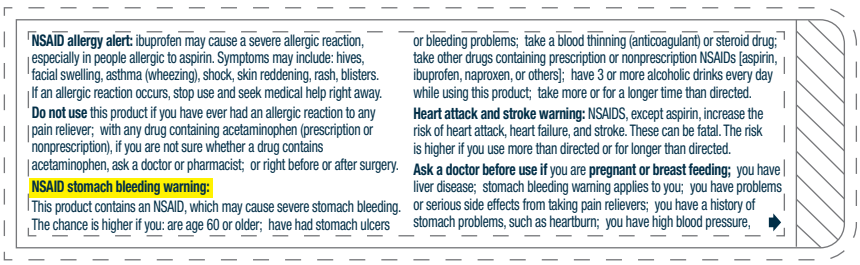
TOP (FACE) PANEL 1



FOR LOT & EXPIRATION AREA, UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE.

BASE PANEL 3

TOP (BACK) PANEL 2

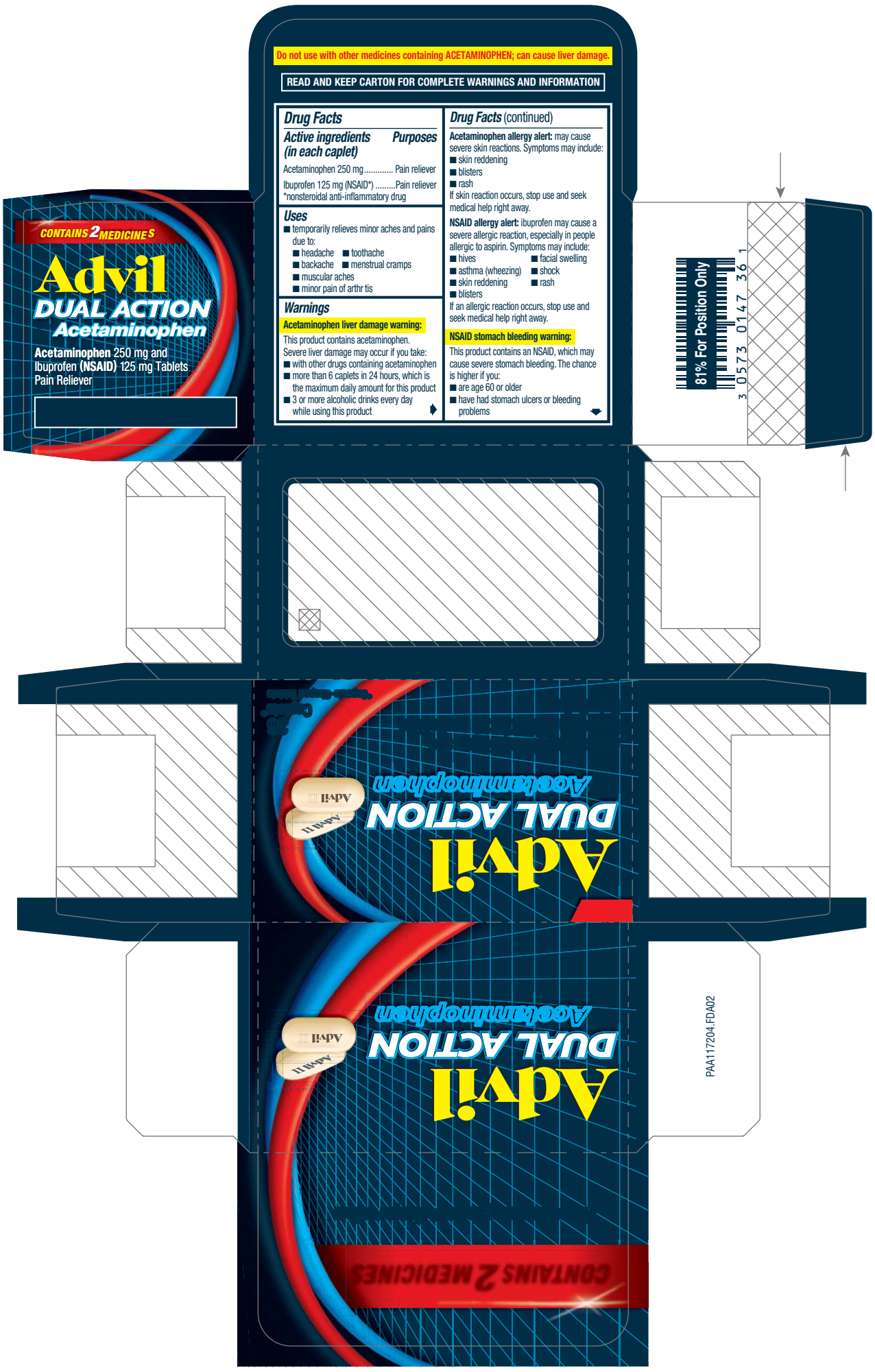


PAA118181.FDA02

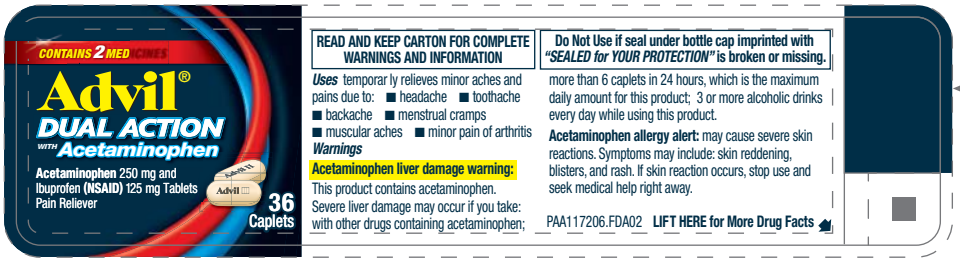
DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	6 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINE	.5 pt

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

PAA117204.FDA02

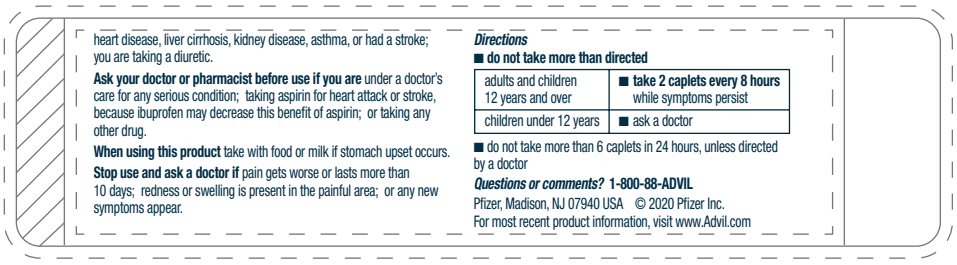


TOP (FACE)
PANEL 1

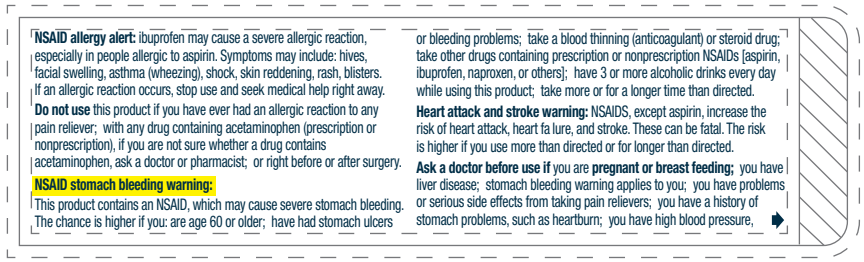


FOR LOT & EXPIRATION AREA, UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE.

BASE
PANEL 3



TOP (BACK)
PANEL 2

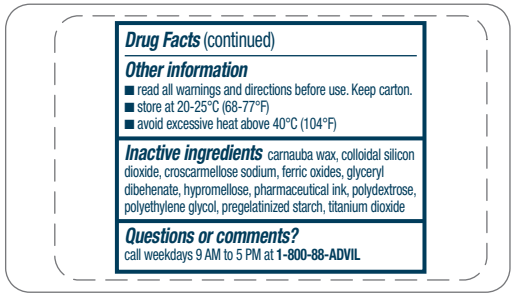


PAA117206.FDA02

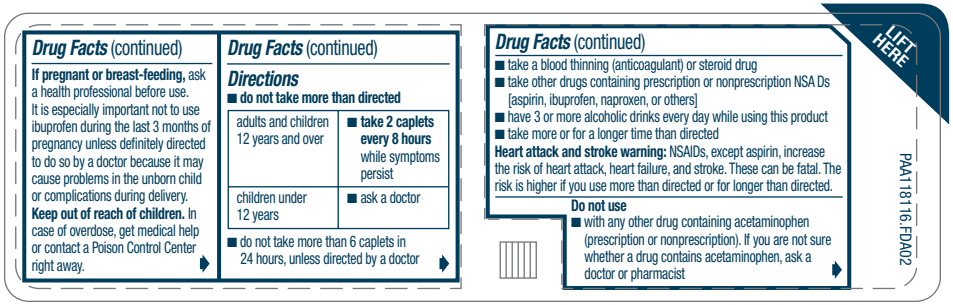
DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	6 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINE	.5 pt

Reference ID: 4558022

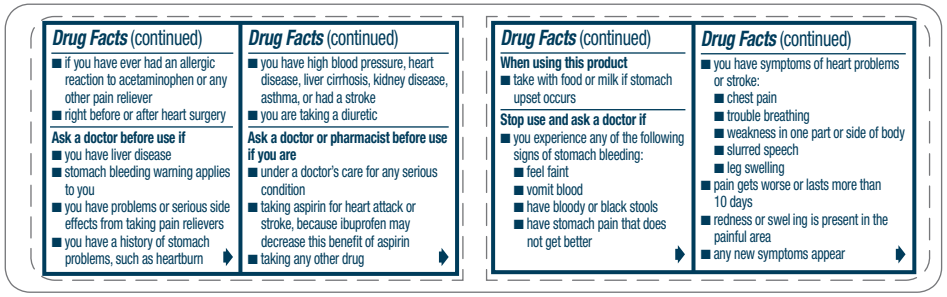
090177e192d89b7e\Final\Final On: 15-Feb-2020 02:59 (GMT)



BASE PANEL



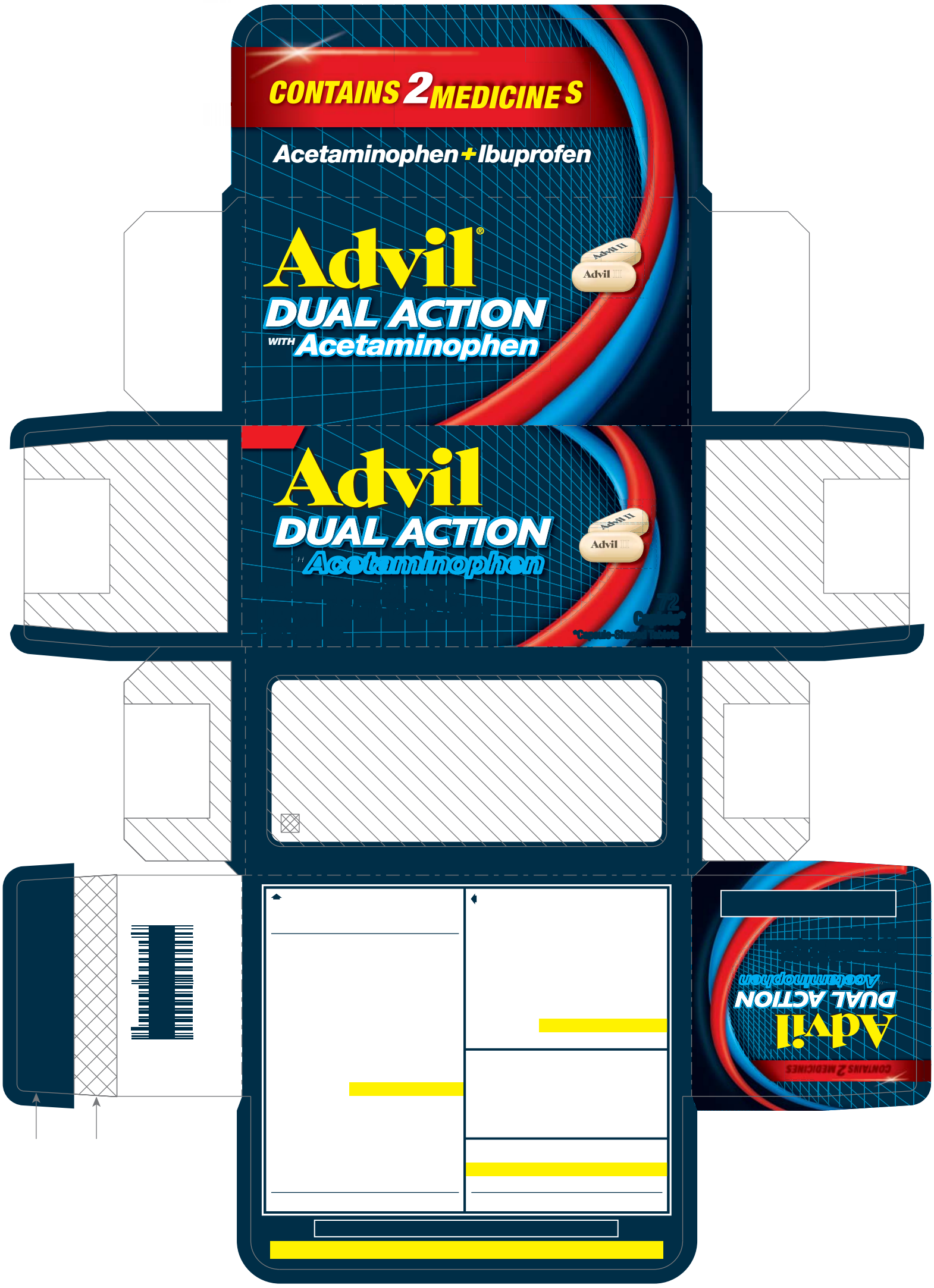
PANEL #4 PANEL #1



PANEL #2 PANEL #3

PAA118116.FDA02

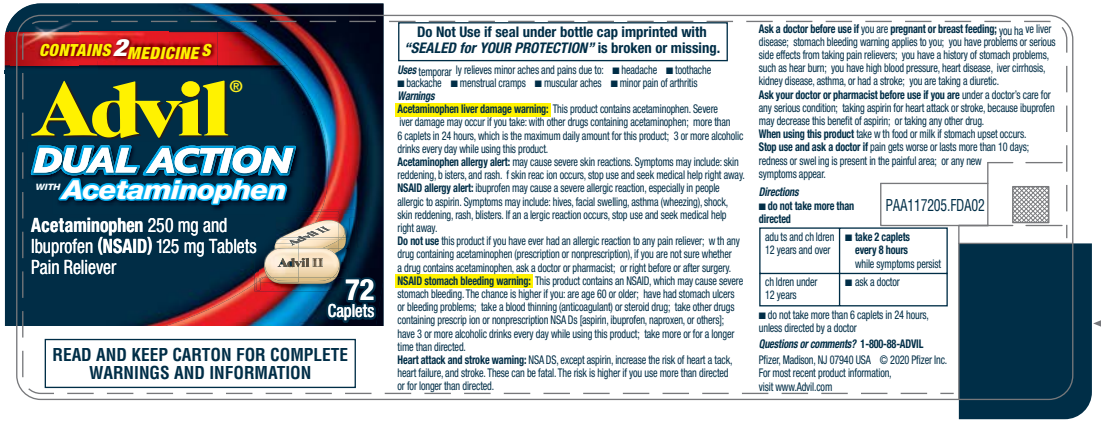
DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	N/A
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces



PAA117820.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

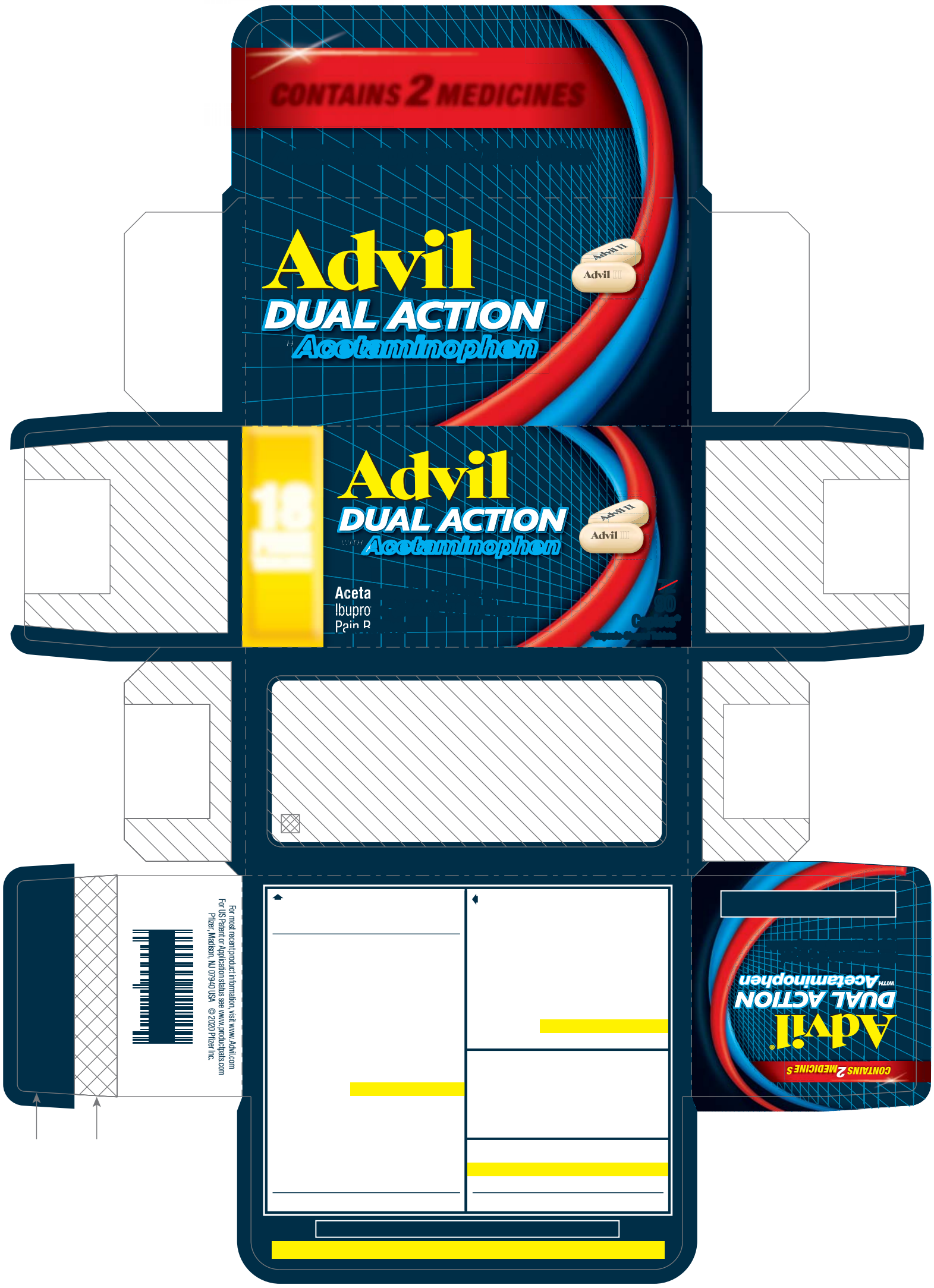
Reference ID: 4568022



UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE FOR LOT & EXPIRATION AREA.

PAA117205.FDA02

MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADINGS/BODY TEXT	4.5 pt
• LEADING	4.95 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	.5 pt



PAA116919.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

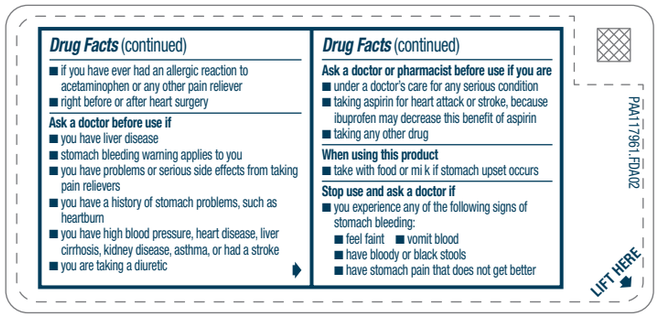
Reference ID: 4568022

UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE FOR LOT & EXPIRATION AREA.

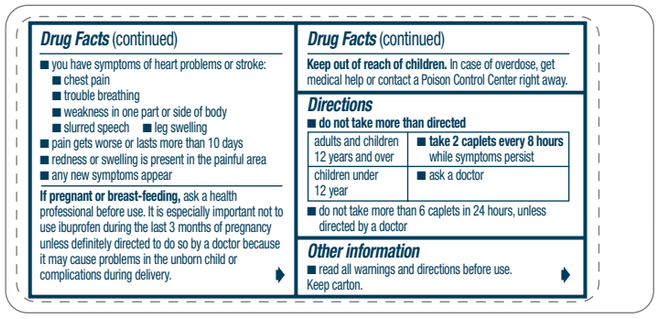
PAA118120.FDA02

MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADINGS/BODY TEXT	4.5 pt
• LEADING	4.95 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	.5 pt

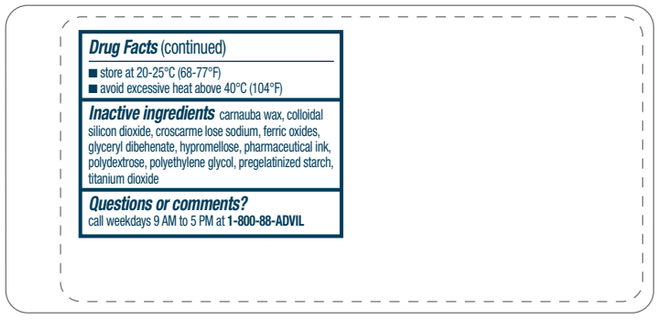
TOP PANEL 1



BACK PANEL 2



BASE PANEL 3



PAA117961.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	N/A
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

CONTAINS 2 MEDICINE S

Acetaminophen + Ibuprofen

Advil®

DUAL ACTION

WITH Acetaminophen

Advil

DUAL ACTION

Acetaminophen

Acetaminophen 250 mg and
Ibuprofen **(NSAID)** 125 mg Tablets
Pain Reliever

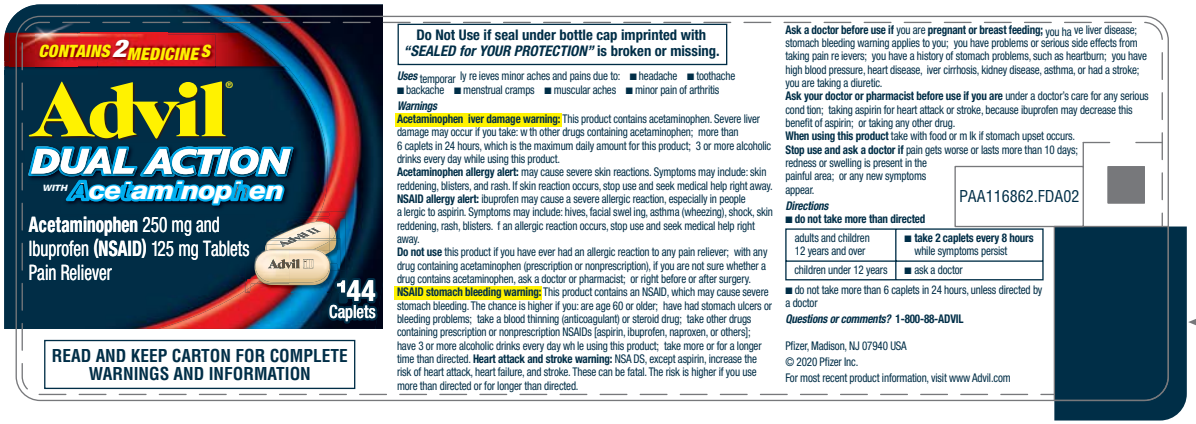
144
Caplets*
*Capsule-Shaped Tablets

PAA116861.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Reference ID: 4568022

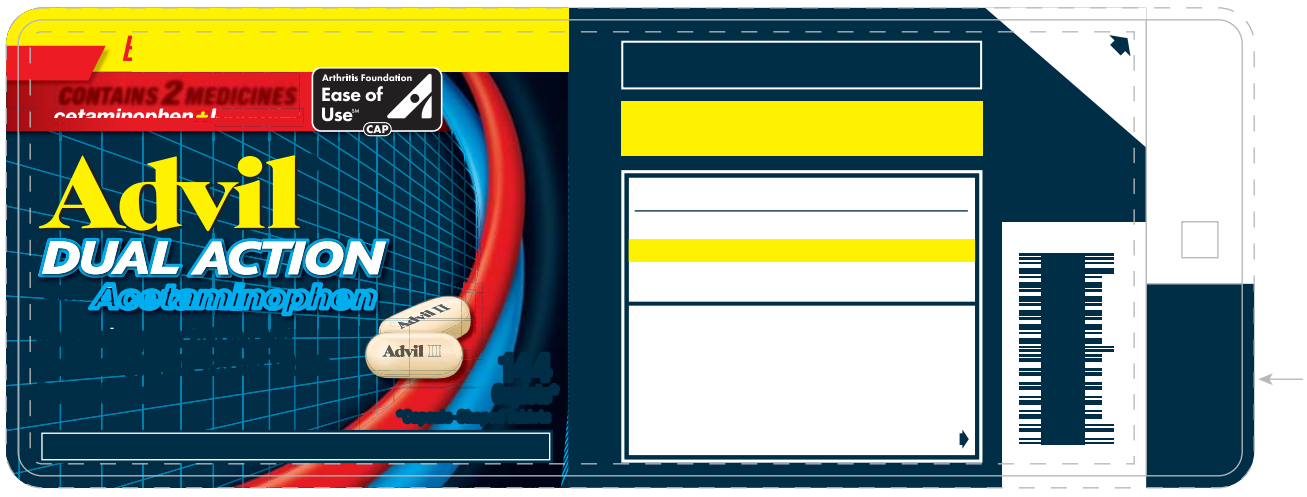
090177e192d89b7c\Final\Final On: 15-Feb-2020 02:55 (GMT)

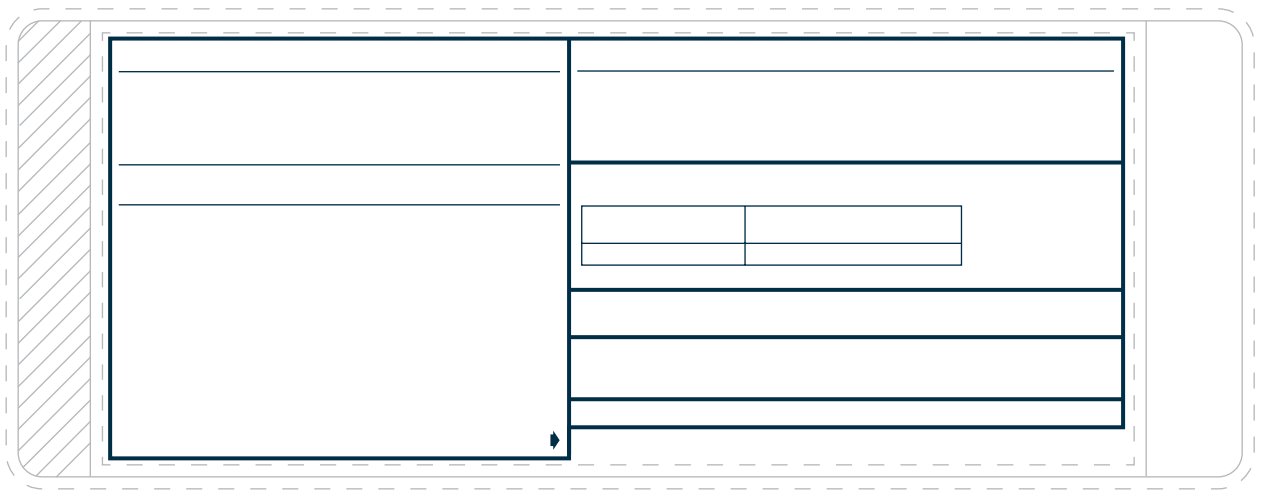


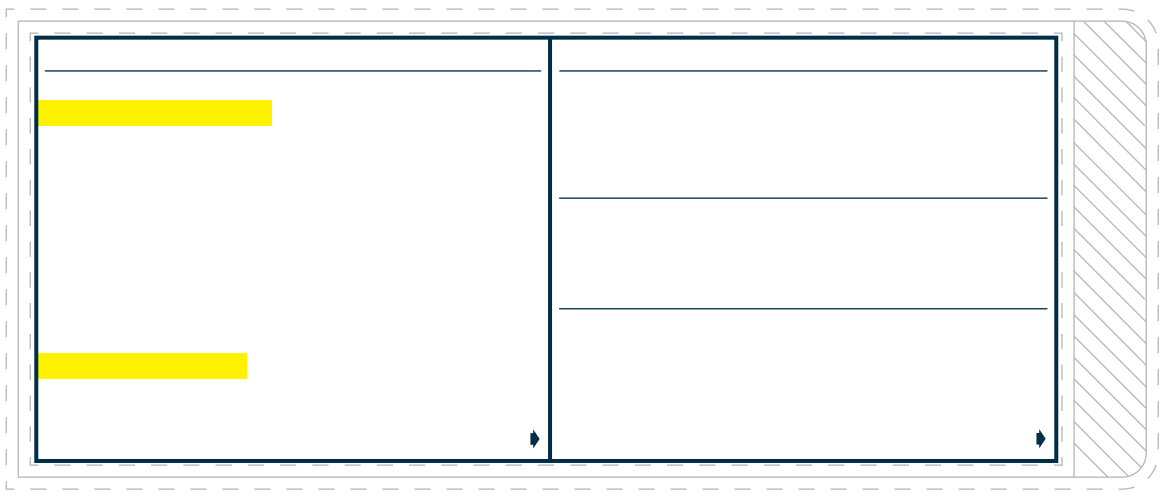
UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE FOR LOT & EXPIRATION AREA.

PAA116862.FDA02

MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADINGS/BODY TEXT	4.5 pt
• LEADING	5 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	.5 pt







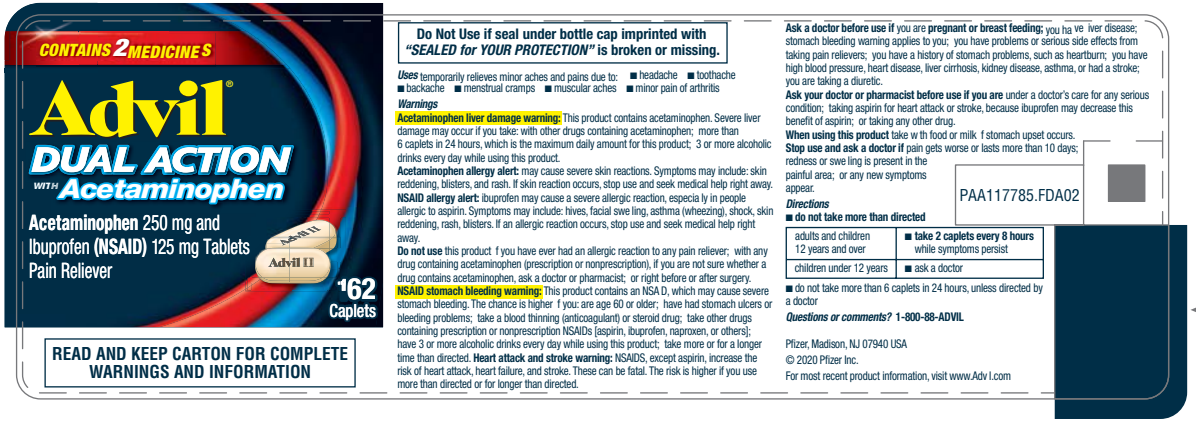
PAA116863.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

PAA116920.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

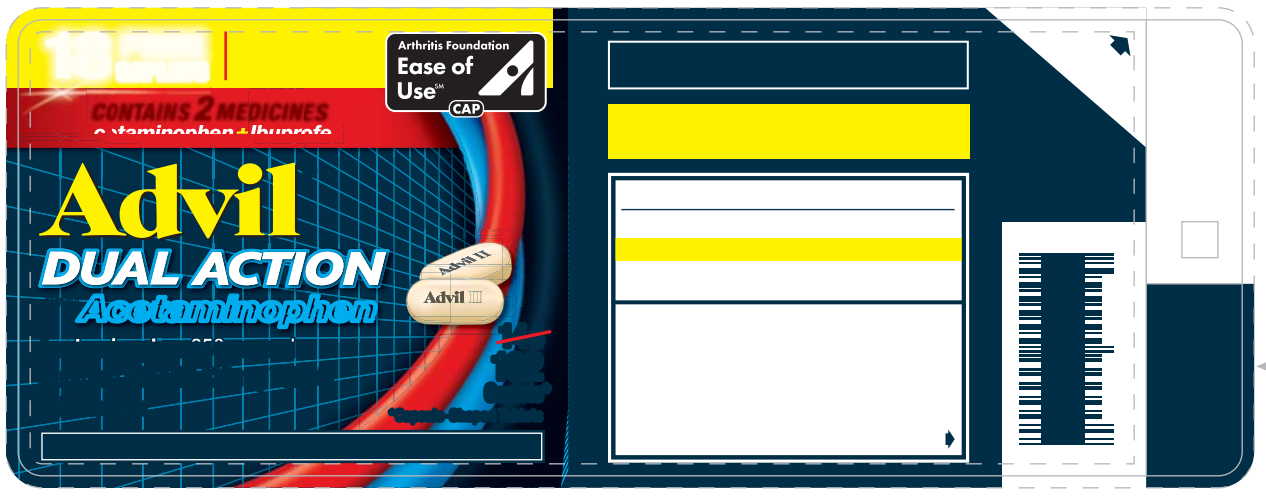
Reference ID: 4568022

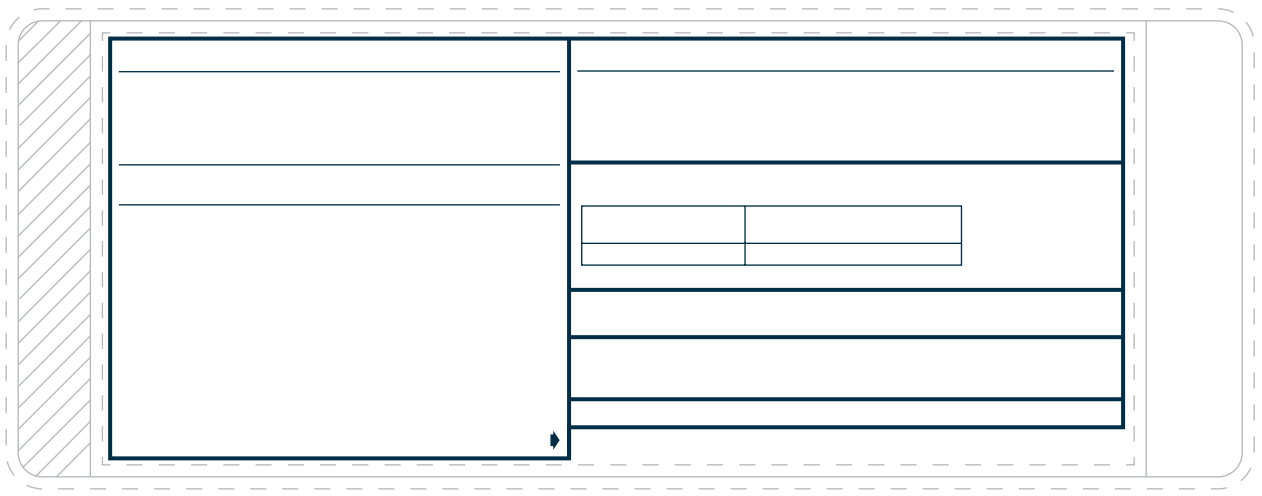


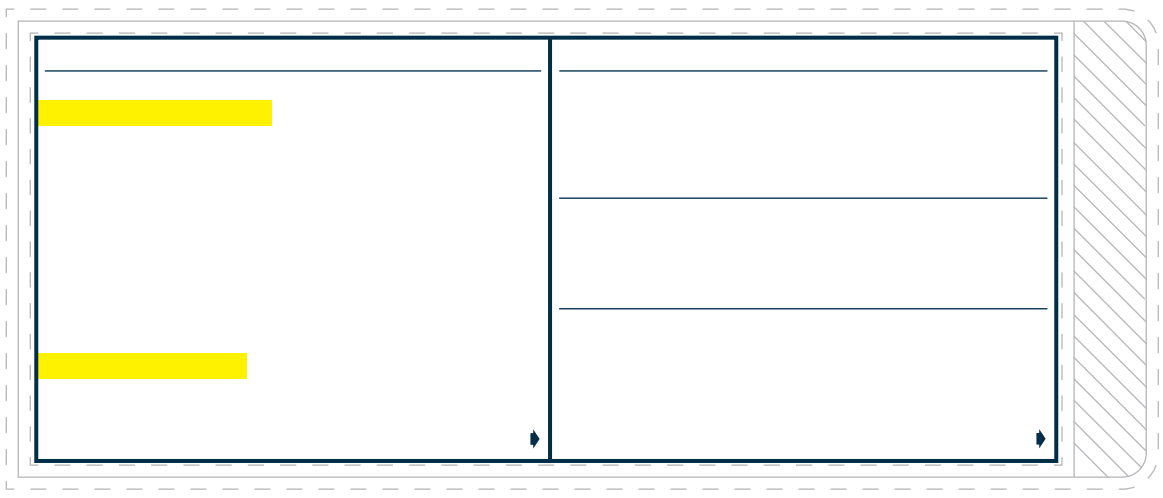
UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE FOR LOT & EXPIRATION AREA.

PAA117785.FDA02

MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADINGS/BODY TEXT	4.5 pt
• LEADING	5 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	.5 pt

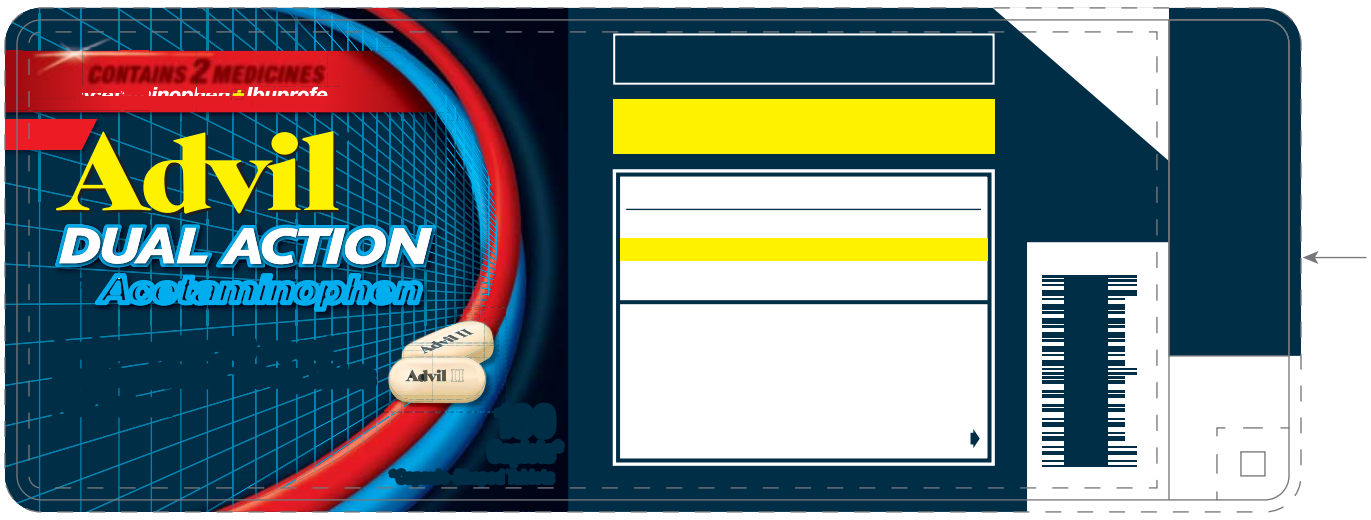


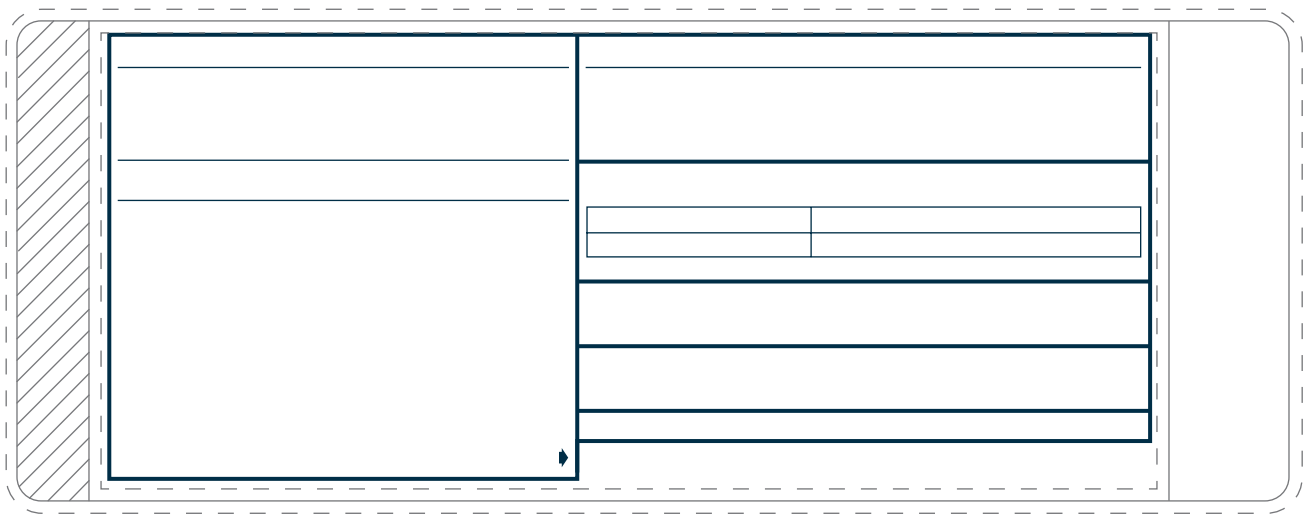


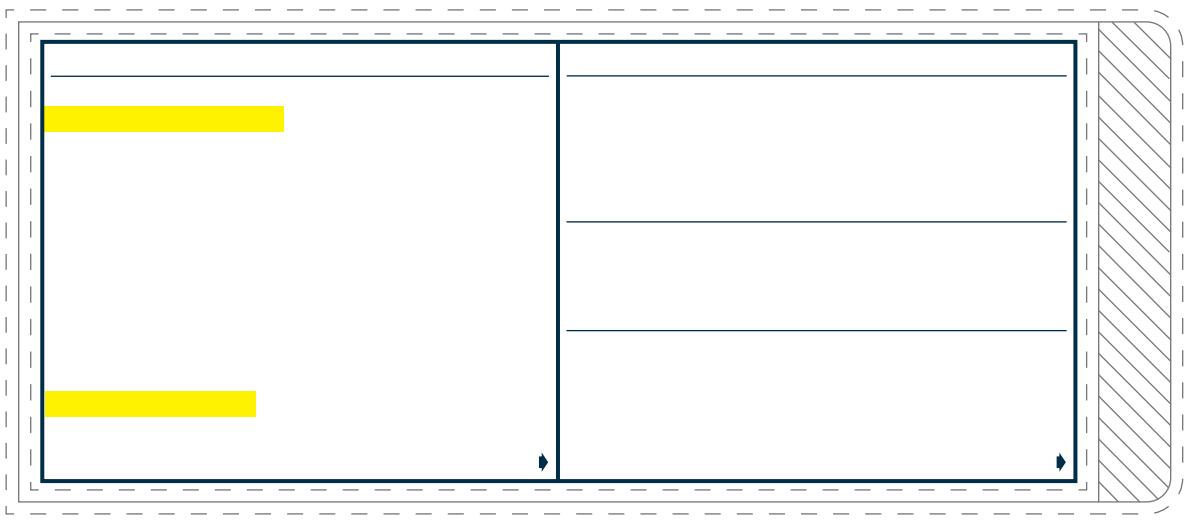


PAA116864.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

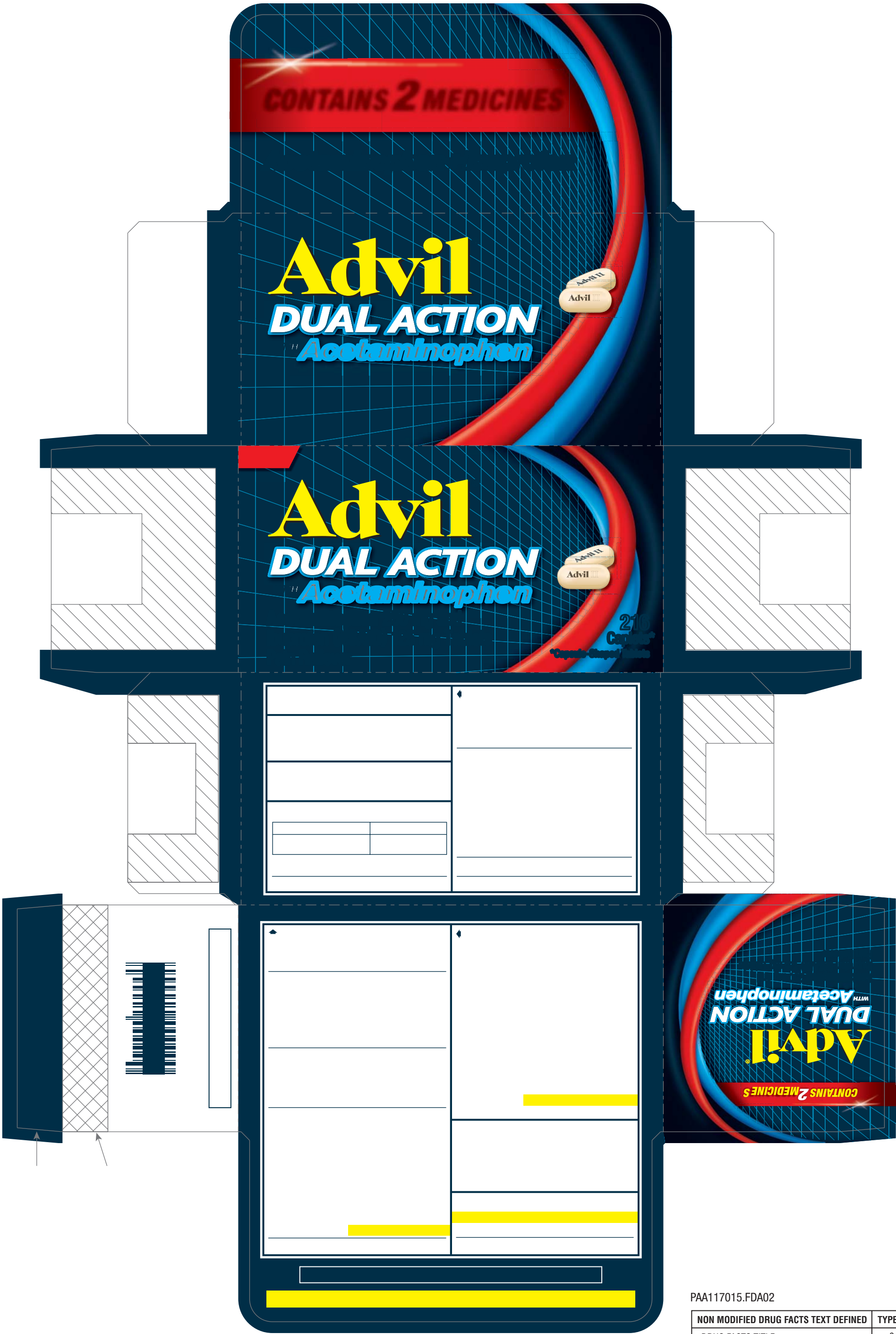






PAA118115.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces



PAA117015.FDA02

NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Reference ID: 4568022

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do Not Use if seal under bottle cap imprinted with *"SEALED for YOUR PROTECTION"* is broken or missing.

Uses temporarily relieves minor aches and pains due to: ■ headache ■ toothache ■ backache ■ menstrual cramps ■ muscular aches ■ minor pain of arthritis

Warnings

Acetaminophen liver damage warning:

This product contains acetaminophen. Severe liver damage may occur if you take: with other drugs containing acetaminophen; more than 6 caplets in 24 hours, which is the maximum daily amount for this product; 3 or more alcoholic drinks every day while using this product.

Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include: skin reddening, b isters, and rash. If skin reaction occurs, stop use and seek medical help right away.

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people a lergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Do not use this product if you have ever had an a lergic reaction to any pain reliever; with any drug containing acetaminophen (prescription or nonprescription), f you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist; or right before or after surgery.

NSAID stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older; have had stomach ulcers or bleeding problems; take a blood thinning (anticoagulant) or steroid drug; take other drugs containing prescription or nonprescription NSA Ds [aspirin, ibuprofen, naproxen, or others]; have 3 or more alcoholic drinks every day while using this product; take more or for a longer time than directed.

Heart attack and stroke warning: NSAIDS, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Ask a doctor before use if you are **pregnant or breast feeding;** you ha ve liver disease; stomach bleeding warning applies to you; you have problems or serious side effects from taking pain relievers; you have a history of stomach problems, such as heartburn; you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke; you are taking a diuretic.

Ask your doctor or pharmacist before use if you are under a doctor's care for any serious condition; taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin; or taking any other drug.

When using this product take w th food or mi k if stomach upset occurs.

Stop use and ask a doctor if pain gets worse or lasts more than 10 days; redness or swel ing is present in the painful area; or any new symptoms appear.

PAA116931.FDA02

Directions

■ **do not take more than directed**

adults and ch ldren 12 years and over	■ **take 2 caplets every 8 hours** wh le symptoms persist
children under 12 years	■ ask a doctor

■ do not take more than 6 caplets in 24 hours, unless directed by a doctor

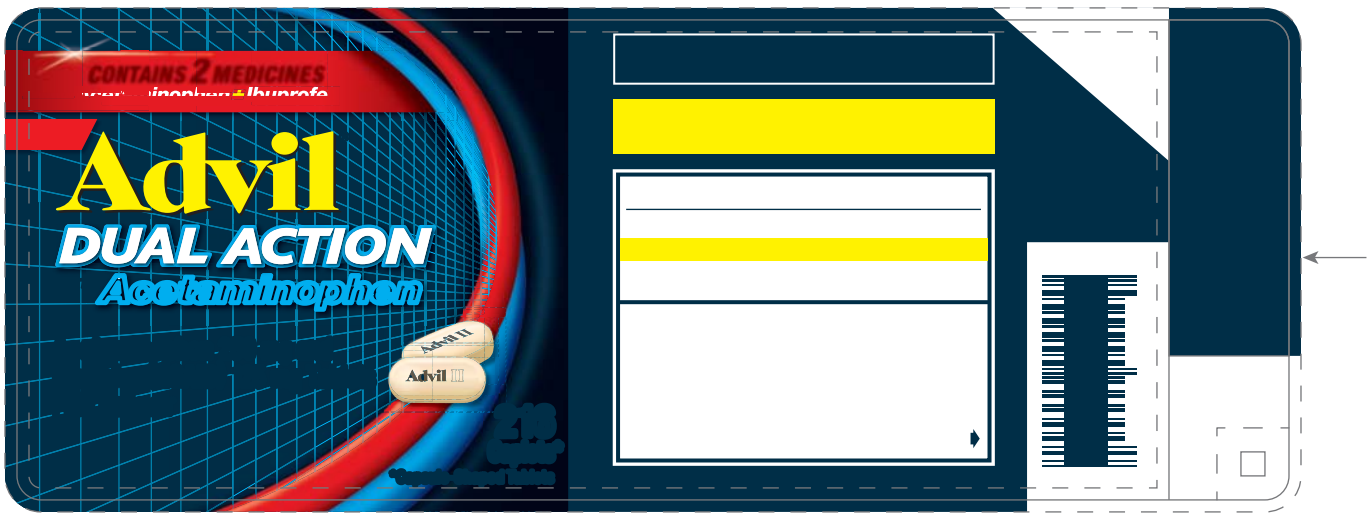
Questions or comments? **1-800-88-ADVIL**

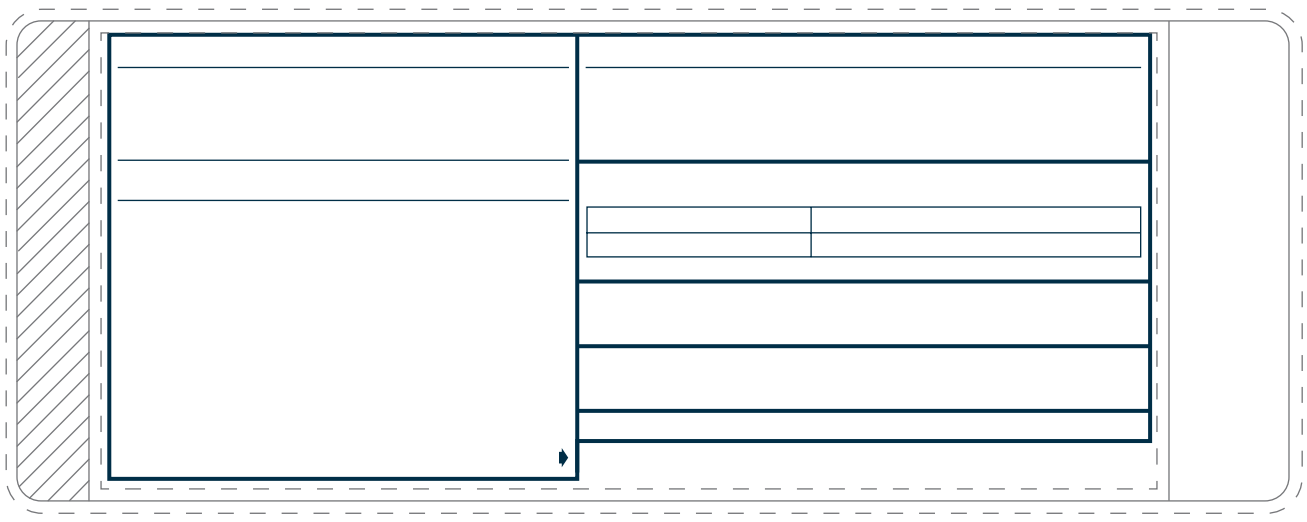
Pfizer, Madison, NJ 07940 USA © 2020 Pfizer Inc.
For most recent product information, visit www.Advil.com

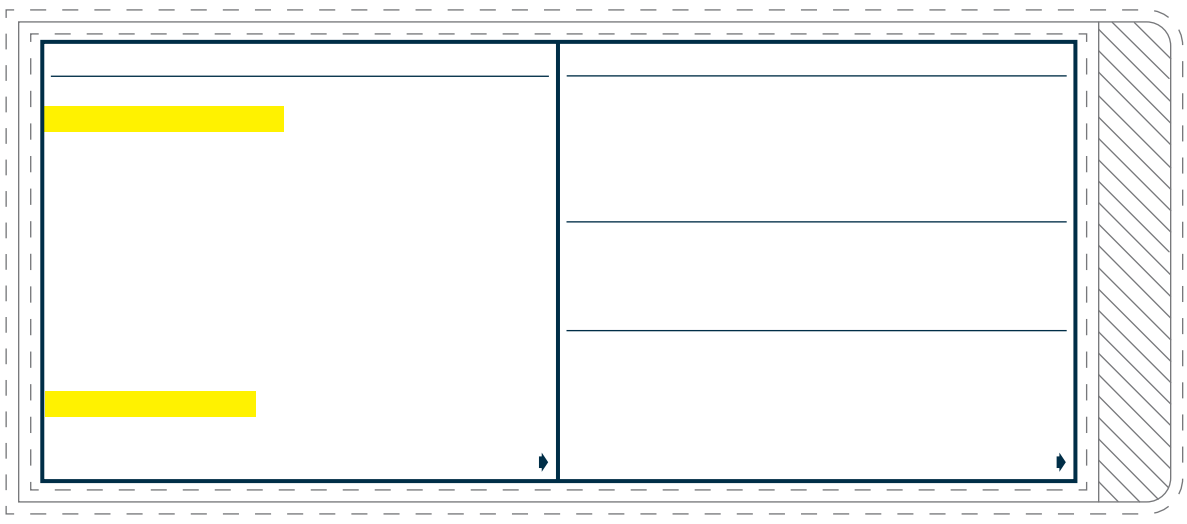
UNVARNISHED AND PRINTED IN BLACK OR DARK BLUE FOR LOT & EXPIRATION AREA.

PAA116931.FDA02

NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	5 pt
• SUBHEADINGS/BODY TEXT	5 pt
• LEADING	5.5 pt
• BULLETS	4 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	.5 pt







PAA116865.FDA02

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

PAA116856.FDA02

NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Do Not Use if seal under bottle cap imprinted with *"SEALED for YOUR PROTECTION"* is broken or missing.

Uses

temporarily relieves minor aches and pains due to: ■ headache ■ toothache ■ backache ■ menstrual cramps ■ muscular aches ■ minor pain of arthritis

Warnings

Acetaminophen liver damage warning: This product contains acetaminophen. Severe liver damage may occur if you take: with other drugs containing acetaminophen; more than 6 caplets in 24 hours, which is the maximum daily amount for this product; 3 or more alcoholic drinks every day while using this product.

Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include: skin reddening, blisters, and rash. If skin reaction occurs, stop use and seek medical help right away.

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Do not use this product if you have ever had an allergic reaction to any pain reliever; with any drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist; or right before or after surgery.

NSAID stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older; have had stomach ulcers or bleeding problems; take a blood thinning (anticoagulant) or steroid drug; take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]; have 3 or more alcoholic drinks every day while using this product; take more or for a longer time than directed.

Heart attack and stroke warning: NSAIDS, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Ask a doctor before use if you are **pregnant or breast feeding;** you ha ve liver disease; stomach bleeding warning applies to you; you have problems or serious side effects from taking pain relievers; you have a history of stomach problems, such as heartburn; you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke; you are taking a diuretic.

Ask your doctor or pharmacist before use if you are under a doctor's care for any serious condition; taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin; or taking any other drug.

When using this product take with food or milk if stomach upset occurs.

Stop use and ask a doctor if pain gets worse or lasts more than 10 days; redness or swelling is present in the painful area; or any new symptoms appear.

Directions

■ **do not take more than directed**

adults and children 12 years and over	■ **take 2 caplets every 8 hours** while symptoms persist
children under 12 years	■ ask a doctor

■ do not take more than 6 caplets in 24 hours, unless directed by a doctor

PAA116857.FDA02

Questions or comments?

1-800-88-ADVIL

Pfizer, Madison, NJ 07940 USA

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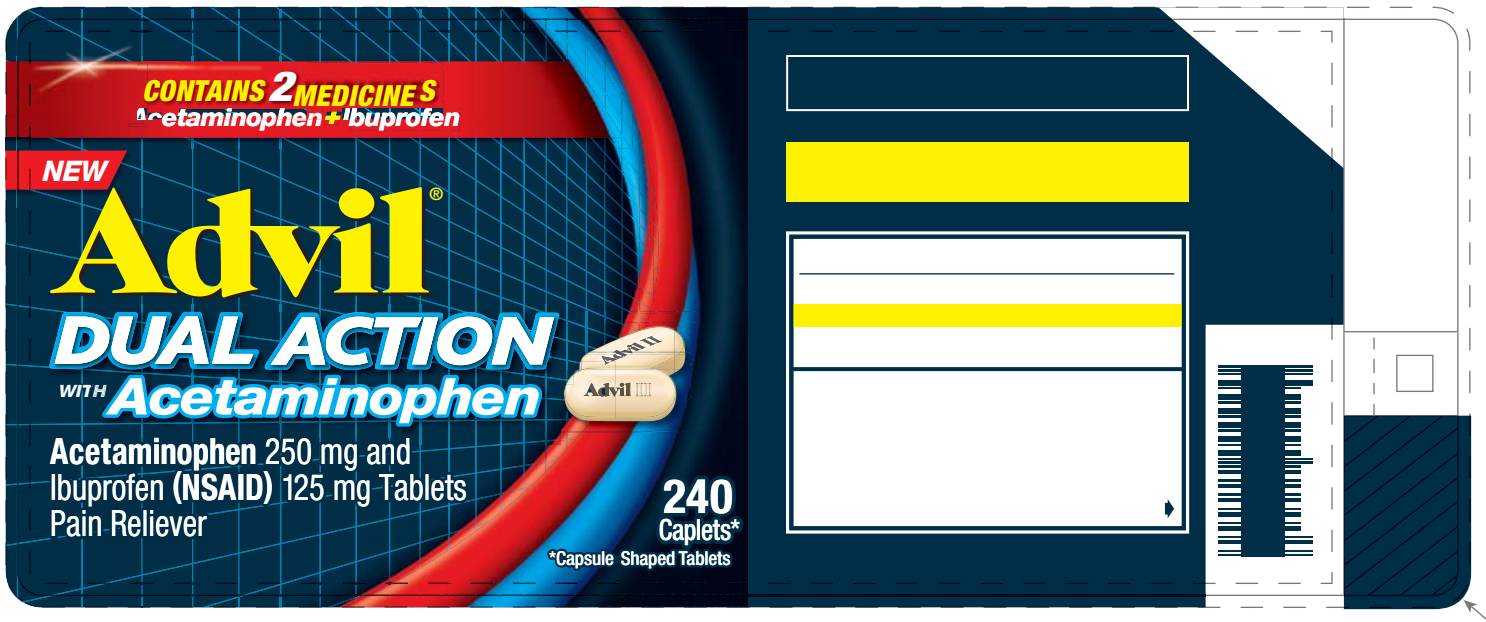
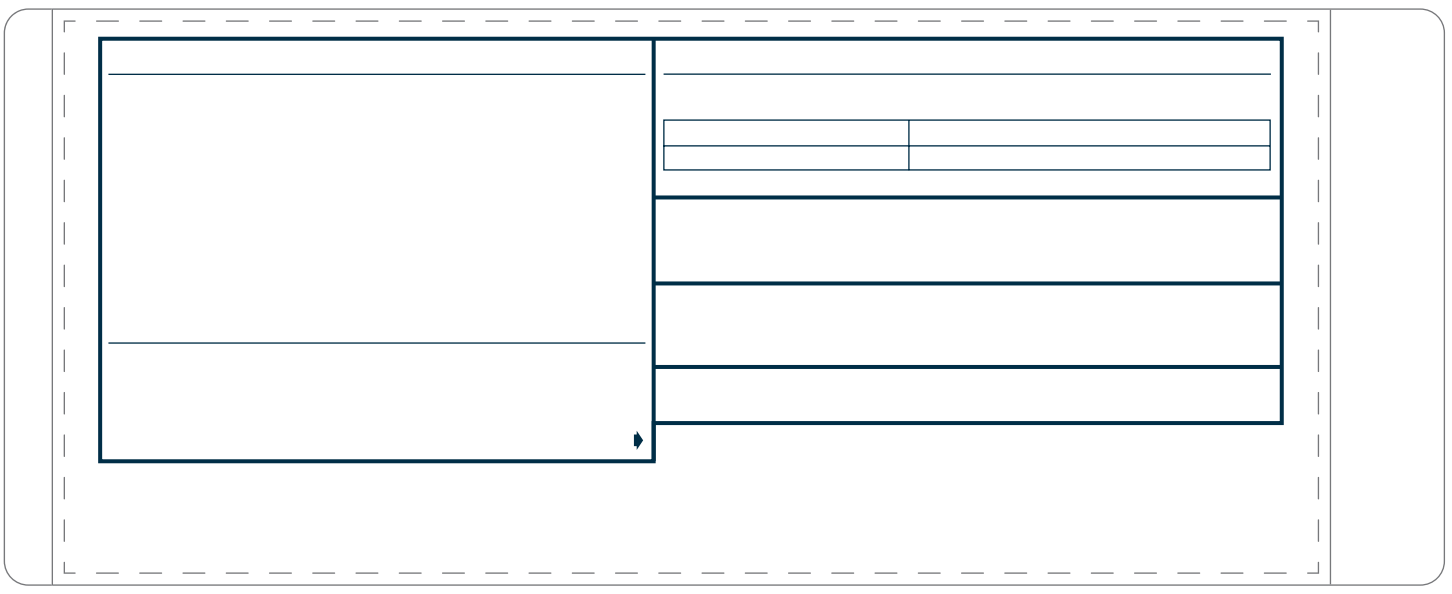
For most recent product information, visit www.Advil.com

PAA116857.FDA02

NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	6 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	.5 pt





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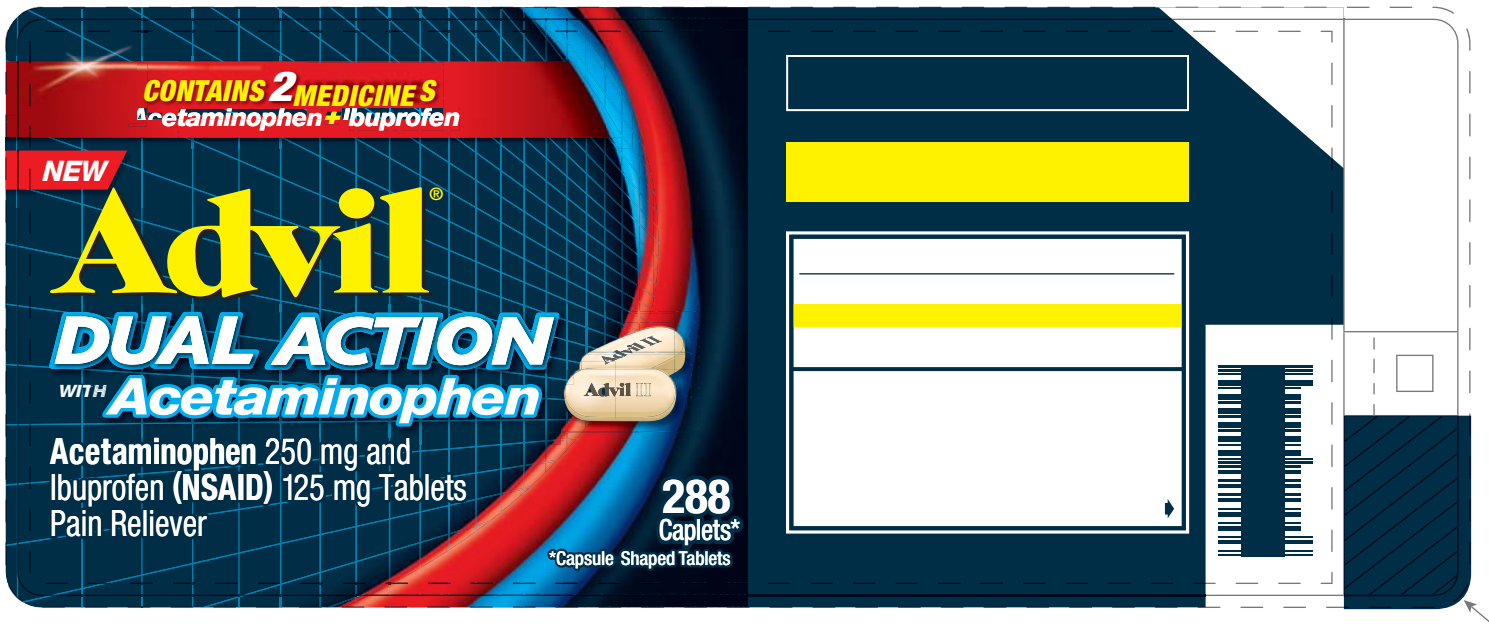
NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces



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NON MODIFIED DRUG FACTS TEXT DEFINED	TYPE SIZE
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• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
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• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Advil Dual Action 18ct or Larger Save $1.00 IRC D000063752

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SAVE $1.00

On any Advil® Dual Action 18ct or larger

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MANUFACTURER'S COUPON **EXPIRES X/XX/XX**

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Advil Dual Action 72ct or Larger Save $2.00 IRC D000063756

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SAVE $2.00

On any Advil® Dual Action 72ct or larger

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MANUFACTURER'S COUPON EXPIRES X/XX/XX

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Advil Dual Action 72ct or Larger Save $3.00 IRC D000063755

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SAVE $3.00

On any Advil® Dual Action 72ct or larger

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MANUFACTURER'S COUPON **EXPIRES X/XX/XX**

Advil Dual Action EZ Open 144ct Save $2.00 IRC D000063757

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MANUFACTURER'S COUPON EXPIRES X/XX/XX

SAVE $2.00

On any Advil® Dual Action EZ Open 144ct

INSIDE

MANUFACTURER'S COUPON EXPIRES X/XX/XX

Reference ID: 4568022

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FRONT

BACK

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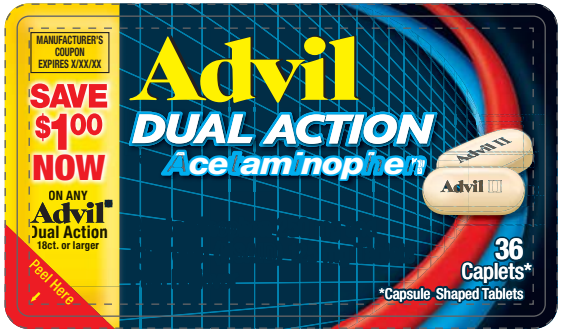

MANUFACTURER'S COUPON | EXPIRES XX/XX/XXXX

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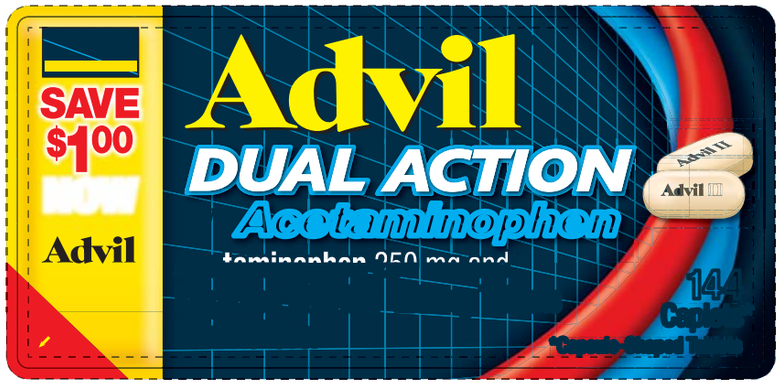

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