



MODIFIED DFL

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>7.0 pt	7.1 pt
Drug Facts	N/A	7 pt	7 pt
(continued):	N/A	7 pt	7 pt
Headings:	N/A	7 pt	7 pt
Subheadings:	N/A	6 pt	6 pt
Text:	N/A	6 pt	6 pt
Bullets:	N/A	5 pt (no larger)	5 pt
Leading:	N/A	+0.5 pt	6.5 pt
Characters Per Inch:	N/A	No more than 39	39

Actual Size 100%



Actual Size 100%



MODIFIED DFL

(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>7.0 pt	7.1 pt
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Headings:	N/A	7 pt	7 pt
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Text:	N/A	6 pt	6 pt
Bullets:	N/A	5 pt (no larger)	5 pt
Leading:	N/A	+0.5 pt	6.5 pt
Characters Per Inch:	N/A	No more than 39	≤ 39

Actual Size 100%



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Bullets:	N/A	5 pt (no larger)	5 pt
Leading:	N/A	+0.5 pt	6.5 pt
Characters Per Inch:	N/A	No more than 39	≤ 39

Actual Size 100%



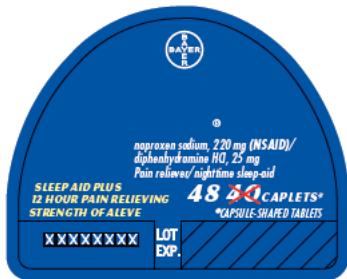
Actual Size 100%



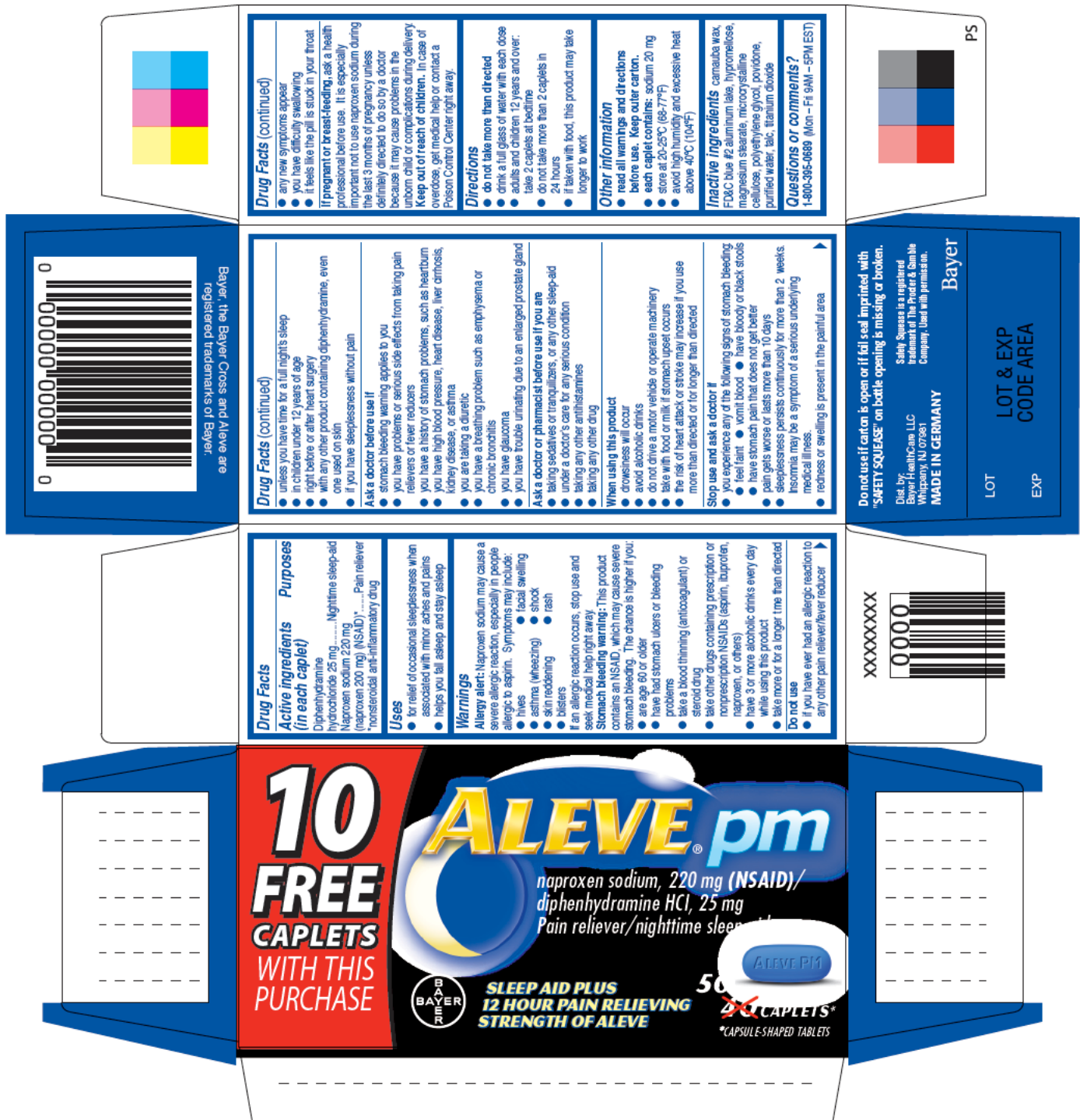
(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>8.0 pt	8.1 pt
Drug Facts (continued):	N/A	8 pt	8 pt
Headings:	N/A	8 pt	8 pt
Subheadings:	N/A	6 pt	6 pt
Text:	N/A	6 pt	6 pt
Bullets:	N/A	5 pt (no larger)	5 pt
Leading:	N/A	+0.5 pt	6.5 pt
Characters Per Inch:	N/A	No more than 39	≤ 39

Actual Size 100%



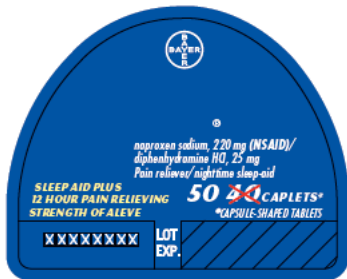
Actual Size 100%



(b) (4)

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Drug Facts Title:	N/A	>8.0 pt	8.1 pt
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Subheadings:	N/A	6 pt	6 pt
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Leading:	N/A	+0.5 pt	6.5 pt
Characters Per Inch:	N/A	No more than 39	≤ 39

Actual Size 100%



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Headings:	N/A	8 pt	8 pt
Subheadings:	N/A	6 pt	6 pt
Text:	N/A	6 pt	6 pt
Bullets:	N/A	5 pt (no larger)	5 pt
Leading:	N/A	+0.5 pt	6.5 pt
Characters Per Inch:	N/A	No more than 39	39

Actual Size 100%



Actual Size 100%

0 000000 000000 0

Bayer, the Bayer Cross and Aleve are registered trademarks of Bayer.

Drug Facts (continued)

Directions

- do not take more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets at bedtime
- do not take more than 2 caplets in 24 hours
- if taken with food, this product may take longer to work

Other information

- read all warnings and directions before use. Keep outer carton.
- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

Inactive ingredients carnauba wax, FD&C blue #2 aluminum lake, hydroxypropylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, purified water, talc, titanium dioxide

Questions or comments?
1-800-395-6188 (Mon - Fri 9AM - 5PM EST)

Bayer

PS

Drug Facts (continued)

- right before or after heart surgery
- with any other product containing diphenhydramine, even one used on skin
- if you have sleeplessness without pain

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic
- you have a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers, or any other sleep-aid under a doctor's care for any serious condition
- taking any other antihistamines
- taking any other drug

When using this product

- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- take with food or milk, if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- pain gets worse or lasts more than 10 days
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium 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.

Do not use if carton is open or if foil seal imprinted with "SAFETY SQUEASE" on bottle opening is missing or broken.

Distributed by:
Bayer HealthCare LLC
Whispery, NJ 07091
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MADE IN GERMANY

LOT LOT & EXP
EXP CODE AREA

Drug Facts

Active ingredients Purposes
(in each caplet)

Diphenhydramine hydrochloride 25 mg.....Nighttime sleep-aid
Naproxen sodium 220 mg.....Pain reliever
Naproxen 200 mg (NSAID)*.....Pain reliever
Nabroxen 200 mg (NSAID)*.....Pain reliever
Nabroxen 200 mg (NSAID)*.....Pain reliever

Uses

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin redness
- facial swelling
- shock
- rash
- blister

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

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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer unless you have time for a full night's sleep
- in children under 12 years of age

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(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>8.0 pt	8.1 pt
Drug Facts	N/A	8 pt	8 pt
(continued):	N/A	8 pt	8 pt
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Leading:	N/A	+0.5 pt	6.5 pt
Characters Per Inch:	N/A	No more than 39	≤ 39

Actual Size 100%



Actual Size 100%

0 000000 000000

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Drug Facts (continued)

Directions

- do not take more than directed
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets at bedtime
- do not take more than 2 caplets in 24 hours
- if taken with food, this product may take longer to work

Other information

- read all warnings and directions before use. Keep out of children's reach.
- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

Inactive ingredients carnauba wax, FD&C blue #2 aluminum lake, hydroxypropyl methylcellulose, polyethylene glycol, polyvinylpyrrolidone, titanium dioxide

Questions or comments?
1-800-395-6388 (Mon - Fri 9AM - 5PM EST)

Bayer

PS

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Bayer, the Bayer Cross and Aleve are registered trademarks of Bayer.

Drug Facts (continued)

right before or after heart surgery
with any other product containing diphenhydramine, even one used on skin
if you have sleeplessness without pain

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn, indigestion, or ulcers
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic
- you have a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers, or any other sleep-aid under a doctor's care for any serious condition
- taking any other anticholinergics
- taking any other drug

When using this product

- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- sleeplessness persists continuously for more than 2 weeks
- hoarseness may be a symptom of a serious underlying medical illness
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless specifically 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.

Do not use if carton is open or if foil seal imprinted with "SAFETY SQUEASE" on bottle opening is missing or broken.

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MADE IN GERMANY

LOT LOT & EXP
EXP CODE AREA

Drug Facts

Active ingredients (in each caplet)

Diphenhydramine hydrochloride 25 mg, --- Nighttime sleep-aid
Naproxen sodium 220 mg (NSAID)* --- Pain reliever
Naproxen 200 mg (NSAID)* --- Pain reliever
Nabroxen 200 mg (NSAID)* --- Pain reliever

Uses

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin redness
- facial swelling
- stomach
- rash
- blistering

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

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 thinner (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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer unless you have time for a full night's sleep
- in children under 12 years of age

XXXXXXX

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(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
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Actual Size 100%



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Drug Facts (continued)

Directions

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- if taken with food, this product may take longer to work

Other information

- read all warnings and directions before use. Keep out of children's reach.
- each caplet contains: sodium 20 mg
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- avoid high humidity and excessive heat above 40°C (104°F)

Inactive ingredients carnauba wax, FD&C blue #2 aluminum lake, hydroxyethylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, purified water, talc, titanium dioxide

Questions or comments?
1-800-395-6388 (Mon - Fri 9AM - 5PM EST)

Drug Facts (continued)

Directions

- right before or after heart surgery
- with any other product containing diphenhydramine, even one used on skin
- if you have sleeplessness without pain

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic
- you have a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers, or any other sleep-aid
- under a doctor's care for any serious condition
- taking any other antihistamines
- taking any other drug

When using this product

- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- pain gets worse or lasts more than 10 days
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the pill is stuck in your throat

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MADE IN GERMANY

LOT LOT & EXP
EXP CODE AREA

Drug Facts

Active ingredients (in each caplet)

Diphenhydramine hydrochloride 25 mg ----- Nighttime sleep-aid

Naproxen sodium 220 mg ----- Pain reliever

(naproxen 200 mg) (NSAID)* ----- Pain reliever

*nonsteroidal anti-inflammatory drug

Uses

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin redness
- facial swelling
- shock
- skin redness
- rash
- blister

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- 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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer unless you have time for a full night's sleep
- in children under 12 years of age

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24 FREE CAPLETS WITH THIS PURCHASE

ALEVE[®] pm

naproxen sodium, 220 mg (NSAID)/
diphenhydramine HCl, 25 mg
Pain reliever/nighttime sleep-aid

SLEEP AID PLUS 12 HOUR PAIN RELIEVING STRENGTH OF ALEVE

104 CAPSULE-SHAPED TABLETS

(b) (4)

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Characters Per Inch:	N/A	No more than 39	≤ 39

Actual Size 100%



Actual Size 100%

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
07/15/2015