



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

20 CAPLETS*
*CAPSULE-SHAPED TABLETS

Drug Facts

Active ingredients
(In each caplet)
Diphenhydramine
Naproxen sodium, 220 mg
(naproxen 220 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 • facial swelling • asthma
(wheezing) • shock • skin redness
• rash
If allergic reaction occurs, stop use and
seek medical help right away. 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

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.

Drug Facts (continued)

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
• 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, asthma, or had a stroke • 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 aspirin for
heart attack or stroke, because naproxen may decrease the
benefit of aspirin • taking any other antihistamines
• taking any other drug

When using this product • drowsiness will occur • avoid
alcoholic drinks • do not drive a motor vehicle or operate
machinery • 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 • 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
• 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

Drug Facts (continued)

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.

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, hydroxyethylcellulose,
magnesium stearate, microcrystalline
cellulose, polyethylene glycol, povidone,
purified water, talc, titanium dioxide

Questions or comments?
1-800-395-0885 (Mon - Fri 9AM - 5PM EST)

**Do not use if carton is open or if foil seal imprinted with
"Bayer HealthCare" on bottle opening is missing or broken.**

Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981
MADE IN GERMANY

LOT/EXP

**LOT & EXP
CODE AREA**

Actual Size 100%

FDA00206-1

DRUG FACTS INFO: (Modified Format - updated 5/18/19)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	7.1 pt
Drug Facts Continued	7 pt	7 pt
Headings*	7 pt-bold italic*	7 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	10 pt
Leading	≥0 pt	0 - 0.5 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines†	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
†† Drug Facts Title to be larger than all other type size used in DFP
† Box Barline may be omitted and color contrast used to highlight
Drug Facts Info



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**

40 CAPLETS*
*CAPSULE-SHAPED TABLETS

Drug Facts

Active ingredients (in each caplet)
Diphenhydramine hydrochloride 25 mg..... Nighttime sleep-aid
Naproxen sodium 220 mg..... 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
Alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
● hives ● facial swelling ● shock
● asthma (wheezing) ● rash ● blisters
● skin redness ● skin peeling
If an allergic reaction occurs, stop use and seek medical help right away. 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, celecoxib, valdecoxib, etc.)
● have had or have a history of heart failure, stroke, or high blood pressure
● take 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
● if you have ever had an allergic reaction to any other pain reliever/fever reducer

Drug Facts (continued)

● drowsiness 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.

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
● **Warnings and directions:** See the back of the caplet for more information.
● **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, hydroxyethylcellulose, polyethylene glycol, polydioxane, purified water, talc, titanium dioxide

Questions or comments?
1-800-395-6689 (Mon-Fri 9AM-5PM EST)

Drug Facts (continued)

● stress you have time for a full night's sleep
● in children under 12 years of age
● right before or after heart surgery
● with any other product containing diphenhydramine, even one used on skin

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, kidney disease, asthma, or had a stroke
● you are taking a diuretic
● you have a breathing problem such as emphysema or chronic bronchitis
● you have glaucoma
● you have prostate enlargement due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are:
● taking aspirin for any serious condition
● taking aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin
● taking any other anti-inflammatories

When using this product
● drowsiness will occur
● avoid alcoholic drinks
● do not drive a motor vehicle or operate machinery
● 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
● you 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
● severe dizziness or lightheadedness
● sleeplessness persists continuously for more than 2 weeks.
Insomnia may be a symptom of a serious underlying medical illness.

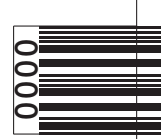
Do not use if caplet is open or if foil seal imprinted with "Bayer HealthCare" on bottle opening is missing or broken.

Sale by Bayer HealthCare LLC
Whispery, NJ 07981
MADE IN GERMANY

LOT/EXP

**LOT & EXP
CODE AREA**

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Actual Size 100%

FDA00207-1

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ^a	8 pt.-bold italic ^a	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 - 0.2 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines ^b	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

^a Headings are to be at least 2x's larger than Body Text.
^b Drug Facts Title to be larger than all other type size used in DFP
^c FDA Recommends 2.5pt. rule

Drug Facts (continued)

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
- 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, asthma, or had a stroke
- 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other antihistamines
- taking any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- 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
- you 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

Drug Facts (continued)

- 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.

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, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, purified water, talc, titanium dioxide

Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

LOT & EXP. AREA

SOFT GRIP® CAP

ALEVE[®] pm

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

SOFT GRIP® CAP

ALEVE[®] pm

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



BAYER

**SLEEP AID PLUS
12 HOUR PAIN RELIEVING
STRENGTH OF ALEVE**

40 CAPLETS*
*CAPSULE-SHAPED TABLETS

PACKAGE IS CHILD-RESISTANT

Drug Facts

Active ingredients (in each caplet)	Purposes
Diphenhydramine hydrochloride 25 mg	Nighttime sleep-aid
Naproxen sodium 220 mg (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
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

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

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.

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Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981
MADE IN GERMANY
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Bayer



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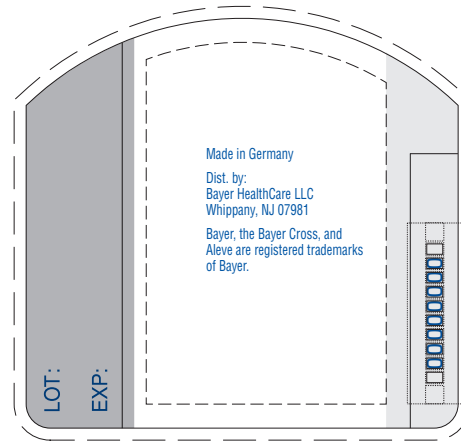
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Actual Size 100%

FDA00208-1

DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt.-bold italic°	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 - 0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines‡	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

° Headings are to be at least 2pts larger than Body Text.
 ** Drug Facts Title to be larger than all other type size used in DFP
 † FDA Recommends 2.5pt. rule



Actual Size 100%

FDA00211-1

DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP
[†] FDA Recommends 2.5pt rule

Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

LOT: **EXP:**

Made in Germany
Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981
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Avea are registered trademarks
of Bayer.

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
- 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.

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.
- 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, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, purified water, talc, titanium dioxide

Questions or comments? 1-800-985-0888
(Mon-Fri 9AM - 5PM EST)

Bayer

Drug Facts
Active Ingredients (in each caplet)
Diphenhydramine hydrochloride 25 mg..... Nighttime sleep-aid
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)Pain reliever
*nonsteroidal anti-inflammatory drug

Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

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Drug Facts (continued)

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
- rash
- facial swelling
- shock
- blisters

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

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

- 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
- 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, asthma, or had a stroke
- 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other antihistamines
- taking any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- take with food or milk if stomach upset occurs



200%



100%

No Varnish area

No Varnish area

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Drug Facts (continued)

● 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.

Directions

- do not take more than directed
- do not take more than 2 caplets in 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, hydroxypropyl methylcellulose, polyethylene glycol, polyethylene glycol, purified water, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon-Fri 9AM-5PM EST)

Bayer

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Drug Facts (continued)

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
- 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, kidney disease, asthma, or had a stroke
- 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other antihistamines
- taking any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- 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
- 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
- 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

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Drug Facts

Active ingredients (in each caplet)

Diphenhydramine hydrochloride 25 mg, ... Nighttime sleep-aid
Naproxen sodium 220 mg
(naproxen 200 mg) (NSAID)*. Pain reliever
*nonsteroidal anti-inflammatory drug

Purposes

- 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
- facial swelling
- asthma (wheezing)
- shock
- skin redness
- rash
- blisters

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

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Actual Size 100%

FDA00212-2

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold italic*	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Binlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2.5pt. rule

Drug Facts (continued)

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
- 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, asthma, or had a stroke
- 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other antihistamines
- taking any other drug

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- 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
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling

Drug Facts (continued)

- 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.

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, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, purified water, talc, titanium dioxide

Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

LOT & EXP. AREA

SOFT GRIP® CAP d33d101

Do not use if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

ALEVE^{pm}
naproxen sodium, 220 mg (NSAID)/
diphenhydramine HCl, 25 mg
Pain reliever/nighttime sleep-aid

SOFT GRIP® CAP

ALEVE^{pm}
naproxen sodium, 220 mg (NSAID)/
diphenhydramine HCl, 25 mg
Pain reliever/nighttime sleep-aid



BAYER

**SLEEP AID PLUS
12 HOUR PAIN RELIEVING
STRENGTH OF ALEVE**

120 CAPLETS*
*CAPSULE-SHAPED TABLETS

PACKAGE IS CHILD-RESISTANT

Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981
PRODUCT OF GERMANY
Bayer, the Bayer Cross, Aleve, and Soft Grip are registered trademarks of Bayer.

PS

Actual Size 100%

FDA00205-1

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold italic*	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.9 - 1.25 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

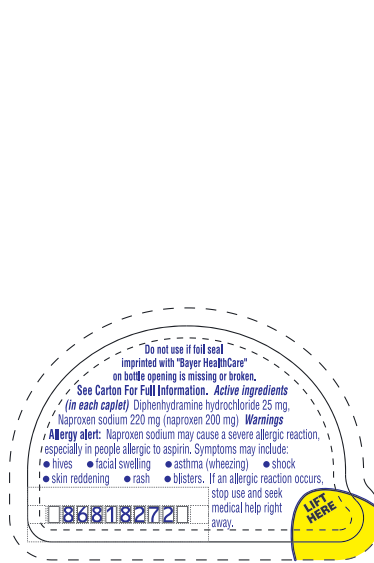
* Headings are to be at least 20% larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2.5pt. rule



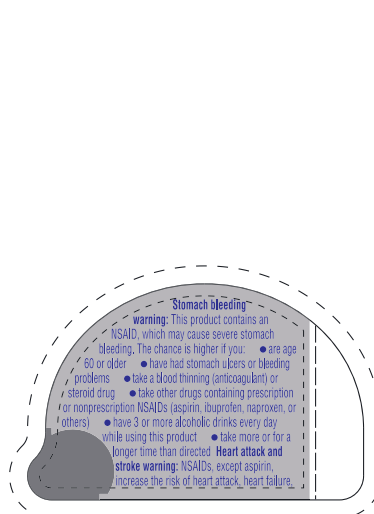
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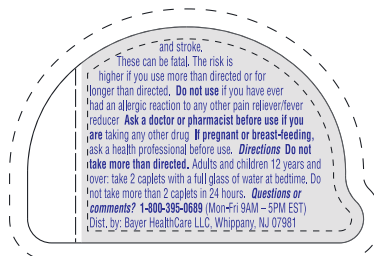
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Panel 1 Top



Panel 2 Inside



Panel 3 Base

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [§]	-
Drug Facts Continued	7 pt [§]	-
Headings	7 pt-bold italic [¶]	5 pt
Subheadings	6 pt [§]	5 pt
Body Text	6 pt [§]	5 pt
Bullets	5 pt	6 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

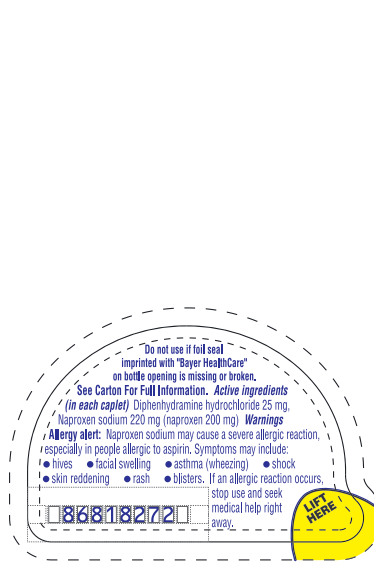
Characters per inch rule is not applicable to ICL.
[§] ICL minimum font size is 4.5 pt.
[¶] < 0.5 pt. leading may be used as long as ascenders and descenders do not touch.
[†] FDA recommends size 2.5 pt. type



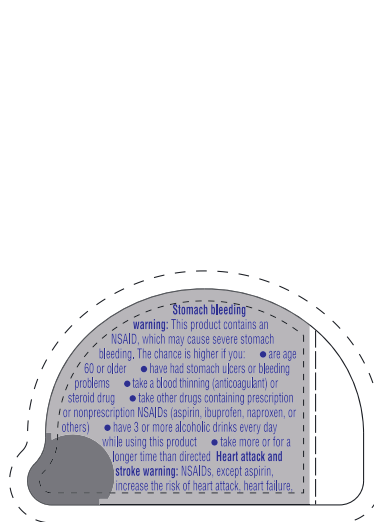
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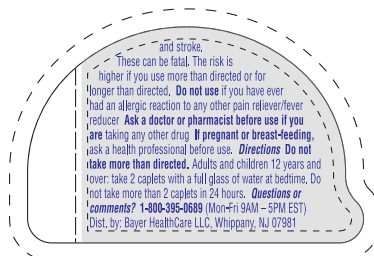
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Panel 1 Top



Panel 2 Inside



Panel 3 Base

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [§]	-
Drug Facts Continued	7 pt [§]	-
Headings	7 pt-bold italic [¶]	5 pt
Subheadings	6 pt [§]	5 pt
Body Text	6 pt [§]	5 pt
Bullets	5 pt	6 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

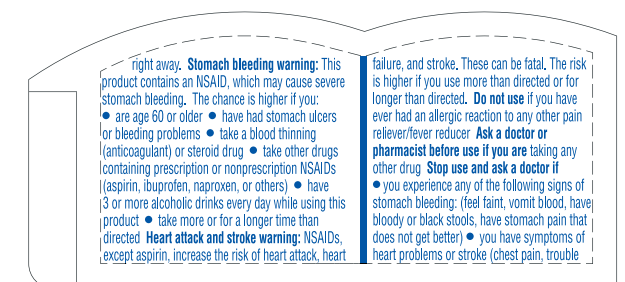
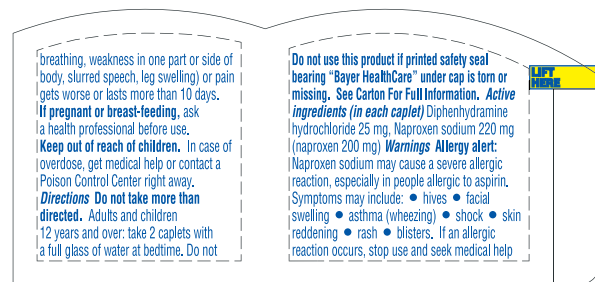
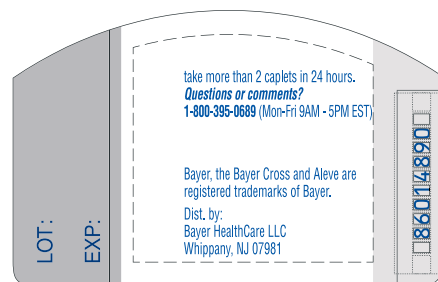
Characters per inch rule is not applicable to ICL.
[§] ICL minimum font size is 4.5 pt.
[¶] < 0.5 pt. leading may be used as long as ascenders and descenders do not touch.
[†] FDA recommends size 2.5 pt. type

200%



100%





DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	-
Drug Facts Continued	8 pt.	-
Headings [†]	8 pt.-bold <i>italic</i> [‡]	-
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	5 pt.
Leading	≥0.5 pt.	6.5 pt.
Hairlines	0.5 pt. rule	-
Box and Barlines [†]	>0.5 pt. rule	-
Characters Per Inch:	No more than 39	≤39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP
[‡] FDA Recommends 2.5pt rule



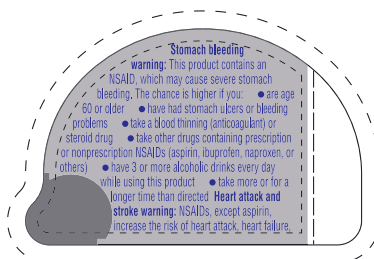
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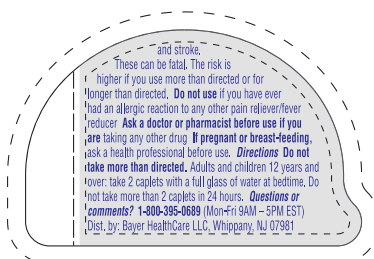
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Panel 1 Top



Panel 2 Inside



Panel 3 Base

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [§]	-
Drug Facts Continued	7 pt [§]	-
Headings	7 pt-bold italic [¶]	5 pt
Subheadings	6 pt [§]	5 pt
Body Text	6 pt [§]	5 pt
Bullets	5 pt	6 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
[§] ICL minimum font size is 4.5 pt.
[¶] < 0.5 pt. leading may be used as long as ascenders and descenders do not touch.
[†] FDA recommends size 2.5 pt. type



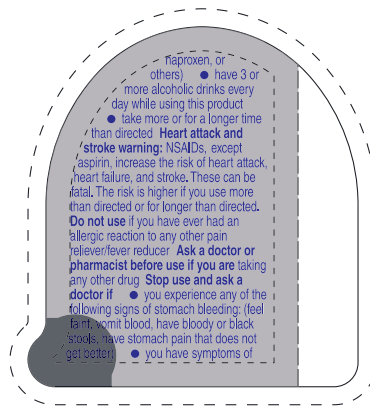
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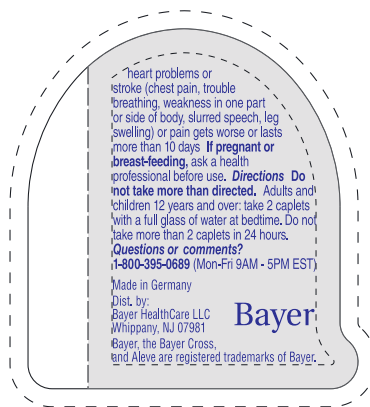
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Panel 1 Top



Panel 2 Inside



Panel 3 Base

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt ^a	-
Drug Facts Continued	7 pt ^a	-
Headings	7 pt-bold italic ^a	5.5 pt
Subheadings	6 pt ^a	5.5 pt
Body Text	6 pt ^a	5.5 pt
Bullets	5 pt	10 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
^aICL minimum font size is 4.5 pt.
^b< 0.5 pt leading may be used as long as ascenders and descenders do not touch.
[†] FDA recommends size 2.5 pt type



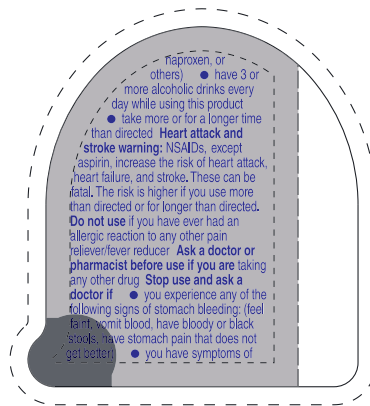
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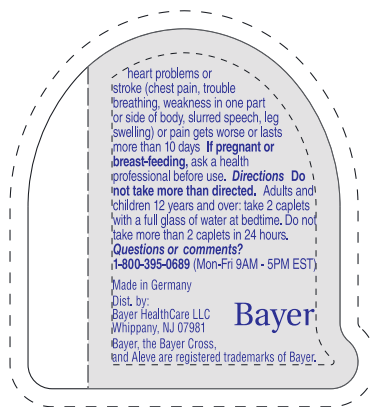
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Panel 1 Top



Panel 2 Inside



Panel 3 Base

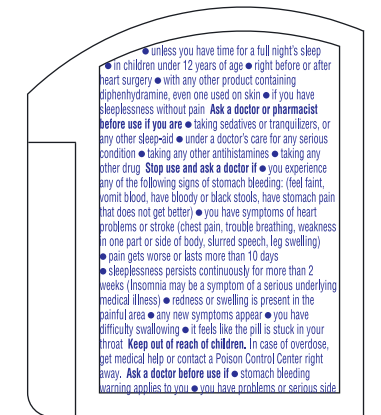
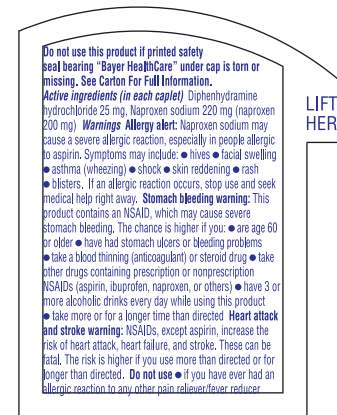
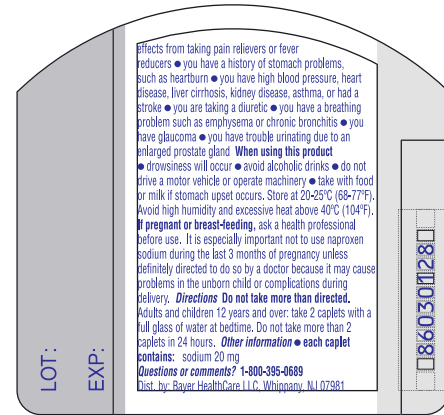
ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt ^a	-
Drug Facts Continued	7 pt ^a	-
Headings	7 pt-bold italic ^a	5.5 pt
Subheadings	6 pt ^a	5.5 pt
Body Text	6 pt ^a	5.5 pt
Bullets	5 pt	10 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
^aICL minimum font size is 4.5 pt.
< 0.5 pt leading may be used as long as ascenders and descenders do not touch.
[†] FDA recommends size 2.5 pt type

This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfda>



Reference ID: 4587317



DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	-
Drug Facts Continued	8 pt	-
Headings [†]	8 pt-bold italic [†]	5 pt
Subheadings	≥6 pt	5 pt
Body Text	≥6 pt	5 pt
Bullets	5 pt	4 pt
Leading	≥0.5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≥39
[†] Headings are to be at least 2pts larger than Body Text. ^{**} Drug Facts Title to be larger than all other type size used in DFP ^{††} FDA Recommends 2.5pt rule		



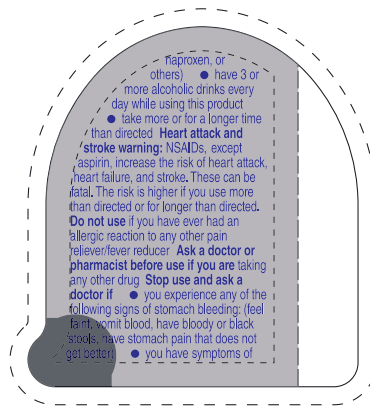
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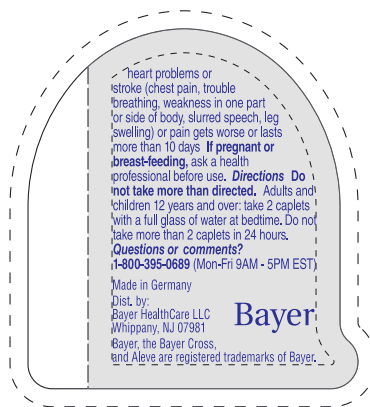
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Panel 1 Top



Panel 2 Inside



Panel 3 Base

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt ^a	-
Drug Facts Continued	7 pt ^a	-
Headings	7 pt-bold italic ^a	5.5 pt
Subheadings	6 pt ^a	5.5 pt
Body Text	6 pt ^a	5.5 pt
Bullets	5 pt	10 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
^aICL minimum font size is 4.5 pt.
^b< 0.5 pt leading may be used as long as ascenders and descenders do not touch.
[†] FDA recommends size 2.5 pt type

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/s/

VALERIE S PRATT
04/06/2020 12:29:06 PM