

Sample - Not for Sale

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** **2 CAPLETS***
*CAPSULE-SHAPED TABLETS

Drug Facts		Drug Facts (continued)
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	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
Uses ● for relief of occasional sleeplessness when associated with minor aches and pains ● helps you fall asleep and stay asleep		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 ● the risk of heart attack or stroke may increase if you use more than directed or for longer than directed
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		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
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		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.
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		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? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

FRONT

BACK

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	N/A	8 pt	8 pt
(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	—

• if you have sleeplessness without pain Ask 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 • drowsiness will occur • 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. **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?** 1-800-395-0689 (Mon-Fri 9-5 EST)
 Bayer HealthCare LLC, Morrisstown, NJ 07960 **MADE IN GERMANY**

While folded on line, tear open at dot or use scissors.
Do not use if pouch is torn or open.



Active Ingredients (in each caplet)
 Diphenhydramine hydrochloride 25 mgNighttime sleep-aid
 Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*Pain reliever
 *nonsteroidal anti-inflammatory drug
Purposes
Use • 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 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

Actual Size 100%

(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>8.0 pt	-
Drug Facts	N/A	8 pt	5.5 pt
(continued):	N/A	8 pt	-
Headings:	N/A	8 pt	5.5 pt
Subheadings:	N/A	6 pt	5.5 pt
Text:	N/A	6 pt	5.5 pt
Bullets:	N/A	5 pt (no larger)	4 pt
Leading:	N/A	+0.5 pt	6 pt
Characters Per Inch:	N/A	No more than 39	36

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

/s/

THERESA M MICHELE
02/25/2015