EXTRA STRENGTH NO-PAIN PM- acetaminophen and diphenhydramine hydrochloride tablet Safrel Pharmaceuticals, LLC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

No-Pain PM - Acetaminophen and Diphenhydramine HCl

Drug Facts

Active ingredients (in each caplet)	Purpose		
Acetaminophen 500 mg	Pain reliever		
Diphenhydramine HCl 25 mg	Nighttime sleep aid		

Uses

temporary relief of occasional headaches and minor aches and pains with accompanying sleeplessness

Warnings

Liver warning

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

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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.
- with any product containing diphenhydramine, even one used on skin
- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

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

Stop use and ask a doctor if

• sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see overdose warning)
- adults and children 12 years and over: take 2 caplets at bedtime
- do not take more than 2 caplets of this product in 24 hours
- **children under 12 years:** do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store between 20-25°C (68-77°F)
- do not use if pouch is torn or open
- see side panel for lot number and expiration date

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, fdc blue #1 aluminum lake, fdc blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, purified water, sodium metabisulfite, sodium starch glycolate, stearic acid, titanium dioxide, talc

Questions or comments?

1-844-384-3723 (Mon-Fri 9am-5pm EST) or www.safrelpharma.com

PRINCIPAL DISPLAY PANEL

Compare to the Active Ingredients in Tylenol PM [®]*

NO-PAIN PM

Description Pain Reliever Description Nighttime Sleep Aid

Acetaminophen, Diphenhydramine HCl

*Compare to Tyleno PM® Active Ingredient	LETE DRUG FACTS <i>each caplet) Purpose</i> Pain reliever/Fever reducer mg Nighttime sleep aid	product contains re liver damage may occur if un 4000 mg of acetaminophen or more alcoholic drinks this product inophen may cause severe skin s may include: blisters a rash	I with any other drug containing n (prescription or not prescription). If re whether a drug contains n, ask a doctor or pharmacist. her product containing line, even one used on skin. under 12 years of age ■ achmon ■ a heavel	ma ■ a breathing problem chronic bronchilis to an enlarged prostate wer: take 2 capiets at e more than 2 capiets of this e more than 2 vears: do ct in children under 12 vears: do the recommended	cause liver damage. ED SAFETY SEAL UNDER SING Pharmaceuticals LLC, www.safrelpharma.com	
Acetaminophen 500 mg Diphenhydramine HCI 25 mg Pain Reliever/ Nighttime Sleep Aid Non-Habit forming 30 Tablets	I FOR COMF ICTS ICTS edient (in en 500mg mine HCl 25	Warnings Liver Warning: This product contai acetaminophen. Severe liver damaç you take ■ more than 4000 mg of in 24 hours ■ with other drugs co in 24 hours ■ with other drugs co acetaminophen ■ 3 or more alcoh everyday while using this product Allery a lert: Acetaminophen may reactions. Symptoms may include: ■ skin reddening ■ blisters ■ ra	inophe inophe inophe any ot anydram yydram ildren idren	 Inver disease a asthma a breathing problem such as emphysema or chronic bronchilis Touble urinating due to an enlarged prostate gland glaucoma Difections Do not exceed recommended dose Adults and children 12 years and over: take 2 caplets at bedtime. A do not take more than 2 caplets of this product in 24 hours. Echildren under 12 years: do not use this adult product in children under 12 years: of ane this will trovide more than the recommended 	dose (overdose) and may cr DO NOT USE IF IMPRINTED CAP IS BROKEN OR MISSII Distributed by: Safrel Ph Bridgewater, MJ 08807 ww	Lot No.: Exp. Date:

acetaminophen and dipher		<u> </u>					
Product Information							
Product Type]	HUMAN OTC DRUG	Ite	em Code (So	n Code (Source) NDC:71309-		
Route of Administration		ORAL					
Active Ingredient/Act	ive Moie	tv					
		lient Name			Basis	of Strength	Strengt
ACETAMINO PHEN (UNII: 36	-		- UNII:362O9	ITL9D)	ACETAMINO	C	500 mg
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMINE UNII:8GTS82S83M) DIPHENHYDROCHLORIDE							25 mg
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	R47K3TBD)	•	Jame				Strength
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P	ackaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71309-006-25	25 in 1 BOX	06/06/2016		
1		2 in 1 POUCH; Type 0: Not a Combination Product			
2	NDC:71309-006-50	50 in 1 BOX	06/06/2016		
2		2 in 1 POUCH; Type 0: Not a Combination Product			
3	NDC:71309-006-02	2 in 1 POUCH	06/06/2016		
3		2 in 1 POUCH; Type 0: Not a Combination Product			
4	NDC:71309-006-10	1000 in 1 BOTTLE	06/06/2016		
4	NDC:71309-006-05	500 in 1 BOTTLE			
4	NDC:71309-006-30	30 in 1 BOTTLE			
4		1 in 1 CARTON; Type 0: Not a Combination Product			
N	Aarketing Info	ormation			
Marketing Category		y Application Number or Monograph Citation	n Marketing Start Date	Marketing End Date	
	TC monograph not fina	al part343	02/09/2016		

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

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Safrel Pharmaceuticals, LLC.