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.

Pain Relief 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, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

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 ®*

Pain Relief PM

★Pain Reliever ★Nighttime Sleep Aid

Acetaminophen, Diphenhydramine HCl

EXTRA STRENGTH NO-PAIN PM

acetaminophen and diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71309-006
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	131
Contains			

Packaging

#	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:71309-006-37	375 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	02/09/2016	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 5/2021 Safrel Pharmaceuticals, LLC.