SOHMED PAIN RELIEF PM- acetaminophen and diphenhydramine hydrochloride tablet
SOHM Inc.

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.

SohMed™ Pain Relief PM

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 everyday while using this product

Although rare, possible reactions to consumption of acetaminophen include three serious skin diseases whose symptoms can include rash, blisters and, in the worst case, widespread damage to the surface of the skin. If you are taking this product and develop a rash or other skin reaction, stop taking this product immediately and seek medical attention.

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 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 or 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. 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)
- See end flap for expiration date and lot number

Inactive ingredients

carnauba wax, FD&C blue #1 aluminium lake, FD&C blue #2 aluminium lake, hypromellose, magnesium stearate, polyethylene glycol, polysorbate 80, powdered cellulose, pregelatinized starch, propylene glycol, shellac, sodium citrate, sodium starch glycolate, titanium dioxide

Contains No Aspirin

Question or comments?

1(856) 2863646

Distributed by : Sohm, Inc.
6920 Knott Ave., Suit A-C
Buena Park, CA 90621

PRINCIPAL DISPLAY PANEL - 24 Caplet Bottle Carton

SohMed™

NDC XXXXXXXXXX

***Compare to the active ingredients in Extra Strength Tylenol® PM**

Extra Strength

Pain Relief PM

Acetaminophen 500 mg, **Diphenhydramine** HCl 25 mg

Pain Reliever / Nighttime Sleep aid

24 Caplets

Non-Habit
Forming

SOHMED PAIN RELIEF PM

acetaminophen and diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50405-007

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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
FD&C Blue No. 2 (UNII: L06K8R7DQK)	
aluminum oxide (UNII: LMI26O6933)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STARCH, CORN (UNII: O8232NY3SJ)	
SHELLAC (UNII: 46N107B71O)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	**Score**	2 pieces
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	CRX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50405-007-24	1 in 1 CARTON		
1		24 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	08/25/2013	

Labeler - SOHM Inc. (009303848)