PERCOGESIC- magnesium salicylate tablet, coated Medtech Products 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.

Percogesic Maximum Strength Backache Relief

Drug Facts

Active ingredient (in each tablet)

Magnesium salicylate tetrahydrate 580 mg (NSAID)*

*nonsteroidal anti-inflammatory drug (equivalent to 467 mg of magnesium salicylate anhydrous)

Purpose

Pain reliever

$\Pi Uses$

Temporarily relieves minor aches and pains associated with

- backache
- muscular aches

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Magnesium salicylate may cause a severe allergic reaction which may include hives, facial swelling, asthma (wheezing), shock.

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (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 are allergic to salicylates (including aspirin) or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn, upset stomach or stomach pain
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic
- you are on a magnesium-restricted diet

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- gout
- diabetes
- arthritis
- anticoagulation (thinning the blood)

Stop use and ask a doctor if

you experience any of the following signs of stomach bleeding:

- feel faint
- have bloody or black stools
- vomit blood
- have stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- new symptoms occur
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present. These could be signs of a serious condition.

If pregnant or breast-feeding

ask a health professional before use.

IKeep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

do not take more than 4 doses in 24 hours. Drink a full glass of water with each dose.

Adults and children 12 years of age and older: take 2 tablets every 6 hours while symptoms persist.

Children under 12 years of age: ask a doctor

Other information

- store at room temperature
- protect from moisture
- Magnesium content: 40 mg per tablet

Inactive ingredients

croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, silica, stearic acid, talc, titanium dioxide

Questions?

1-800-443-4908

PRINCIPAL DISPLAY PANEL

PERCOGIS MAXIMUM STRENGTH BACKACHE RELIEF 48 COATED CAPLETS



PERCOGESIC

magnesium salicylate tablet, coated

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:63029-051 Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SALICYLATE (UNII: 41728 CY7UX) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MAGNESIUM SALICYLATE	467 mg

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	16 mm	
Flavor		Imprint Code	BR	
Contains				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:63029-051-48	1 in 1 CARTON	0 1/0 5/20 10	
1	48 in 1 BOTTLE; 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	0 1/0 5/20 10		

Labeler - Medtech Products Inc. (122715688)

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