

MEDIQUE BACK PAIN RELIEF- magnesium salicylate tetrahydrate tablet, film coated

Unifirst First Aid Corporation

Medique Back Pain Relief

Drug Facts

Active ingredient (in each caplet)

Magnesium Salicylate Tetrahydrate (NSAID*) 580 mg
(equivalent to 467.2 mg of anhydrous magnesium salicylate)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

For the temporary relief of minor backache pain

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 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 alcohol 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.

Ask a doctor before use if

■ stomach bleeding warning applies to you

■ you have a history of stomach problems such as heartburn

■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

■ you have asthma

■ you are taking a diuretic

Ask a doctor or pharmacist before use if you are taking a prescription drug for

■ gout

■ diabetes

■ arthritis

Stop use and ask a doctor if

■ an allergic reaction occurs. Seek medical help right away.

■ 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

■ if ringing in the ears or loss of hearing occurs

■ new symptoms occur

■ 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. **It is especially important not to use magnesium salicylate at 20 weeks or later in pregnancy unless specifically 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 (1-800-222-1222) right away.

Directions

■ drink a full glass of water with each dose

Adults and children: (12 years and over)

Take 2 caplets every 6 hours, not to exceed 8 caplets in 24 hours.

Children under 12 years:

Do not use unless directed by a doctor

Other information

- each caplet contains: magnesium 40 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, stearic acid, titanium dioxide, triacetin

Questions or comments? 1-800-634-7680

Medique®

Back Pain Relief

Pain Reliever/ Anti-Inflammatory

Pull to Open

Magnesium Salicylate Tetrahydrate (NSAID) 580 mg

80 Caplets (40 x 2)

Tamper Evident Unit Dose Packets

Medique®
Back Pain Relief
Pain Reliever/Anti-Inflammatory
Magnesium Salicylate Tetrahydrate (NSAID) 580 mg

Drug Facts
Active ingredient (in each caplet): Magnesium Salicylate Tetrahydrate (NSAID) 580 mg (equivalent to 402.2 mg of anhydrous magnesium salicylate) nonsteroidal anti-inflammatory drug. Purpose: Pain reliever.

Uses
For the temporary relief of minor backache pain.

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 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 alcohol 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 to any other pain reliever/fever reducer.

Ask a doctor before use if
■ stomach bleeding warning applies to you
■ you have a history of stomach problems such as heartburn
■ you have high blood pressure, heart disease, liver trouble, or kidney disease
■ you have asthma
■ you are taking a diuretic. (continued on opposite panel)

Medique®
Back Pain Relief
Pain Reliever/Anti-Inflammatory
Pull to Open
Magnesium Salicylate Tetrahydrate (NSAID) 580 mg
80 Caplets (40 x 2)

Drug Facts (continued)
Ask a doctor or pharmacist before use if you are taking a prescription drug for:
■ gout
■ diabetes
■ arthritis.

Stop use and ask a doctor if
■ an allergic reaction occurs. Seek medical help right away.
■ 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
■ ringing in the ears or loss of hearing occurs
■ new symptoms occur
■ 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 care professional before use. It is especially important not to use magnesium salicylate at 26 weeks or later in 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 (1-800-222-1222) right away.

Directions
■ drink a full glass of water with each dose.

Adults and children (12 years and over) Take 2 caplets every 6 hours, not to exceed 8 caplets in 24 hours.
Children under 12 years: Do not use unless directed by a doctor.

Drug Facts (continued)
Other information
■ each caplet contains: magnesium 40 mg
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
■ tamper evident sealed packets
■ do not use any opened or torn packets.

Inactive ingredients
hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, stearic acid, titanium dioxide, triacetin.

Questions or comments? 1-800-634-7680

Reorder #07480
Manufactured for
Medique Products
Fort Myers, FL 33967
1-800-634-7680
www.medicueproducts.com

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MEDIQUE BACK PAIN RELIEF

magnesium salicylate tetrahydrate tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-074
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SALICYLATE (UNII: 41728CY7UX) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MAGNESIUM SALICYLATE	580 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Caplet)	Size	17mm
Flavor		Imprint Code	44;338
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-074-80	40 in 1 BOX	09/26/2022	
1	NDC:47682-074-99	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-074-36	75 in 1 BOX	12/12/2022	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-074-99	2 in 1 PACKET; Type 0: Not a Combination Product	09/26/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/26/2022	

Labeler - Unifirst First Aid Corporation (832947092)

