

BACKACHE RELIEF- magnesium salicylate tablet, film coated

CVS Pharmacy

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.

CVS 44-338

Active ingredient (in each caplet)

Magnesium salicylate
tetrahydrate 580 mg (NSAID)*
(equivalent to 467.2 mg of anhydrous magnesium salicylate)
*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever

Use

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 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.

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

- 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
- redness or swelling is present
- 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

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 during the last 3 months of 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: 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 50 mg**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

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

Questions or comments?

1-800-426-9391

Principal Display Panel

CVS Health™

**Compare to the active
ingredient in Extra Strength Doan's®†**

NDC 59779-338-08

EXTRA STRENGTH

Backache Relief

MAGNESIUM SALICYLATE

TETRAHYDRATE (NSAID)

Pain reliever

Relieves backache pain

Actual Size

24 ANALGESIC CAPLETS

**TAMPER EVIDENT: DO NOT USE IF
CARTON IS OPENED OR IF BLISTER
UNIT IS TORN, BROKEN, OR SHOWS
ANY SIGNS OF TAMPERING**

†This product is not manufactured or distributed by Novartis
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EXTRA STRENGTH

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Pain reliever

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B-0231-338-08-H
ORG051233808



Drug Facts

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each caplet) Purpose
Magnesium salicylate tetrahydrate 580 mg (NSAID)* Pain reliever (equivalent to 467.2 mg of anhydrous magnesium salicylate)
*nonsteroidal anti-inflammatory drug

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Drug Facts (continued)

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Questions or comments? 1-800-426-9391



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OMIT A

BACKACHE RELIEF

magnesium salicylate tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-338
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	44;338
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-338-08	3 in 1 CARTON	11/07/1998	12/21/2021
1		8 in 1 BLISTER PACK; 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	11/07/1998	12/21/2021

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(59779-338)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(59779-338)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(59779-338)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(59779-338)

Revised: 10/2019

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