# BACK PAIN RELIEF EXTRA STRENGTH DOANS - magnesium salicylate tablet, film coated Wildman Business Group

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#### **ACTIVE INGREDIENT**

# 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**

## **Purpose**

Pain reliever

#### INDICATIONS & USAGE

#### Uses

For the temporary relief of minor backache pain

#### WARNINGS

# 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

**Do not use** if you are allergic to salicylates (including aspirin) or any other pain reliever/fever reducer.

#### **ASK DOCTOR**

#### 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 DOCTOR/PHARMACIST

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

- gout
- diabetes
- arthritis

#### STOP USE

### 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.

#### PREGNANCY OR BREAST FEEDING

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 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**

**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.

#### **DOSAGE & ADMINISTRATION**

#### **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 SAFETY INFORMATION

#### 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 INGREDIENT**

# Inactive ingredients

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

### **QUESTIONS**

Questions or comments? (888) 602-0288

# Principal Display Panel - 50 Caplet Box Label

#### 2550

**BACK PAIN RELIEF** 

Magnesium Salicylate Tetrahydrate 580 mg (NSAID)

Pain Reliever / Anti-Inflammatory

Pull to Open

50 Caplets

2 Per Packet

The Provision

First Aid

Line™

BY WILDMAN



5220

2550

2550

# **Drug Facts**

Active ingredient (in each caplet) Purpose Magnesium Salicylate

Tetrahydrate (NSAID\*) 580 mg. (equivalent to 467.2 mg of anhydrous magnesium salicylate) nonsteroidal anti-inflammatory drug

#### Uses

For the temporary relief of minor backache pain

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

#### Drug Facts (continued)

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
- 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

(Continued on opposite panel)

Magnesium Salicylate Tetrahydrate 580 mg (NSAID)

Pain Reliever / Anti-Inflammatory





Retain carton for complete product information

2550BOX Rev. 7/22/22 Mfg. 24

2550

2550

#### Drug Facts (continued)

#### 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

Drug Facts (continued)

■ drink a full glass of water with each dose





- 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 20 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 nedical help or contact a Poison Control Center (1-800-222-1222) right away

(12 years and over) exceed 8 caplets in 24 hours.

Children under 12 Do not use unless directed by a years:

#### 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? (888) 602-0288

Manufactured for: Provision by Wildman Warsaw, IN 46580

Pain Reliever / Anti-Inflammatory 50 Caplets 2 Per Packet



580 mg

Retain carton for complete product information

Manufactured for Provision by Wildman Warsaw, IN 46580



#### BACK PAIN RELIEF EXTRA STRENGTH DOANS

magnesium salicylate tablet, film coated

#### **Product Information**

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:84269-2550

**Route of Administration ORAL** 

## **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength Strength** Magnesium Salicylate (UNII: 41728CY7UX) (Salicylic Acid - UNII: O414PZ4LPZ) Magnesium Salicylate

**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**

white (white) Color Score no score

Shape	CAPSULE (Caplet)	Size	17mm
Flavor		Imprint Code	44;338
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:84269- 2550-2	50 in 1 BOX	07/01/2024		
1		2 in 1 PACKET; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/01/2024	

# **Labeler -** Wildman Business Group (016677338)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	MANUFACTURE(84269-2550)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Medique Products		086911794	PACK(84269-2550)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Prestige Packaging		080667761	PACK(84269-2550)

Revised: 7/2024 Wildman Business Group