

## **BACKPRIN- magnesium salicylate tetrahydrate tablet, film coated HART Health**

*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.*

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### **BACKPRIN**

#### ***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***

Temporarily relieves minor back pain

#### ***Warnings***

##### **Reye's syndrome:**

Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's Syndrome, a rare but serious illness reported to be associated with salicylates.

##### **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 asthma, high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you** take any drug for diabetes, gout or arthritis

**Stop use and ask a doctor if**

- an allergic reaction occurs, seek medical help right away
- fever worsens or lasts more than 3 days
- pain worsens or lasts more than 10 days
- you experience any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, or stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- new symptoms occur
- 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 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 right away. 1-800-222-1222

***Directions***

**Do not take more than directed.**

Adults and children 12 years of age and over:

- take 2 caplets with a full glass of water every 6 hours while symptoms persist
- do not take more than 8 caplets in 24 hours unless directed by a doctor

Children under 12 years: ask a doctor

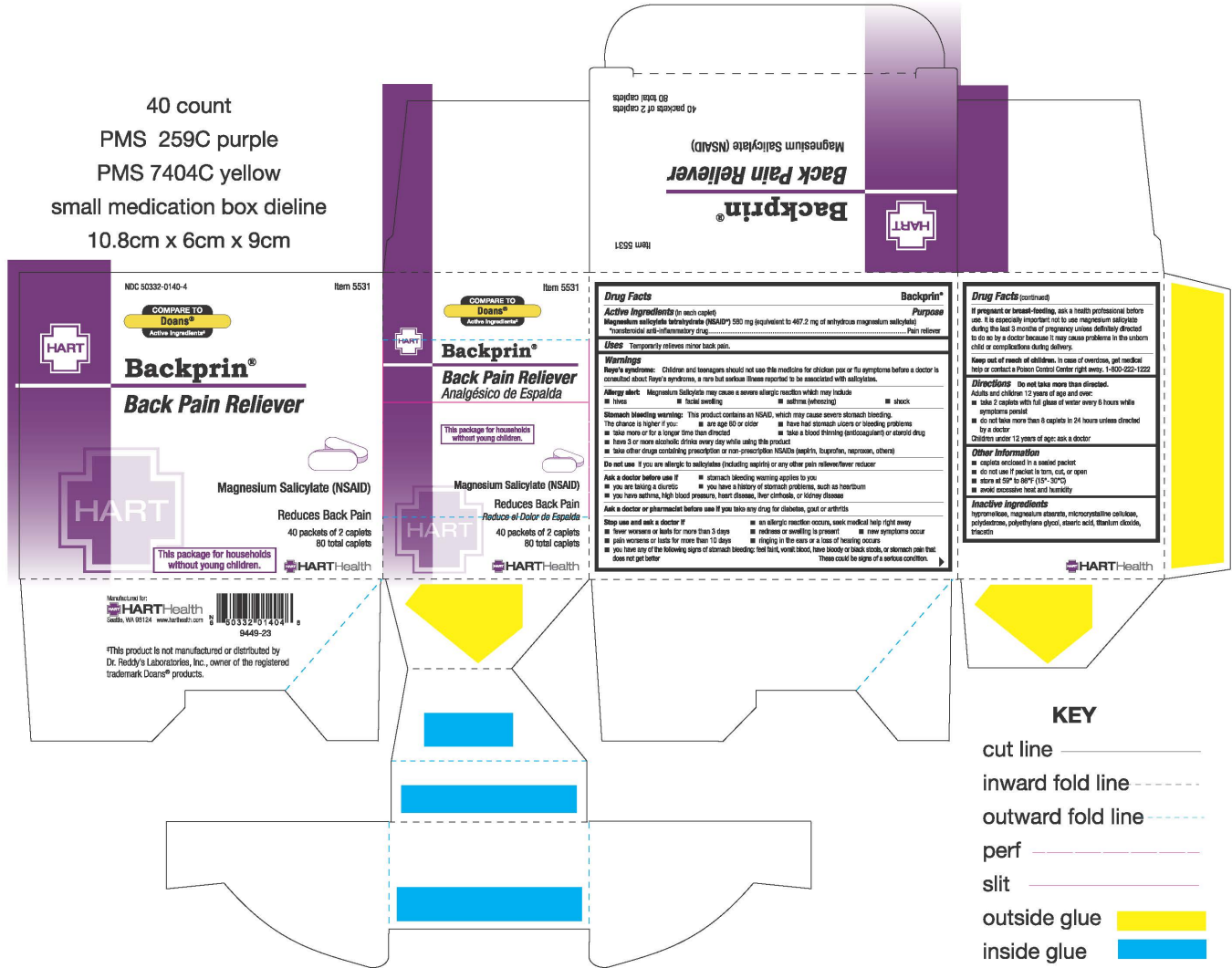
***Other information***

- caplets enclosed in a sealed packet
- do not use if packet is torn, cut or open

- store at 59° to 86°F (15°-30°C)
- avoid excessive heat and humidity

### Inactive ingredients

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



## BACKPRIN

magnesium salicylate tetrahydrate tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50332-0140
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0140-4	40 in 1 BOX	01/09/2023	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0140-7	100 in 1 BOX	01/09/2023	
2		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 not final	part343	01/09/2023	

**Labeler** - HART Health (069560969)

Revised: 8/2023

HART Health