BACKPRIN- acetaminophen, caffeine, salicylamide tablet 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.

BACKPRIN

Active Ingredients (in each tablet):

Acetaminophen 250 mg

Caffeine 50 mg

Magnesium Salicylate (NSAID*) 290 mg (*nonsteroidal anti-inflammatory drug)

Purpose:

Pain Reliever/Fever Reducer

Pain Reliever Aid

Pain Reliever/Fever Reducer

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: Acetaminophen and Magnesium Salicylate may cause severe allergic reaction which may include hives, skin reddening, blisters, rash, facial swelling, asthma (wheezing), or shock.

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is highter if you:

- take more or for a longer time than directed
- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or non-prescription NSAID (aspirin, ibuprofen, naproxen, others)

Do not use:

• if you have ever had an allergic reaction to any other pain reliever/fever reducer

• with any other drug containing acetaminophen (prescription or non-prescription)

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you

- take a blood thinning (anticoagulant) or steroid drug
- take any drug for diabetes, gout or arthritis
- do not know if other drugs you are taking contain acetaminophen
- take any other drug containing an NSAID

Stop use and ask a doctor if:

- an allergic reaction occurs, seek medical help right away
- fever worsens or lasts for more than 3 days
- redness or swelling is present
- new symptoms occur
- pain worsens or lasts for more than 10 days
- ringing in the ears or a loss of hearing occurs
- you have any of the following signs of stomach bleeding: feel faint, vomit blood, have bloods or black stools, or stomach pain that does not get better

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 salicylates 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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symtoms. 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:

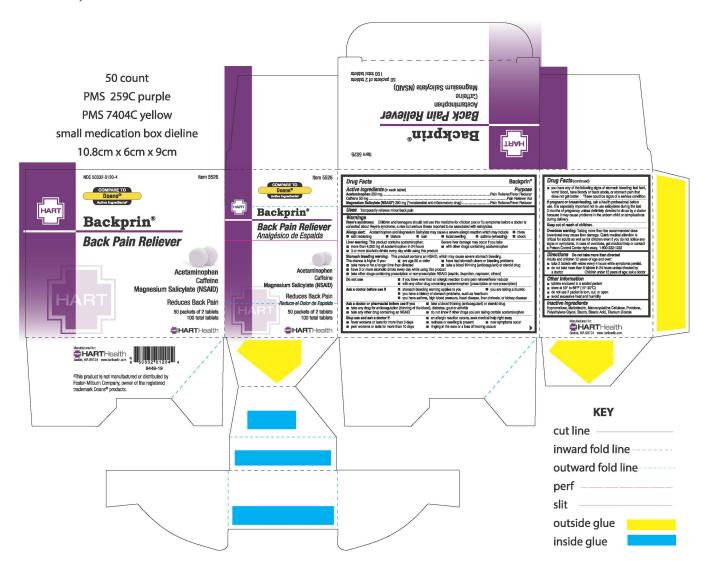
- take 2 tablets with water every 4 hours while symptoms persist.
- do not take more than 8 tablets in 24 hours unless directed by a doctor

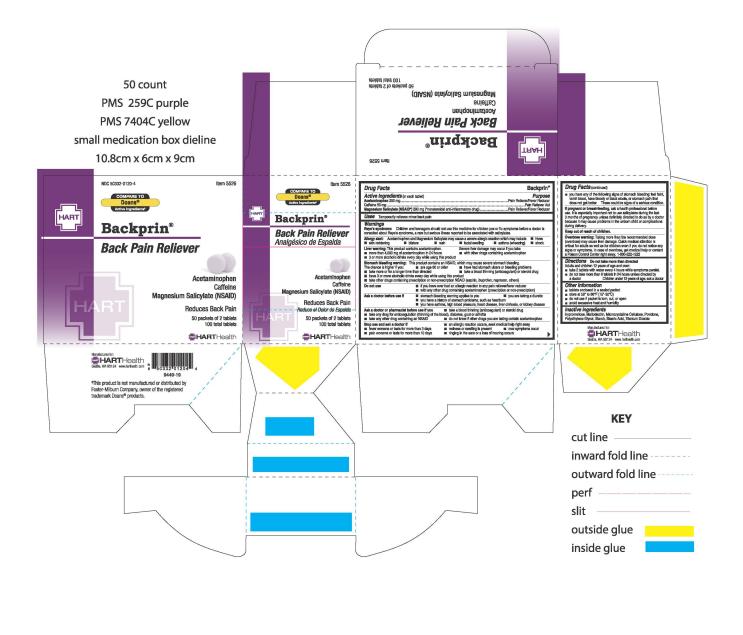
Children under 12 years of age: ask a doctor

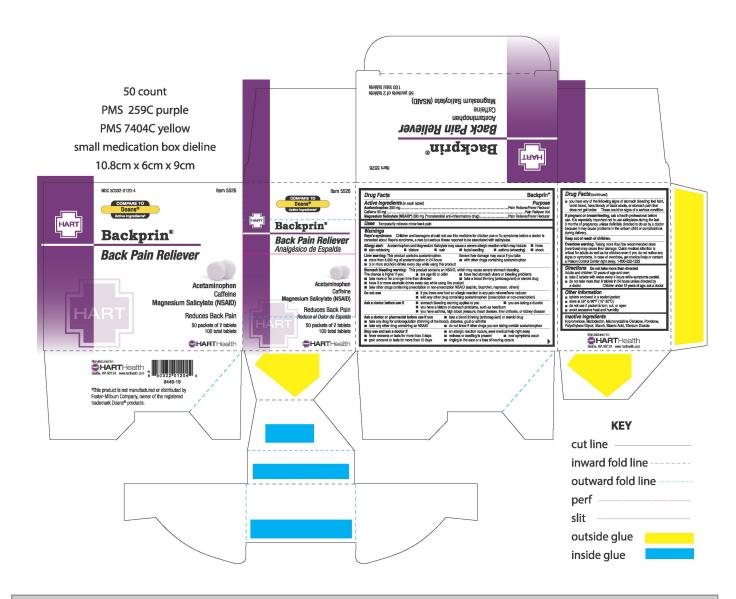
Inactive Ingredients:

Hypromellose, Maltodextrin, Microcystalline Cellulose, Povidone, Polyethylene Glycol, Starch,

Stearic Acid, Titanium Dioxide







BACKPRIN

acetaminophen, caffeine, salicylamide tablet

Product Information	Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0116
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	50 mg	
MAGNESIUM SALICYLATE (UNII: 41728 CY7UX) (SALICYLIC ACID - UNII:O414PZ4LPZ)	MAGNESIUM SALICYLATE	290 mg	

Inactive Ingredients		
Ingredient Name	Strength	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		

PO VIDO NE (UNII: FZ989 GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0116-4	50 in 1 BOX, UNIT-DOSE	07/14/2000	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0116-2	125 in 1 BOX, UNIT-DOSE	07/14/2000	
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	07/14/2000	

Labeler - HART Health (069560969)

Revised: 6/2020 HART Health