

DOANS EXTRA STRENGTH- magnesium salicylate tablet
Dr. Reddy's Laboratories Inc.

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.

Doan's[®]
Extra Strength

Drug Facts

Active ingredient (in each caplet)

Magnesium salicylate tetrahydrate 580 mg (NSAID)¹ (equivalent to 467.2 mg of anhydrous magnesium salicylate)

¹ 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:
 - vomit blood
 - feel faint
 - have bloody or black stools
 - 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

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- 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?

1-800-790-6417

PRINCIPAL DISPLAY PANEL - 24 Caplet Bottle Box

NDC 55741-224-24

EXTRA STRENGTH

DOAN'S®

MAGNESIUM SALICYLATE TETRAHYDRATE 580 mg each (NSAID)

PAIN RELIEVER

RELIEVES

BACKACHE

PAIN

24 CAPLETS

Drug Facts (continued)

Directions

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- adults: 2 caplets every 6 hours, not to exceed 8 caplets in 24 hours
- drink a full glass of water with each dose

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

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Drug Facts (continued)

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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. Magnesium salicylate may cause a severe allergic reaction, which may include:

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- facial swelling
- asthma (wheezing)
- shock

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- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Use for the temporary relief of minor backache pain

Active ingredient (in each caplet) Magnesium salicylate tetrahydrate 580 mg (NSAID) *.....Pain reliever (equivalent to 467.2 mg of amylorolus magnesium salicylate) *non-steroidal anti-inflammatory drug

Drug Facts RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Purpose

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

Ask a doctor before use if

- 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 or other medicine

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- feel faint
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TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF ALIEN UNITS TOBAC, PROJECTIONS SHOW ANY SIGNS OF TAMPERING



No Print/No Varnish Area
 Lot no. & Exp. Date

EXTRA STRENGTH

DOAN'S[®]

MAGNESIUM SALICYLATE TETRAHYDRATE 580 mg each (NSAID)
PAIN RELIEVER

24 CAPLETS

NDC 55741-224-24

EXTRA STRENGTH

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MAGNESIUM SALICYLATE TETRAHYDRATE 580 mg each (NSAID)
PAIN RELIEVER

RELIEVES BACKACHE PAIN

24 CAPLETS

B-0385-62-5-08
 ORG051233808

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DOANS EXTRA STRENGTH

magnesium salicylate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55741-224
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
hypromelloses (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6B0)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
polydextrose (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
stearic acid (UNII: 4ELV7Z65AP)	
titanium dioxide (UNII: 15FIX9V2JP)	
triacetin (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	DOANS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55741-224-24	1 in 1 BOX	05/24/2016	
1		24 in 1 BOTTLE; 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	05/24/2016	

Revised: 6/2016

Dr. Reddy's Laboratories Inc.