

**ASPIRIN REGULAR STRENGTH- aspirin tablet, coated
REMEDYREPACK 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.

Rugby 44-227

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - menstrual pain
 - a cold
 - toothache
 - muscle pain
 - minor pain of arthritis
- or as recommended by your doctor

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: Aspirin may cause a severe allergic reaction, which may include:

- facial swelling
- hives
- shock
- asthma (wheezing)

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

- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- are age 60 or older

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

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

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- diabetes
- arthritis
- gout

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:
 - vomit blood
 - feel faint
 - have bloody or black stools
 - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- new symptoms occur
- pain gets worse or lasts more than 10 days
- 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 aspirin 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

- **do not take more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 1 to 2 tablets every 4 hours not to exceed 12 tablets in 24 hours unless directed by a doctor
- children under 12 years: do not use unless directed by a doctor

Other information

- 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

black iron oxide, cellulose, colloidal anhydrous silica, corn starch, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, polydextrose, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, shellac wax, simethicone, sodium alginate, sodium bicarbonate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?

1-800-645-2158

DRUG: Aspirin Regular Strength Regular Strength

GENERIC: Aspirin

DOSAGE: TABLET, COATED

ADMINISTRATION: ORAL

NDC: 70518-2684-0

COLOR: orange

SHAPE: ROUND

SCORE: No score

SIZE: 10 mm

IMPRINT: 44;227

PACKAGING: 30 in 1 BLISTER PACK

ACTIVE INGREDIENT(S):

- ASPIRIN 325mg in 1

INACTIVE INGREDIENT(S):

- SHELLAC
- DIMETHICONE
- TRIETHYL CITRATE
- TRIACETIN
- TITANIUM DIOXIDE
- TALC

- STEARIC ACID
- SODIUM BICARBONATE
- SODIUM ALGINATE
- WATER
- POWDERED CELLULOSE
- Polyvinyl Acetate Phthalate
- POLYETHYLENE GLYCOL, UNSPECIFIED
- POLYDEXTROSE
- HYPROMELLOSE, UNSPECIFIED
- FD&C YELLOW NO. 6
- D&C YELLOW NO. 10 ALUMINUM LAKE
- STARCH, CORN
- SILICON DIOXIDE
- PROPYLENE GLYCOL
- FERROSO FERRIC OXIDE

<p>Regular Strength Aspirin</p> <p>Enteric Coated</p> <p>325 mg</p> <p>Tablet</p> <p>QTY: 30</p> 	<p>NDC #: 70518-2684-00</p> <p>Expires:</p> <p>LOT #:</p> <p>Source NDC: 00536-1232-01</p> <p>MFG: Rugby Labs, Livonia, MI 48150</p> <p>Keep this and all medication out of the reach of children</p>	
<p>Directions For Use: See Package Insert</p> <p>Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]</p> <p>Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762</p> <p style="text-align: right;">NOT FOR RETAIL SALE</p>		

ASPIRIN REGULAR STRENGTH			
aspirin tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70518-2684(NDC:0536-1232)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	325 mg
Inactive Ingredients			

Ingredient Name	Strength
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;227
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70518-2684-0	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/10/2020	

Labeler - REMEDYREPACK INC. (829572556)