

REGULAR STRENGTH ENTERIC COATED ASPIRIN- aspirin tablet, coated A-S Medication Solutions

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.

gc 921

Active ingredient (in each tablet)

Aspirin 325 mg(NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- for the temporary relief of minor aches and pains
- ask your doctor about other uses for aspirin

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:

- 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 aspirin or any other pain reliever/fever reducer.

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- taking a prescription drug for diabetes, gout or arthritis

Stop use and ask a doctor if

- 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
- an allergic reaction occurs. Seek medical help right away
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

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 right away.

Directions

- drink a full glass of water with each dose
- swallow whole, do not chew or crush
- do not exceed recommended dose
- adults and children 12 years and older: take 1-2 tablets every 4 hours, as needed, not more than 12 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

Other information

- store at room temperature 15°C - 30°C (59°F - 86°F)
- for institutional use only

Inactive ingredients

cellulose, D&C yellow
#10 lake, FD&C yellow #6 lake, hypromellose, iron

oxide, PEG, polydextrose, polyvinyl acetate phthalate, propylene glycol, shellac wax, silica, simethicone, sodium alginate, sodium bicarbonate, starch, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate. May also contain acetylated monoglycerides, croscarmellose sodium, hypromellose phthalate, methacrylic acid, mineral oil, polysorbate 80, sodium lauryl sulfate.

HOW SUPPLIED

Product: 50090-4462

NDC: 50090-4462-1 30 TABLET, COATED in a BOTTLE

NDC: 50090-4462-3 100 TABLET, COATED in a BOTTLE

NDC: 50090-4462-5 90 TABLET, COATED in a BOTTLE

Aspirin



REGULAR STRENGTH ENTERIC COATED ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4462(NDC:57896-921)
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
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
STARCH, CORN (UNII: O8232NY35J)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	44;227
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4462-5	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2019	
2	NDC:50090-4462-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2019	
3	NDC:50090-4462-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/01/2000	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4462) , REPACK(50090-4462)

Revised: 9/2020

A-S Medication Solutions