

ASPIRIN ENTERIC COATED, REGULAR STRENGTH- aspirin tablet, delayed release

Gendose Pharmaceuticals, LLC

Aspirin 325 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain from arthritis
 - headache
 - menstrual pain
 - pain and fever of colds
 - toothache
 - muscle 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: 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
- 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 high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

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

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

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 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 (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 while symptoms last
- do 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)

Inactive ingredients

black iron oxide, cellulose, colloidal anhydrous silica, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

Questions or comments?


Call 1-888-676-7161

PRINCIPAL DISPLAY PANEL


NDC 77333-035-20

Aspirin 325 mg
Enteric Coated Tablets
Pain Reliever (NSAID)

UD 150 Tablets (15x10)



(01) 0 03 77333 035 20 A



Drug Facts

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:
• minor pain from arthritis
• headaches • menstrual pain • pain and fever of colds • toothache • muscle pain

Warnings
Rybe'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, changes in behavior with nausea and vomiting occur, consult a doctor promptly. These symptoms could be an early sign of Rybe's syndrome, a rare but serious illness.

Drug Facts (continued)

Allergy alert: Aspirin may cause 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, etc.) • take aspirin or NSAIDs 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 • 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 high blood pressure, diabetes, liver disease, or kidney disease • you are taking a diuretic • you have asthma

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, an allergic reaction occurs. Swallowing helps right away. Stop use immediately if the following signs of stomach bleeding • feel faint or dizzy • vomit blood • have bloody or black stools • have stomach pain that does not get better • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • ringing in the ears or a loss of hearing occurs. 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 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 (1-800-222-1222) right away.

Directions • do not take more than directed • drink a full glass of water with each dose • do not take more than 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)

Inactive ingredients black iron oxide, cellulose, colloidal anhydrous silica, D&C yellow #10 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate.

Questions or Comments? Call 1-888-676-7161

ASPIRIN ENTERIC COATED, REGULAR STRENGTH

aspirin tablet, delayed release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77333-035
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)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	44;227
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77333-035-20	150 in 1 BOX	05/15/2026	
1	NDC:77333-035-25	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/15/2026	

Labeler - Gendose Pharmaceuticals, LLC (080257510)

Registrant - Gendose Pharmaceuticals, LLC (080257510)

