REGULAR STRENGTH ENTERIC COATED ASPIRIN- aspirin tablet, coated Bryant Ranch Prepack

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
- if you ever had an allergic reaction to this product or any of its ingredients

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 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 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 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: do not use unless directed by a doctor

Other information

store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (59°F - 86°F)

Inactive ingredients

black iron oxide, cellulose, corn starch, D&C yellow #10 lake, FD&C yellow #6 lake, hypromellose, polydextrose,

polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, shellac wax, silicon dioxide, simethicone, sodium alginate, sodium bicarbonate, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate.

Questions or comments?

1-800-540-3765

HOW SUPPLIED

Aspirin 325 mg(NSAID)* *nonsteroidal anti-inflammatory drug.

NDC: 71335-0513-1: 30 Tablets in a BOTTLE

NDC: 71335-0513-2: 60 Tablets in a BOTTLE

NDC: 71335-0513-3: 100 Tablets in a BOTTLE

NDC: 71335-0513-4: 90 Tablets in a BOTTLE

NDC: 71335-0513-5: 20 Tablets in a BOTTLE

NDC: 71335-0513-6: 45 Tablets in a BOTTLE

NDC: 71335-0513-7: 120 Tablets in a BOTTLE

NDC: 71335-0513-8: 7 Tablets in a BOTTLE

Repackaged/Relabeled by: Bryant Ranch Prepack, Inc.

Burbank, CA 91504

Aspirin E.C 325 mg Tablet



Each tablet contains: Aspirin, USP 325 mg

Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) (see

Keep this and all drugs out of the reach of children.

Take with food.

Dispense in a tight, light-resistant container with a child-resistant closure.

NDC 71335-0513-1

Aspirin Tablets USP

325 mg

BRP

30 Tablets

Repackaged by: Bryant Ranch Prepack, Inc. Burbank, CA 91504 USA Manufactured by: Geri-Care Pharmaceutical Corp



REGULAR STRENGTH ENTERIC COATED ASPIRIN

aspirin tablet, coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71335-0513(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			
FERROSOFERRIC OXIDE (UNII: XM0M87F357)				
STARCH, CORN (UNII: O8232NY3SJ)				
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: 46N107B710)				
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: 92RU3N3Y10)				

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:71335- 0513-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2019		
2	NDC:71335- 0513-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/16/2021		
3	NDC:71335- 0513-3	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2019		
4	NDC:71335- 0513-4	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/04/2019		
5	NDC:71335- 0513-5	20 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2020		
6	NDC:71335-	45 in 1 BOTTLE; Type 0: Not a Combination	0410313034		

O	0513-6	Product	U4/U3/ZUZ4	
7	NDC:71335- 0513-7	120 in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2020	
8	NDC:71335- 0513-8	7 in 1 BOTTLE; Type 0: Not a Combination Product	04/03/2024	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M013	07/01/2000		

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-0513), RELABEL(71335-0513)

Revised: 4/2024 Bryant Ranch Prepack