

**ENTERIC COATED ASPIRIN- aspirin tablet, coated**  
**Chain Drug Consortium, LLC**

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**pv 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
- for arthritis conditions affecting children under 12 years of age, consult a doctor immediately

### **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)

### **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.

**package label**

**Drug Facts (continued)**  
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children under 12	ask a doctor

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**Inactive ingredients:** cellulose, D&C yellow #10 lake, FD&C yellow #6 lake, hypromellose, iron oxide, PEG, polydextrose, polyvinyl acetate phthalate, propylene glycol, silica, simethicone, sodium alginate, sodium bicarbonate, starch, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate, wax. May also contain acetylated monoglycerides, croscarmellose sodium, hypromellose phthalate, methacrylic acid, mineral oil, polysorbate 80, sodium lauryl sulfate

  
 DISTRIBUTED BY:  
 CHAIN DRUG CONSORTIUM, LLC.  
 UPARC, BLDG. A3, SUITE 338  
 1020 WILLIAM PITT WAY  
 PITTSBURGH, PA 15238  
 WWW.CHAINDRUGCONSORTIUM.COM

 If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.  
 \* This product is not manufactured or distributed by the owner of the registered trademark ECOTRIN®

NDC 68016-722-12  
 COMPARE TO THE ACTIVE  
 INGREDIENT IN ECOTRIN®\*

 Enteric Coated  
**Aspirin** Tablets 325 mg  
**REGULAR STRENGTH ASPIRIN (NSAID)**  
 For the temporary relief of minor  
 arthritis pain & inflammation  
**125 Tablets**



**TAMPER EVIDENT:** Do not use if imprinted seal under cap is missing or broken.

**Drug Facts** SAVE CARTON FOR COMPLETE DRUG FACTS

Active ingredient (in each tablet)	Purpose
Aspirin 325 mg (NSAID-nonsteroidal anti-inflammatory drug)	Pain reliever

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

**Warnings**  
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**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

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**Drug Facts (continued)**

• 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  
 • for arthritis conditions affecting children under 12 years of age, consult a doctor immediately

**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



# ENTERIC COATED ASPIRIN

aspirin tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-722
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYVINYL ACETATE PHTHALATE</b> (UNII: 58QVG85GW3)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM ALGINATE</b> (UNII: C269C4G2ZQ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 68016-722			

1	NDC:68016-722-12	1 in 1 CARTON	04/01/2015	
1		125 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68016-722-30	300 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2015	08/31/2022

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	04/01/2015	

**Labeler** - Chain Drug Consortium, LLC (101668460)

**Registrant** - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023

Chain Drug Consortium, LLC