

## **REGULAR STRENGTH ENTERIC COATED ASPIRIN- aspirin tablet, coated** **Geri-Care Pharmaceutical Corp**

*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.*

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**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 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

## package label

**Drug Facts**

<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Aspirin 325 mg (NSAID)*	Pain reliever
*nonsteroidal anti-inflammatory drug	

**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



NDC 57896-921-10

**Regular Strength  
Enteric  
Coated  
Aspirin**

**Pain Reliever (NSAID)**

*Tamper Evident:* Do not use if imprinted seal under cap is missing or broken.

**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	ask 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

DIST. BY: GERI-CARE PHARMACEUTICALS CORP. REV 0521L  
1650 63 Street, Brooklyn, New York 11204



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**1000 Tablets 325 mg each**

REGULAR STRENGTH ENTERIC COATED ASPIRIN			
aspirin tablet, coated			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57896-921
<b>Route of Administration</b>	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: O8232NY3SJ)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C YELLOW NO. 6 (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: 3WJQ05DW1A)
<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
1	NDC:57896-921-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2012	
2	NDC:57896-921-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2012	
3	NDC:57896-921-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2012	
4	NDC:57896-921-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2012	
5	NDC:57896-921-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2018	

### Marketing Information

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

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Geri-Care Pharmaceutical Corp		611196254	repack(57896-921)

Revised: 10/2021

Geri-Care Pharmaceutical Corp