

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

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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
- 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

### package label

**Drug Facts**

**Active ingredient (in each tablet)**  
Aspirin 325 mg (NSAID)\*.....Pain reliever  
\*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

NDC 57896-921-10



**REGULAR STRENGTH  
ENTERIC COATED  
ASPIRIN  
325 mg  
PAIN RELIEVER (NSAID)**

**1000 Tablets**

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

**Drug Facts (continued)**

**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  
These can 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 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	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, silica, 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 0523L  
1295 Towbin Avenue, Lakewood, NJ 08701



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## 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
<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
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	08/01/2022
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 Drug	M013	07/01/2000	

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

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

