# ADULT LOW DOSE ENTERIC COATED ASPIRIN- aspirin tablet, coated Geri-Care Pharmaceutical Corp

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gc 983

# Active ingredient (in each tablet)

Aspirin 81 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 your 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 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

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 4-8 tablets every 4 hours, as needed, not more than 48 tablets in 24 hours, or as directed by a doctor
- children under 12 years: ask a doctor

### Other information

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

# Inactive ingredients

cellulose, croscarmellose sodium, D&C Yellow #10 Lake, lactose monohydrate, methacrylic acid co-polymer, PEG, polacrilin potassium, polyvinyl alcohol, silica, sodium lauryl sulfate, soya powder, talc, titanium dioxide, triethyl citrate

# **Questions or comments?**

1-800-540-3765

# package label



ADULT LOW DOSE ENTERIC COATED PAIN RELIEVER (NSAID)



500 Tablets

the stomach bleedir

Tamper Evident: Do not use if imprinted seal

# under cap is missing or broken

**Drug Facts** 

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

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a vomit blood

of the follo

stools

taking a prescription drug for diabetes, gout or arthritis

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■ you have a history of stomach problems, such as heartburn ■ you have: □ high blood pressure □ heart disease □ liver cirrhosis □ kidney disease

warning applies to you ■ you are

lsk a doctor before use if ■

**Drug Facts** (continued)

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polacrilin potassium, polyviny sodium, D&C Yellow #10 Lake lactose monohydrate, methacrylic acid Inactive ingredients: cellulose co-polymer, PEG, alcohol,

Questions or comments?1-800-540-3765 silica, sodium lauryl sulfate, soya talc, titanium dioxide, triethyl citrate

**REV 0422B** 

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Dist. by: Geri-Care PHARIMACEUTICALS CORP

Product of India

295 Towbin Ave, Lakewood, NJ 0870

Do not use if you are allergic to aspirin or any other

pain reliever/fever

\*This product is not manufactured or distributed by

the owner of the registered trademark Bayer $^{\otimes}$ 

STOP PEELING

# ADULT LOW DOSE ENTERIC COATED ASPIRIN

aspirin tablet, coated

**Product Information** 

HUMAN OTC DRUG NDC:57896-983 **Product Type** Item Code (Source)

**Route of Administration** ORAL

**Active Ingredient/Active Moiety** 

**Basis of Strength** Strength Ingredient Name ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) **ASPIRIN** 81 mg

**Inactive Ingredients Ingredient Name** Strength CROSCARMELLOSE SODIUM (UNII: M280L1HH48)

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)

POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

SOYBEAN (UNII: L7HT8F1ZOD)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

SODIUM LAURYL SULFATE (UNII: 368GB5141J)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics					
Color	yellow	Score	no score		
Shape	ROUND	Size	6mm		
Flavor		Imprint Code	P		
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:57896-983- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021			
2	NDC:57896-983- 12	120 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021			
3	NDC:57896-983- 50	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2022			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M013	07/01/2021			

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

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023 Geri-Care Pharmaceutical Corp