REGULAR STRENGTH ASPIRIN- aspirin tablet, coated CARDINAL HEALTH, INC.

LDR 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 or as recommended by your doctor

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 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 may 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 (1-800-222-1222) right away.

Directions

- drink a full glass of water with each dose
- swallow whole, do not chew or crush
- do not exceed recommended dose

| | take 1-2 tablets every 4 hours, |
|-----------|---------------------------------|
| | as needed, not more than 12 |
| years and | tablets in 24 hours, or as |
| older | directed by a doctor |
| children | ask a doctor |
| under 12 | |

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, silica, simethicone, sodium alginate, sodium bicarbonate, starch, stearic acid, talc, titanium dioxide, triacetin, triethyl citrate, wax.

Questions or comments?

1-800-540-3765

package label



REGULAR STRENGTH ASPIRIN

aspirin tablet, coated

| Product Information | uct Information | | | |
|----------------------------|-----------------|--------------------|----------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0014 | |
| Route of Administration | ORAL | | | |

| Active Ingredient/Active Moiety | | |
|--|--------------------------|----------|
| Ingredient Name | Basis of Strength | Strength |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | AS PIRIN | 325 mg |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM) | | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | | |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357) | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | | |
| POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3) | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | | |

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|---|--|
| 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) | |
| | |

| Product Characteristics | | | |
|-------------------------|--------|--------------|----------|
| Color | orange | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | | Imprint Code | 44;227 |
| Contains | | | |

| l | Packaging | | | | |
|---|-----------|----------------------|--|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:70000- 0014-1 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 04/01/2019 | |

| Marketing In | arketing Information | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M013 | 04/01/2019 | |
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Labeler - CARDINAL HEALTH, INC. (063997360)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 10/2023 CARDINAL HEALTH, INC.