

GENCARE-ASPIRIN LOW DOSE PAIN RELIEVER (NSAID)- aspirin tablet
Pioneer Life Sciences, LLC

Gencare-Aspirin Low Dose Pain reliever (NSAID)

Active Ingredient (in each tablet)

Aspirin 81mg (NSAID)*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses:

- for the temporary relief of minor aches and pains or as recommended by your doctor.
Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief
- ask your doctor about other uses for Safety Coated 81 mg Aspirin

Warnings:

Reye's syndrome

Children and teenagers who have or are recovering from chickenpox 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 have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for • gout • diabetes • arthritis

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away
- 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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs

PREGNANCY

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

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
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

OTHER INFORMATION

- store at room temperature. Avoid excessive heat above 40°C (104°F).

INACTIVE INGREDIENTS

Triacetin, Stearic Acid, Povidone, Triethyl citrate, Sodium Lauryl Sulfate, Microcrystalline Cellulose, Starch Corn, Pregelatinized Starch, Silicon Dioxide, Methacrylic Acid - Ethyl Acrylate copolymer, Titanium Dioxide, Sodium Bicarbonate, Talc, D & C Yellow No. 10, Hypromellose 2910 (6 Mpa.S)

QUESTIONS OR COMMENTS?

Call +1-(732) 994-2808 or email support@gencare.health

Compare to BAYER® LOW DOSE ASPIRIN active ingredient.

Aspirin Low Dose

pain reliever (nsaid)

Safety Coated Aspirin Regimen

81 mg 500 tablets

not actual size

Drug Facts

Active ingredient (in each tablet)
Aspirin 81 mg (NSAID)* Pain reliever
*nonsteroidal anti-inflammatory drug

Uses: • for the temporary relief of minor aches and pains or as recommended by your doctor. **Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief** • ask your doctor about other uses for Safety Coated 81 mg 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

(continued under label)

†This product is not manufactured or distributed by Bayer Healthcare, LLC owner of the Registered Trademark BAYER® Low Dose Aspirin Tablets Distributed by: **Gencare Consumer Products, LLC** 40E Cottlers Ln, Suite A, East Brunswick, NJ 08816 www.gencare.health

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PEEL HERE

Drug Facts (continued)

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 have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if • stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, or kidney disease • you are taking a diuretic • you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for • gout • diabetes • arthritis

Stop use and ask a doctor if • an allergic reaction occurs. Seek medical help right away • 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 • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • redness or swelling is present • new symptoms occur • ringing in the ears or a 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 (1-800-222-1222) right away.

Directions: • drink a full glass of water with each dose • adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor • children under 12 years: consult a doctor

Other information: • store at room temperature. Avoid excessive heat above 40°C (104°F).

Other ingredients: Triacetin, Stearic Acid, Povidone, Triethyl Citrate, Sodium Lauryl Sulfate, Microcrystalline Cellulose, Starch, Corn, Pregelatinized Starch, Silicon Dioxide, Methacrylic Acid - Ethyl Acrylate Copolymer, Titanium Dioxide, Sodium Bicarbonate, Talc, D&C Yellow No. 10, Hypromellose 2910 (6 Mpa.S)

Questions or comments? Call +1 (732) 994-2808 or email support@gencare.health

.5" Glue Area

GENCARE-ASPIRIN LOW DOSE PAIN RELIEVER (NSAID)

aspirin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72090-037
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
Triacetin (UNII: XHX3C3X673)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Povidone (UNII: FZ989GH94E)	
Triethyl Citrate (UNII: 8Z96QXD6UM)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER (2:1; 600000 MW) (UNII: XRK36F13ZZ)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Sodium Bicarbonate (UNII: 8MDF5V39QO)	
Talc (UNII: 7SEV7J4R1U)	
D&C Yellow No. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	S17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-037-01	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/07/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	11/07/2024	

Labeler - Pioneer Life Sciences, LLC (014092742)

Registrant - Pioneer Life Sciences, LLC (014092742)

Revised: 11/2024

Pioneer Life Sciences, LLC