

**PAIN RELIEVER / LOW DOSE ASPIRIN- aspirin tablet, chewable
PHARMAMED USA INC**

ASPIRIN 81mg Chewable Tablets

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
- ask your doctor about other uses for this product

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

- this product for at least 7 days after tonsilectomy or oral surgery unless directed by a doctor
- if you have 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 have asthma
- you are taking a diuretic

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

- 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
- allergic reaction occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- 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 accidental overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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

- Tamper Evident: Do not use if the safety seal under the cap is broken or missing
- Store at room temperature (15°-30°C) 59°F- 86°F
- Avoid excess heat and moisture

Inactive ingredients

Corn starch, dextrose monohydrate, FD&C yellow #6, flavor, silicon dioxide, sodium saccharine and stearic acid.

Questions or comments?

Adverse drug event call: (866) 562-2756 (Mon-Fri 8AM to 4PM EST)

Package Label Principal Display Panel

PHARMAMED

NDC 84289-366-36

Manufactured in the U.S.A

Pain Reliever (NSAID) / Low Dose

ASPIRIN


Aspirin 81 mg

36 CHEWABLE

Aspirin regimen

Orange Flavored

***Compare to the active ingredient in BAYER Chewable Aspirin**

 <p>NDC 84289-366-36</p> <p>Manufactured in the U.S.A</p> <p>Pain reliever (NSAID) / Low Dose</p> <h1>Aspirin</h1> <p>Aspirin 81 mg</p> <p>36 CHEWABLE TABLETS</p> <p>Aspirin regimen</p> <p>Orange flavored</p> <p>*Compare to the active ingredient in BAYER CHEWABLE ASPIRIN</p>	<p>NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN</p>	<p>Drug facts</p> <p>Active ingredients (in each tablet)</p> <p>Aspirin 81 mg (NSAID)*..... Pain reliever/ nonsteroidal anti-inflammatory drug</p> <p>Purpose</p> <p>Pain reliever</p> <p>Uses</p> <p>• for the temporary relief of minor aches and pains or as recommended by your doctor • ask your doctor about other uses for this product</p> <p>Warnings</p> <p>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.</p> <p>Allergy Alert: Aspirin may cause a severe allergic reaction which may include: •Hives •Facial swelling •Asthma (wheezing) •Shock</p> <p>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.</p>	<p>Drug facts (continued)</p> <p>Do not use</p> <p>•If you are allergic to aspirin or any other pain reliever/fever reducer •this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor</p> <p>Ask a doctor before use if</p> <p>•You have a history of stomach problems, such as heartburn •you have high blood pressure, heart disease, liver cirrhosis or kidney disease •you have asthma •you are taking a diuretic</p> <p>Ask a doctor or pharmacist before use if you are taking a prescription drug for •gout •diabetes •arthritis</p> <p>Stop use and ask a doctor if</p> <p>•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 •allergic reaction occurs •pain gets worse or lasts more than 10 days •redness or swelling is present •any new symptoms occur •ringing in the ears or loss of hearing occurs</p> <p>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.</p>	<p>Drug facts (continued)</p> <p>Keep out of reach of children. In case of accidental overdose, get medical help or contact a poison control center right away</p> <p>Directions</p> <p>•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</p> <p>Other information</p> <p>•Tamper evident: Do not use if safety seal under cap is broken or missing</p> <p>•store at room temperature (15 - 30C)</p> <p>•avoid excess heat and moisture</p> <p>Inactive ingredients Corn starch, dextrose monohydrate, FD&C yellow #6, flavor, silicon dioxide, sodium saccharine and stearic acid.</p> <p>Questions? Adverse drug event call: (866) 562-2756 M-F 8AM - 4PM</p>	<p>BIAR CODE</p> <p>Lot</p> <p>Exp</p>
		<p>Manufactured by : Pharbest Pharmaceuticals, Inc. 14 Engineers Lane Farmingdale, NY 11735.</p> <p>Distributed by: Pharmamed USA Inc. 3778 SW 30th Ave Hollywood, FL 33312.</p>			

PAIN RELIEVER / LOW DOSE ASPIRIN

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84289-366(NDC:16103-366)
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
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	8mm
Flavor	ORANGE	Imprint Code	PH034
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84289-366-36	36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2024	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	10/01/2024	

Labeler - PHARMAMED USA INC (065607328)

Registrant - PHARBEST PHARMACEUTICALS, INC. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
PHARBEST PHARMACEUTICALS, INC.		557054835	repack(84289-366)

Revised: 6/2024

PHARMAMED USA INC