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 alergic 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 alergic 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 yelow #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

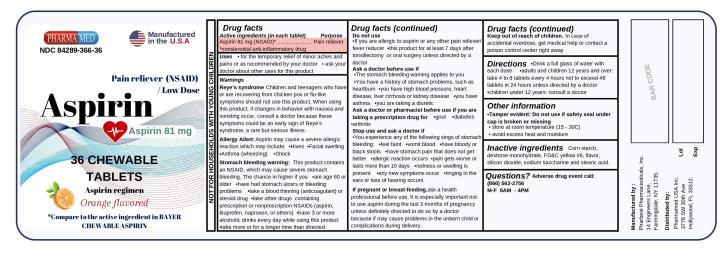
Aspirin 81 mg

36 CHEWABLE

Aspirin regimen

Orange Flavored

*Compare to the active ingredient in BAYER Chewable Aspirin



PAIN RELIEVER / LOW DOSE ASPIRIN

aspirin tablet, chewable

Product Inform	mation						
Product Type		HUMAN OTC DRUG	Item Code (S	Source)	NDC:84289-	-366(NDC:	16103-366)
Route of Admini	stration	ORAL					
Active Ingredie	ent/Active	Moiety					
Ingredient Name					Basis of Strength		
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)			76E)	ASPIRIN		8	1 mg
Inactive Ingre	dients						
Ingredient Name						Strength	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)							-
STEARIC ACID (UNI	I: 4ELV7Z65AP)					
FD&C YELLOW NO	. 6 (UNII: H77\	/EI93A8)					
SILICON DIOXIDE (UNII: ETJ7Z6XE	3U4)					
STARCH, CORN (UN	NII: 08232NY35	ij)					
DEXTROSE MONOR	HYDRATE (UNI	I: LX22YL083G)					
Product Chara	cteristics						
Color orange		ige S	Score			no score	
Shape ROU		ND	Size			8mm	
Flavor ORA		NGE	Imprint Code			PH034	
Contains							
Packaging							
# Item Code	de Package Description				ing Start ate		eting End Date
	36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product						
			Not a	10/01/2024	1		

1				
				1
				- 1
Marketing In	formation			
Marketing Category		Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)		10/01/2024	

Labeler - PHARMAMED USA INC (065607328)

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

Revised: 6/2024

PHARMAMED USA INC