

CHEWABLE ASPIRIN LOW DOSE- chewable aspirin 81mg tablet, chewable
Ulai Health LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

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 Chewable Aspirin 81 mg

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 tonsillectomy 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 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 get worse or lasts more than 3 days
 - redness or swelling is present
 - 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 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 exceed 48 tablets in 24 hours unless directed by a doctor
children under 12 years	ask a doctor

Other information

- store at 20-25⁰C (68-77⁰F)
- avoid excess heat and moisture

Inactive ingredients

corn starch, dextrose monohydrate, FD&C yellow #6, orange flavor, silicon dioxide, sodium saccharine, stearic acid

Questions or comments?

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

PHARBEST

NDC 73057-366-11

Manufactured in the USA

ASPIRIN REGIMEN

Chewable

Aspirin

Low Dose

81^{mg} Pain Reliever (NSAID)

*Comapre to the active ingredient in BAYER® Chewable Aspirin

Orange Flavored

1000 TABLETS

Talk to your doctor or other healthcare provider before using this product for your heart.

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ASPIRIN REGIMEN

Chewable Aspirin
Low Dose
81^{mg} Pain Reliever (NSAID)
*Compare to the active ingredient in BAYER® Chewable Aspirin
Orange Flavored
1000 TABLETS

Talk to your doctor or other healthcare provider before using this product for your heart.

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN
TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

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 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 take aspirin. Aspirin use in these children and teenagers can lead to 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 pain or bleeding in the past ■ are taking aspirin or 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/reducer ■ this product ■ 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 ■ diabetes ■ atr fibrils

Stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away, especially if you have ■ hives ■ swelling of the face, lips, tongue, or throat ■ 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

Keep out of reach of children. 7 cases of 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
■ 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 ■ ask a doctor

Other information
■ store at 20-25°C (68-77°F) ■ avoid excess heat and moisture
Inactive ingredients: corn starch, dextrose monohydrate, FbC, yellow #6, orange flavor, silicon dioxide, sodium saccharine, citric acid

Questions or comments?
(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

*This product is not manufactured or distributed by Bayer, owner or registered trademark of Bayer® Chewable Aspirin.

Distributed by:
DLI HEALTH, LLC
Alexandria, VA 22312

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CHEWABLE ASPIRIN LOW DOSE

chewable aspirin 81mg tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73057-366
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
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STARCH, CORN (UNII: O8232NY3SJ)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

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:73057-366-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2019	
2	NDC:73057-366-05	36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	06/28/2019	

Labeler - Ulai Health LLC (081181535)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)