

LEADER LOW DOSE ASPIRIN- aspirin tablet, chewable
CARDINAL HEALTH

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

- for the temporary relief of minor aches and pains or as recommended by your doctor
- ask your doctor about other uses for this product

Warning

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

- facial swelling
- shock
- hives
- asthma (wheezing)

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
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more or for a longer time than directed
- have had stomach ulcers or bleeding problems
- 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

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking a diuretic

- you have asthma
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease

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
- an allergic reaction occurs
- any new symptoms occur
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- ringing in the ears or loss of hearing occurs

These could be signs of a serious illness.

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 (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 unless directed by a doctor	not to exceed 48 tablets in 24 hours
children under 12 years	consult a doctor	

Other information

- store at room temperature (15⁰-30⁰C)
- 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: 1-866-562-2756

Compare to Bayer® Chewable Low Dose Aspirin active ingredient***

Leader

Low Dose

Aspirin

81 mg

Chewable Orange

Pain Reliever (NSAID)

Orange Flavored

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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

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Ask a doctor before use if
 ■ the 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

Drug Facts (continued)

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
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TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

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Do not use if you are allergic to aspirin or any other pain reliever/fever reducer. This product is not manufactured or distributed by Bayer® HealthCare LLC, owner of the registered trademark Bayer® Low Dose Chewable Aspirin. 09/2014

LEADER LOW DOSE ASPIRIN

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49781-084
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
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-084-99	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	09/20/2014	

Labeler - CARDINAL HEALTH (097537435)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Revised: 9/2014

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