

LOW DOSE ASPIRIN- aspirin tablet, chewable

Walgreen Company

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.

Walgreens 44-397

Active ingredient (in each chewable 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

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
- shock
- 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
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- have 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- 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
- for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor
- 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 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

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - vomit blood
 - have bloody or black stools
 - feel faint
 - have stomach pain that does not get better
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

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
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- adults and children 12 years and over: take 4 to 8 chewable tablets every 4 hours not to exceed 48 chewable tablets in 24 hours unless directed by a doctor
- children under 12 years: do not use unless directed by a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, flavor, maltodextrin, sucralose

Principal Display Panel

VALUE SIZE

NDC 0363-0397-07

Walgreens

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

Aspirin 81

81 mg CHEWABLE TABLETS
PAIN RELIEVER (NSAID)

**CHEWABLE
LOW DOSE**

**HEART
HEALTH••**

108

CHEWABLE
TABLETS

(3 BOTTLES: 36 TABLETS PER BOTTLE)

ACTUAL SIZE

CHERRY FLAVOR

Chew or crush tablets completely before swallowing. Do not swallow tablets whole.

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

†Walgreens Pharmacist Survey

††This product is not manufactured or distributed by Bayer AG, owner of the registered trademark Bayer® Chewable Low Dose Aspirin.

50844 REV1118A39707

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

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Aspirin 81

Compare to Bayer® Chewable Low Dose Aspirin active ingredient^{††}

Walgreens

VALUE SIZE

LOT-1603-0303 CON

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Drug Facts (continued)

Active ingredient (in each chewable tablet) Aspirin 81 mg (NSAID)
Purpose ... pain reliever

Uses For the temporary relief of minor aches and pains or as recommended by your doctor

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 or flu-like symptoms occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Drug Facts (continued)

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- 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 thinner (anticoagulant) or steroid drug
- take 3 or more alcoholic drinks every day while using this product
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or

- others)
- take more or for a longer time than directed
- if you are allergic to aspirin or any other pain reliever (never reduce
- for at least 7 days after having surgery or oral surgery unless directed by a doctor
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if

- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver disease, 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: vomit blood
- have bloody or black stools
- find dark
- have stomach pain that does not get better

- These could be signs of a serious condition.
- 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 distinctly 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

- Take 1 or 2 tablets with water, 4 to 8 chewable tablets every 4 hours not to exceed 48
- adults and children 12 years and over; take 4 to 8 chewable tablets every 4 hours not to exceed 48
- children under 12 years: do not use unless directed by a doctor

Other information

- Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- See end flap for expiration date and lot number

Drug Facts (continued)

Inactive ingredients: corn starch, D&C red #27 aluminum lake, D&C red #30 aluminum lake,

diacetyl, glycerol, flavor, hydrocodone, sucrose

Questions or comments? 1-800-426-9391

Walgreens Pharmacist Survey

This product is not manufactured or distributed by Bayer AG, owner of the

registered trademark Bayer® Chewable Low Dose Aspirin.

ORG0618-F
REV0119

No print/No varnish area
Lot no/Exp date

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

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REV1118A39707

PHARMACIST
RECOMMENDED
Trusted since 1901™
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Health expertise
you rely on.™

to move
ve.



44-397A

LOW DOSE ASPIRIN

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0397
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
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTRATES (UNII: G263MI44RU)	
STARCH, CORN (UNII: O8232NY3SJ)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	8mm
Flavor	CHERRY	Imprint Code	44;397
Contains			

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:0363-0397-07	3 in 1 CARTON	09/04/2001	
1		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL		part343	09/04/2001	

Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(0363-0397)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(0363-0397)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(0363-0397)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(0363-0397)