

LOW DOSE ASPIRIN CHEWABLE- aspirin tablet, chewable
Healthlife of USA

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.

LOW DOSE ASPIRIN CHEWABLE

Drug Facts

Active Ingredient (in each Tablet)

Aspirin 81mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever

Uses

- temporarily relieves minor aches and pains
- for other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur.

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 behaviour 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
- hives
- 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
- 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

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
- 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 THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING
- store at 25°C (77°F); excursion permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

Inactive Ingredients

- Butylated Hydroxytoluene
- Dextrates
- FD&C Yellow No.6
- Cellulose, Microcrystalline
- Corn Starch
- Orange
- Modified corn starch
- Saccharin sodium
- Stearic acid

Principal Display Panel

Low Dose

ASPIRIN 81mg

30 Chewable Tablets

HealthLife NDC 69517-136-30

LOW DOSE ASPIRIN REGIMEN

ASPIRIN

CHEWABLE
Orange Flavored
Pain Reliever (NSAID)

30 CHEWABLE TABLETS **81mg**

SEE NEW WARNINGS INFORMATION

Distributed by: HealthLife of USA LLC
Rahway, NJ 07065

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each tablet) Purpose
Aspirin 81 mg (NSAID)¹.....Pain Reliever
nonsteroidal anti-inflammatory drug

Uses ■ Temporarily relieves minor aches and pains ■ For other uses, see your doctor, but do not use for more than 10 days without consulting your doctor because serious side effects may occur

Warning See box for complete warnings

Reye's syndrome: Children and teenagers who have or are recovering from chickenpox or measles should not use this product. Children using this product or taking aspirin should be watched for signs 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 aspirin or other drugs ■ take other drugs containing aspirin or nonsteroidal NSAID (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

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.

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

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Lot No.:

Exp. Date:

No Varnish

LOW DOSE ASPIRIN CHEWABLE

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69517-136
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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
DEXTRATES (UNII: G263MI44RU)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
ORANGE (UNII: 5EVU04N5QU)	
STARCH, CORN (UNII: O8232NY3SJ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	TCL;334

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69517-136-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/09/2017	

Labeler - Healthlife of USA (079656178)**Establishment**

Name	Address	ID/FEI	Business Operations
Time-Cap Labs, Inc.		037052099	manufacture(69517-136)

Revised: 10/2017

Healthlife of USA