TOPCARE ASPIRIN- aspirin tablet, chewable Topco Associates LLC

Topco Associates LLC. Aspirin 81 mg Drug Facts

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

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 have ever had an allergic reaction to any other pain reliever/fever reducer
- 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 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 gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or loss of hearing occurs

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 at 20 weeks or later in 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 chewable 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

store at 20-25°C (68-77°F)

Inactive ingredients

corn starch, dextrose excipient, FD&C yellow no. 6 aluminum lake, flavors, saccharin sodium

Questions or comments?

Principal Display Panel

TopCare® health

COMPARE TO BAYER® CHEWABLE ASPIRIN ACTIVE INGREDIENT

LOW DOSE

ASPIRIN REGIMEN

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

Aspirin 81 mg

Chewable • PAIN RELIEVER (NSAID)

36 TABLETS

actual size

ORANGE FLAVOR



TOPCARE ASPIRIN

aspirin tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-467
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: 08232NY3SJ)			
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			

Product Characteristics			
Color	ORANGE	Score	no score
Shape	ROUND	Size	8mm
Flavor	ORANGE	Imprint Code	L467
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800-467- 68	1 in 1 CARTON	08/24/1992		
1		36 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:36800-467- 08	3 in 1 CARTON	01/17/2018		
2		36 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/24/1992	

Labeler - Topco Associates LLC (006935977)

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