

TOPCARE ASPIRIN- aspirin tablet, chewable
Topco Associates 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.

Topco Associates LLC. Aspirin 81 mg Drug Facts

Active ingredient (in each tablet)

Aspirin 81 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

temporarily relieves 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 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 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:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
 - ringing in the ears or loss of hearing occurs
 - pain gets worse or lasts more than 10 days
 - fever gets worse or lasts more than 3 days
 - new symptoms occur
 - redness or swelling is present

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 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 while symptoms persist.

Do not exceed 48 tablets in 24 hours or as directed by a doctor.

- children under 12 do not use unless directed by a doctor

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

corn starch, dextrose excipient, FD&C yellow #6 aluminum lake, flavors, saccharin sodium

Questions or comments?

1-888-423-0139

Principal Display Panel

ADULT LOW STRENGTH – ASPIRIN REGIMEN

Chewable - Orange Flavor

Aspirin 81 mg

Pain Reliever (NSAID)

actual size

COMPARE TO ST. JOSEPH® CHEWABLE ASPIRIN 81 mg active ingredient

TopCare®

NDC 36800-259-68

ADULT LOW STRENGTH • ASPIRIN REGIMEN**

Chewable • Orange Flavor

Aspirin 81 mg

• Pain Reliever (NSAID)

COMPARE TO ST. JOSEPH® CHEWABLE ASPIRIN 81 mg active ingredient†

36 TABLETS

QUALITY GUARANTEED

GLUTEN FREE

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

LOT NO. EXP. 259568 88 CH

0 36800 13584 0

Drug Facts (continued)

Questions or comments?
1-888-423-0139

RETAIN CARTON FOR COMPLETE INFORMATION

**Talk to your doctor before starting an aspirin regimen. Aspirin is not right for everyone.

†This product is not manufactured or distributed by St. Joseph's Health Products, LLC, distributor of St. Joseph® Chewable Aspirin 81 mg.

DISTRIBUTED BY TOPCO ASSOCIATES LLC
7711 GROSS POINT ROAD, SKOKIE, IL 60077
©TOPCO PER112 topcare@topco.com

QUALITY GUARANTEED

Drug Facts (continued)

- new symptoms occur
- ringing in the ears or loss of hearing occurs
- redness or swelling is present

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 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 while symptoms persist. Do not exceed 48 tablets in 24 hours or as directed by a doctor.
- **children under 12** do not use unless directed by a doctor

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients corn starch, dextrose excipient, FD&C yellow #6 aluminum lake, flavors, saccharin sodium



Drug Facts

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

Uses temporarily relieves 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:
 ■ have had stomach ulcers or bleeding problems ■ are age 60 or older
 ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ▶

Drug Facts (continued)

- take a blood thinning (anticoagulant) or steroid drug
- 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 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 asthma
 ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
 ■ 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:
 ■ feel faint ■ vomit blood
 ■ have stomach pain that does not get better ■ have bloody or black stools
 ■ pain gets worse or lasts more than 10 days
 ■ fever gets worse or lasts more than 3 days ▶





TOPCARE ASPIRIN

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:36800-259
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (ASPIRIN)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM	
STARCH, CORN	

Product Characteristics

Color	ORANGE (Light Orange)	Score	no score
Shape	ROUND	Size	8mm
Flavor	ORANGE	Imprint Code	L467
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-259-68	1 in 1 CARTON		
1		36 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/28/2006	

Labeler - Topco Associates LLC (006935977)

