

TOPCARE EFFERVESCENT ANTACID AND PAIN RELIEF- aspirin, citric acid, sodium bicarbonate tablet, effervescent

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.

Top Care Effervescent Antacid & Pain Relief

Active ingredients

Aspirin 325 mg (NSAID)*

Citric acid 1000 mg

Sodium bicarbonate (heat-treated) 1916 mg

*Nonsteroidal anti-inflammatory drug

Purpose

Aspirin 325 mg (NSAID)*.....Pain reliever

Citric acid 1000 mg Antacid

Sodium bicarbonate (heat-treated) 1916 mg Antacid

*Nonsteroidal anti-inflammatory drug

Uses for the temporary relief of

- heartburn, acid indigestion and sour stomach when accompanied by headache or body aches and pains
- upset stomach with headache from overindulgence in food or drink
- pain alone (headaches or body 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 a nonsteroidal anti-inflammatory drug (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

■ if you are allergic to aspirin ■ if overly full from food or drink. ■ ask a doctor if severe stomach pain occurs after taking this product.

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 a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

■ presently taking a prescription drug. Antacids may interact with certain prescription drugs.
■ taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis

When using this product

■ do not take more than 8 tablets (adults) or 4 tablets (60 years and over) in a 24-hour period or use the maximum dosage for more than 10 days

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. Seek medical help right away.
■ pain lasts for more than 10 days or gets worse ■ new symptoms occur
■ redness or swelling is present ■ ringing in the ears or a loss of hearing occurs

If pregnant or breastfeeding,

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.

Keep out of reach of children.

In case of overdose,

get medical help or contact a Poison Control Center right away.

Directions

■ Do not exceed recommended dosage ■ To avoid serious injury, completely dissolve tablets in 4oz. of water before taking.
■ adults and children 12 years and over (up to 60 years of age): 2 tablets every 4 hours - do not exceed 8 tablets in 24 hrs
■ 60 years and over: 2 tablets every 4 hours - do not exceed 4 tablets in 24 hrs

Take this product any time - morning, noon or night - when you need relief from heartburn, acid

indigestion, sour stomach with headache or body aches and pains.

Place two (2) tablets in 4 oz. of water. Dissolve tablets completely. You do not have to drink any of the residue that may be on the bottom of the glass. The medicines are in the water.

Other information

- each tablet contains: sodium 524 mg
- store at room temperature (59°-86°F)

Inactive ingredients

- none

Questions or comments?

1-888-423-0139

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

36 EFFERVESCENT TABLETS
ORIGINAL FLAVOR

TopCare health™

Effervescent Antacid & Pain Relief

ASPIRIN (NSAID) / PAIN RELIEVER
CITRIC ACID/ANTACID
SODIUM BICARBONATE/ANTACID

FAST RELIEF OF:

- Acid Indigestion
- Upset Stomach
- Heartburn with Headache
- Body Aches & Pains

36 EFFERVESCENT TABLETS ORIGINAL FLAVOR

Drug Facts (continued)

- 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 a sodium-restricted diet

Ask a doctor or pharmacist before use if you are ■ presently taking a prescription drug. Antacids may interact with certain prescription drugs. ■ taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis

When using this product do not take more than 8 tablets (adults) or 4 tablets (60 years and over) in a 24-hour period or use the maximum dosage for more than 10 days

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. Seek medical help right away.
- pain lasts for more than 10 days or gets worse
- new symptoms occur
- redness or swelling is present
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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

- do not exceed recommended dosage
- to avoid serious injury, completely dissolve tablets in 4 oz. of water before taking

adults and children 2 tablets every 4 hours do not exceed 8 tablets in 24 hours
12 years and over (up to 60 years of age)
60 years and over 2 tablets every 4 hours do not exceed 4 tablets in 24 hours

Other information

- each tablet contains: sodium 524 mg
- store at room temperature (59°-86°F)

Inactive ingredients

- none

Questions or comments? 1-888-423-0139

Take this product any time – morning, noon or night – when you need relief from heartburn, acid indigestion, sour stomach with headache or body aches and pains.

MORNINGS

NOONTIME

EVENINGS

Place two (2) tablets in 4 oz of water. Dissolve tablets completely.

You do not have to drink any of the residue that may be on the bottom of the glass. The medicines are in the water.

TopCare health™ NDC 36800-421-68

COMPARE TO ALKA-SELTZER®**
ACTIVE INGREDIENTS*

Drug Facts

Active ingredients (in each effervescent tablet)

Active ingredients	Purpose
Aspirin 325 mg (NSAID)*	Pain reliever
Citric acid 1000 mg	Antacid
Sodium bicarbonate (heat-treated) 515 mg	Antacid
*Nonsteroidal anti-inflammatory drug	

Uses for the temporary relief of

- heartburn, acid indigestion and sour stomach when accompanied by headache or body aches and pains
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- hives ■ facial swelling ■ asthma (wheezing) ■ shock

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Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer ■ if you are allergic to aspirin ■ if overly full from food or drink. Ask a doctor if severe stomach pain occurs after taking this product.

Ask a doctor before use if ■ stomach bleeding warning applies to you

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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com

Manufactured in the U.S.A. with domestic and imported ingredients

QUALITY GUARANTEED

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

*This product is not manufactured, distributed or licensed by Bayer, the maker of Alka-Seltzer®

PN: 42168 TC C1 R: 09/17

42168 TC C1

TOPCARE EFFERVESCENT ANTACID AND PAIN RELIEF

aspirin, citric acid, sodium bicarbonate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-421
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
SODIUM BICARBONATE (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1ZRA3Q20)	SODIUM BICARBONATE	1916 mg
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	1000 mg

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	25mm
Flavor		Imprint Code	L421
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-421-68	36 in 1 CARTON	08/11/2014	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part343	08/11/2014	

Labeler - Topco Associates LLC (006935977)

Revised: 1/2019

Topco Associates LLC