

TOPCARE PAIN RELIEVER SIMPLE RELIEF- caffeine, choline salicylate solution
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.

TOPCARE PAIN RELIEVER SIMPLE RELIEF

TopCare Pain Reliever Simple Relief™
(choline salicylate & caffeine), solution

Topco Associates LLC

--

Topco Associates LLC. Pain Reliever Drug Facts
Drug Facts

Active Ingredients per 30mL

Caffeine 65 mg

Choline Salicylate (NSAID)* 870 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever Aid

Pain Reliever / Fever Reducer (NSAID)

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - minor arthritis pain
 - muscle aches
 - menstrual cramps
 - backache
- temporarily reduces fever

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

Salicylates (NSAIDs) may cause a severe allergic reaction which may include:

- hives
- skin reddening

- rash
- 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 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 ever had an allergic reaction to salicylates (including aspirin) or any other pain reliever/fever reducer.

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have a history of stomach problems such as heartburn, upset stomach, stomach pain, or ulcers
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if

- under a doctor's care for any serious condition
- taking a prescription drug for anticoagulation (thinning of the blood), diabetes, gout, or arthritis.

When using this product

- limit the use of caffeine containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heartbeat
- the recommended dose of this product contains about as much caffeine as a cup of coffee

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 7 days
- fever gets worse or lasts more than 3 days
- ringing in the ears or loss of hearing occurs
- redness or swelling is present
- new symptoms occur
- symptoms do not improve
- ringing in the ears or loss of hearing occurs

If pregnant or breast-feeding, □

ask a health professional before use. It is especially important not to use salicylates (NSAIDs) 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

- adults and children 12 years of age and over: take 30 mL every 6 hours, while symptoms persist
- do not exceed 4 doses in 24 hours unless directed by a doctor
- children under 12 years of age: ask a doctor
- use enclosed dose cup

Other Information

- each 30mL contains: **Sodium 19 mg**
- tamper evident: Do not use if foil seal under cap is broken or missing.
- read all product information before using
- store at 68° to 86°F (20° to 30°C)
- avoid excessive heat and humidity

Inactive Ingredients

citric acid anhydrous, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol

Questions or comments?

Call 1-888-423-0139

PRINCIPAL DISPLAY PANEL

NDC 36800-518-34

Pain

Simple Relief

8 OZ FL (237mL)

NDC 36800-518-34

TopCare®

Pain Simple Relief™

- Pain Reliever/Fever Reducer (NSAID)
Choline Salicylate 870mg
- Pain Reliever Aid
Caffeine 65mg

Relieves:

- Headache
- Backache
- Muscle Ache
- Minor Arthritis Pain
- Menstrual Cramps

Dye Free • Sugar Free • Alcohol Free
Gluten Free • Flavor Free • Acetaminophen Free



8 FL OZ (237mL)

Tamper evident: do not use if
foil seal under cap is broken or
missing

Dose every 6 hours.

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
© TOPCO GMR416
QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



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



<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> feel faint * vomit blood * have bloody or black stools * have stomach pain that does not get better * symptoms do not improve * pain gets worse or lasts more than 10 days * ringing in the ears or loss of hearing occurs * redness or swelling is present * any new symptoms appear * fever gets worse or lasts more than 3 days <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use salicylates (NSAIDs) 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.</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 12 years of age and over: take 30 mL every 6 hours, while symptoms persist. ▶ 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> do not exceed 4 doses in 24 hours unless directed by a doctor. children under 12 years of age: ask a doctor. * use enclosed dose cup. <p>Other information</p> <ul style="list-style-type: none"> each 30mL contains: Sodium 19mg read all product information before using store at room temperature 68-86°F (20-30°C) avoid excessive heat and humidity tamper evident: do not use if foil seal under cap is broken or missing. <p>Inactive ingredients</p> <p>anhydrous citric acid, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol</p> <p>Questions or comments? Call 1-888-423-0139</p> <p>R062816M KEEP LEAFLET AFTER OPENING</p>	<p>LIFT HERE FOR DRUG FACTS</p> <p>Tamper evident: do not use if foil seal under cap is broken or missing</p> <p>Dose every 6 hours.</p> <p>DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 © TOPCO GMR416 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com</p>  <p>This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.</p> 	<p>Drug Facts</p> <p>Active ingredients Purpose (in each 30 mL)</p> <p>Caffeine 65 mg.....Pain reliever aid Choline Salicylate (NSAID)* 870 mg *nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <p>Temporarily relieves minor aches and pains due to:</p> <ul style="list-style-type: none"> headache * minor arthritis pain muscular aches * menstrual cramps backache * temporarily reduces fever <p>Warnings</p> <p>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: Salicylates (NSAIDs) may cause a severe allergic reaction which may include:</p> <ul style="list-style-type: none"> hives * skin reddening * rash facial swelling * shock asthma (wheezing) 	<p>Drug Facts (continued)</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> 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 non-prescription 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 <p>Do not use if you have ever had an allergic reaction to salicylates (including aspirin) or any other pain reliever/fever reducer.</p> <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> stomach bleeding warning applies to you you have high blood pressure, heart disease, liver cirrhosis, or kidney disease you are taking a diuretic 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> you have a history of stomach problems such as heartburn, upset stomach, stomach pain, or ulcers * you have asthma <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> under a doctor's care for any serious condition taking a prescription drug for diabetes, gout, or arthritis <p>When using this product</p> <ul style="list-style-type: none"> limit the use of caffeine-containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat the recommended dose of this product contains about as much caffeine as a cup of coffee take with food or milk if stomach upset occurs <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding:
---	--	---	--	---	--

TOPCARE PAIN RELIEVER SIMPLE RELIEF

caffeine, choline salicylate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-518
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg in 30 mL
CHOLINE SALICYLATE (UNII: KD510K1IQW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K0OR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-518-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	09/06/2016	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 6/2016

TOPCO ASSOCIATES LLC