# EFFERVESCENT COLD RELIEF- aspirin, chlorpheniramine maleate, phylephrine bitartrate 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.

-----

#### **TopCare Effervescent Cold Relief**

#### **Active ingredients**

#### **Active ingredients**

(in each effervescent tablet) . . . . . . . . . . Purpose

Chlorpheniramine maleate 2 mg . . . . . . . . . Antihistamine

Phenylephrine Bitartrate 7.8 mg . . . . . . . . . . Nasal decongestant

#### **Purpose**

(in each effervescent tablet)	Purpose
-------------------------------	---------

Chlorpheniramine maleate 2 mg . . . . . . . . . Antihistamine

Phenylephrine Bitartrate 7.8 mg . . . . . . . . . . Nasal decongestant

#### Uses

- temporarily relieves these symptoms due to the common cold
- sneezing nasal congestion sore throat
- headache minor aches and pains runny nose
- sinus congestion and pressure
- 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.

<sup>\*</sup>Nonsteroidal anti-inflammatory drug

<sup>\*</sup>Nonsteroidal anti-inflammatory drug

**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 **t**ake more or for a longer time than directed

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do Not Use

**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 you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product. ■ if you have ever had an allergic reaction to this product or any of its ingredients.

#### Ask a doctor before use if

**Ask a doctor before use if** ■ stomach bleeding warning applies to you ■ you have a history of stomach problems such as heartburn vou have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic

#### Ask a doctor before use if you have

Ask a doctor before use if you have ■ asthma ■ glaucoma ■ diabetes ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis 

been placed on a sodium-restricted diet

# Ask a doctor or pharmacist before use if you are

Ask a doctor or pharmacist before use if you are 

you are taking sedatives or tranquilizers presently taking a prescription drug

■ taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis

# When using this product

When using this product **■** do not exceed recommended dosage

- you may get drowsy
- avoid alcoholic drinks
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

#### Stop use and ask a doctor if

**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 or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- ringing in the ears or a loss of hearing occurs
- nervousness, dizziness or sleeplessness occurs

# If pregnant or breast-feeding

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.

Keep out of reach of children.

#### In case of overdose

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- do not use more than directed (see overdose warning)
- adults and children 12 years and over: take 2 tablets completely dissolved in 4 oz of water every 4 hours
- do not take more than 8 tablets in 24 hours

■ children under 12 years: ask a doctor

#### Other information

each tablet contains: sodium 464 mg

- phenylketonurics: contains phenylalanine 9 mg per tablet
- store at room temperature (59°-86°F)

### **Inactive ingredients**

acesulfame potassium, aspartame, citric acid, docusate sodium, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

Questions or Comments?

Call 1-888-423-0139

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Stop use and ask a doctor if III you experience any of the following signs of Septimistry may occur, especially in children
 Individual septimistry may increase drowsiness and tranquilizers may increase drowsiness be careful when driving a motor vehicle or operating machinery.

When using this product **m** do not exceed recommended dosage **m** you may get drowsy **m** svoid alcoholic drinks

Ask a doctor petore use if you have a sahma a glacoma a diabetes

\*\*Ex a doctor betore use if you have a sahma a glacoma a betore

\*\*Inyfold disease a Troub e unifaing due to an enlarged prostate gland

\*\*Ex breathing problem such as employeren or chronic brombilla B a been

placed on a sodium-restricted diet?

\*\*Ext a doctor or pharmacist before use if you are a labing sederives or

\*\*Exercity and a such a such

orinetty and volorine many of the control prompts of the control pro

ousnit a doctor promptly. Sore throat warming: It sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, sonsult a doctor promptly. or a longer time than directed

Drug Facts (continued)

Warnings

Neye's syndrome: Children and leenagers who have or are levevering from children pox or flu-like symptoms should force the children pox or flu-like symptoms should here of the children pox or flu-like symptoms or flowers and present a floorest consult a doctor with neuses and vomiting occur, consult a doctor because a lever set and tender of the symptoms of the symptom

■ sneezing ■ nasal congestion ■ sore throat
■ headache ■ minor aches and pains ■ runny nose
■ sinus congestion and pressure
■ temporarily reduces fever e temporarily relieves these symptoms due to the

รอรก

esequuq (tablesi trables) (1) masseribite dasse ii) masseribite seribite (masseribite) (1) masseribite seribite (masseribite) (1) masseribite seribite (1) masseribite seribite (1) masseribite seribite (1) masseribite seribite (1) masseribite (1) masserib

Active ingredients

Drug Facts



# **Effervescent Cold Relief**

ASPIRIN (NSAID)/PAIN RELIEVER-FEVER REDUCER • CHLORPHENIRAMINE MALEATE/ANTIHISTAMINE PHENYLEPHRINE BITARTRATE/NASAL DECONGESTANT



**20** EFFERVESCENT TABLETS

ORIGINAL FLAVOR

NDC 36800-768-20



+TopCare.

**Effervescent Cold Relief** 

ASPIRIN (NSAID)/PAIN RELIEVER-FEVER REDUCER CHLORPHENIRAMINE MALEATE/ANTIHISTAMINE PHENYLEPHRINE BITARTRATE/NASAL DECONGESTANT

#### **FAST RELIEF OF:**

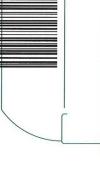
- Nasal Congestion
- Runny Nose
- **Body Aches**
- Sore Throat

# · Headache &

Sinus Pressure

20 EFFERVESCENT TABLETS

0 0



#### Drug Facts (continued)

Other information each tablet contains; sodium 464 mg
phenylketonurics; contains
phenylalanine 9 mg per tablet
store at room temperature
(59°-86°F)

Inactive ingredients acesulfame potassium, aspartame, citric acid, docusate sodium, flavors, mannitol, povidone, sodium benzoate

odium bicarbonate CQuestions or comments? Call 1-888-423-0139

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

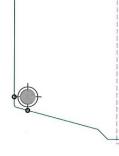
DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 © TOPCO TOWA0621 QUESTIONS? 1-888-423-0139 co.com www.topcan Visit here for more information:

http://topbrnds.com/48zzqf



DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED

PN: 87360 TC C3 REV: 05/21



Drug Facts (continued)

an allergic reaction occurs. Seek medical help right away a pain or nasal congestion gets worse or lasts more than 7 days a fever gets worse or lasts more than 3 days a new symptoms occur are redness or swelling is present a ringing in the ears or a loss of hearing occurs an environment.

utziniess ut steephesiess uccurs
if pregnant or breast-feeding, ask
a health professional before use. It
is especially important not to us
aspirin during the last 3 months
of pregnancy unless definitely
directed to do so by a doctor
because it may oause 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

do not use more than directed (see overdose warning)
 adults and children 12 years and

over: take 2 tablets completely dissolved in 4 oz of water every

4 hours
do not take more than 8 tablets in 24 hours
children under 12 years: ask a doctor

Directions

aspirin, chlorpheniramine maleate, phylephrine bitartrate tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-768
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
PHENYLEPHRINE BITARTRATE (UNII: 2703Q5ML57) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg	

Inactive Ingredients				
Ingredient Name	Strength			
MANNITOL (UNII: 30WL53L36A)				
POVIDONE K30 (UNII: U725QWY32X)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM BICARBONATE (UNII: 8MDF5V39QO)				
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)				
ASPARTAME (UNII: Z0H242BBR1)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
DOCUSATE SODIUM (UNII: F05Q2T2JA0)				

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

F	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:36800-768- 20	10 in 1 CARTON	07/01/2010			
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	part341	07/01/2010	

# Labeler - Topco Associates LLC (006935977)

Revised: 11/2021 Topco Associates LLC