WINCO FOODS EFFERVESCENT COLD RELIEF- aspirin, chlorpheniramine maleate, and phenylephrine bitartrate tablet, effervescent WinCo Foods, 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.

Effervescent Cold Relief Tablets

Active ingredients

Aspirin 325 mg (NSAID)*
Chlorpheniramine maleate 2 mg
Phenylephrine Bitartrate 7.8 mg

*Nonsteroidal anti-inflammatory drug

Purpose

Uses

temporarily relieves these symptoms of the common cold:

- fever sneezing nasal congestion sore throat headache
- minor aches and pains runny nose
- sinus congestion and pressure

Uses

temporarily relieves these symptoms of the common cold

- fever sneezing nasal congestion sore throat headache
- minor aches and pains runny nose
- sinus congestion and pressure

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

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

- 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.

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 are taking sedatives or tranquilizers.

You have ■ 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

 \blacksquare presently taking a prescription drug \blacksquare 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 and children 12 years and over) in a 24-hour period or as directed by doctor.

- do not use more than directed 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

- 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,

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 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 4-6 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 to report an adverse event call 800-824-1706 Monday - Friday 9am - 4pm MST

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

00

00

Stop use and ask a doctor if \blacksquare you experience any of the following signs of stomach bleeding \blacksquare feel faint \blacksquare you experience \blacksquare have bloody or black stools a alcohol, sedatives and tranquilizers may increase drowsiness be careful when driving a motor vehicle or operating machinery When using this product do not take more than 8 tablets (abults and children T2 years and over) an act A-not one than diversed by doctor.

I not use more than directed II you may get drowsy and continue than directed III you may get drowsy and value of the continue III and the product of the continue III and the product of the continue III and the product of the continue III and the c

fisk a doctor or pharmacist before use if you are ■ presently taking a prescription drug for anticoagulation (thinning mischood), diabetes, gout or arthritis

Animy American Strong May No. 1994. See a see a

r emotional conditions, or Parkinson's disease), or for 2 weeks after stopp Do not use

you have ever had an allergic reaction to any other pain reliever/fever
reducer ≡ if you are allergic to aspirim ≡ if you are now taking a prescription
reducer ≡ if you are allergic to aspirim ≡ if you are now taking a prescription
reducer ≡ if you are allergic to include the prescription of the prescription o

ousnit a doctor prompuy.

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,

Drug Facts (continued)

DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED

drug = take other drugs containing prescription or non-prescription NSAIDs (asplini, ibuprofen, naproxen, or othe = nave 3 or more alcoholic drinks every day while using t product = take more or for a longer time than directed Alfidergy alert Aceptin mass severe allergic reaction which may include: a hives a facial swelling.
Stomach heeding warning: This product contains a severe allergia should a floods.
Stomach bleeding warning: This product contains a nonsevere schomach bleeding. The chance is higher if you a servere schomach bleeding. The chance is higher if you a set severe schomach bleeding. The chance is higher if you a set severe schomach bleeding. The chance is higher if you a set severe schomach heeding was a severe schomach bleeding in the severe in the severe is a severe scholar or severe in the severe is a severe school and the severe in the severe is a severe school and the severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe is a severe school and severe in the severe school and severe is a severe school and severe in the severe is a severe school and severe in the severe in the severe is a severe school and severe in the severe in the severe is a severe school and severe in the severe in th

Page 4, syndrome: Children and teenagers who have or are ecovering from chicken be or of the like syndromes bound to tee this product. When using this product, it changes in sharkor with neases and vomiting occur, consult a doctor secesses these syndromes could be and shy give the syndrome, a rise but selvor lineses. Mamings

temporarily relieves these symptoms of the common cold:

Tever III sneezing III nasal congestion III sone throat

III slinus congestion and pressure

III slinus congestion and pressure รอรก

nis9.....*(diazM) gm 3SE nhiqes gm S etselsm enimeninenpolriO gm 8.7 etsethetid enhiqelynerf gm 9.7 etsethetid enhiqelynerge uga 6.7 etsethetid enhiqelynergenov nimstaintinA. Pain reliever/fever reducer esodin_q (in each effervescent tablet) Active ingredients

Drug Facts

WinCo

EFFERVESCENT Cold Relief

ASPIRIN (NSAID)/PAIN RELIEVER-FEVER REDUCER CHLORPHENIRAMINE MALEATE/ANTIHISTAMINE

Original

20 Effervescent





Drug Facts (continued)

■ 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

I regenant or preast-feeding sek a

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

to do so by a ductum accessor chair cause problems in the unborn child or compil-cations during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

- do not use more than directed (see
- on ord 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 4-6 hours
 do not take more than 8 tablets
 in 34 hours
- in 24 hours

 in children under 12 years: ask a doctor

**Compare to active ingredients in ALKA-SELTZER PLUS® COLD



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

Fast Relief of: Headaches, Sneezing, Nasal Congestion Runny Nose, Sinus Pain & Pressure



Original



Drug Facts (continued)

Other information

sodium 464 mg
phenylketonurics; contains
phenylalanine 9 mg per tablet
store at room temperature

Or to report an adverse event call 800-824-1706 Monday - Friday 9am - 4pm MST

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

*This product is not manufactured or distributed by BAYER GROUP, distributor of ALKA-SELTZER PLUS® COLD.

100% SATISFACTION GUARANTEE



PN: 87360 WN C1 REV: 06/14





WINCO FOODS EFFERVESCENT COLD RELIEF

aspirin, chlorpheniramine maleate, and phenylephrine bitartrate tablet, effervescent

Product Information	duct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-109	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLORPHENIRAMINE - UNII: 3U6I01965U)	CHLORPHENIRAMINE MALEATE	2 mg	
PHENYLEPHRINE BITARTRATE (UNII: 2703Q5ML57) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg	

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
ASPARTAME (UNII: Z0H242BBR1)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
DOCUSATE SODIUM (UNII: F05Q2T2JA0)		
MANNITOL (UNII: 30WL53L36A)		
POVIDONE K30 (UNII: U725QWY32X)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:67091-109- 20	10 in 1 CARTON	07/02/2014		
1		2 in 1 POUCH; Type 0: Not a Combination Product			

Marketing Information				
	Marketing	Application Number or Monograph	Marketing Start	Marketing End
	Category	Citation	Date	Date

OTC monograph final part341 07/02/2014

Labeler - WinCo Foods, LLC (056098817)

Revised: 5/2021 WinCo Foods, LLC