# EFFERVESCENT ORANGE COLD RELIEF- aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent H. E. Butt Grocery Company

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.

-----

#### **HEB Effervescent Cold Relief**

# **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

# 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 non-steroidal 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 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

**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

**Ask a doctor before us if 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

 $\blacksquare$  taking sedatives or tranquilizers  $\blacksquare$  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 a 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 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 use more than directed (see overdose warning)
- adults and children 12 years and over: take 2 tablets completely dissolved in 4 ounces 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, FD&C red #40, FD&C yellow #6, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

Questions or comments?

Call (1-888-228-6937)

Package Label.Principle Display Panel

Sup use and ask a doctor if **m** you experience any of the following signs of shores head to be advantage of the section occurs.

Acks doctor not plannes at help ne use if you are ill aking sedefives or Acks doctor or plannes at help as press plan dug ill being a press plan the dug for a money and a fine bood, debedes, gouth or affirities who may go doctor. Ill also be of the dug for a sed teched by a doctor, a you may got doctor. It is a constant to the dug for a sed teched by a doctor, who may got doctor. It is a sed teched by a doctor. It is a constant to the dug for the dug fo

Saks a dector hetore use if you have  $\blacksquare$  glaucome  $\blacksquare$  detoeles  $\blacksquare$  thrould use the color by the discostance of discostance is a breaching the color by the discostance of discostance of the discostance of discostance

wy dreilgge grinew igheald hamde ≡ These solder hobols stabl rightesen low ≡ mudhealdes has anel dong deendat by vidalde seat low ≡ ens low ≡ seaseb yenthár or abonte seal, seaseb hreaf jascean blood hindif ≡ sealaráta ≡ mercellom seala nor til sea en anadararana. Eleba

Do not use # fivo have ever had an allegib reachon hoany other pain Do not use # fivo have ever had an allegib reachon being when the less when a fivo use now being need promotione control mentions in the fivo house to the season, or no depression, paycharts or enrollment and more or a season and 2 weeks after stopping the MAD liding. If you do not have it should be promoted the stopping the season of presenting the product 2 weeks after stopping and a season of the product 2 weeks after a first paych and a season of the product 2 weeks after a first paych and a season of the product 2 weeks and a first paych and a season of the product 2 weeks and a first paych and a season of the product 2 weeks and a first paych and a season of the product 2 weeks and a first paych and a season of the product 2 weeks and a first paych and a season of the product 2 weeks a first paych and a season of the product 2 weeks a first paych and a season of the product 3 weeks a first paych and a season of the paych and a season of the paych 3 weeks a first paych and a season of the paych 3 weeks a first paych and a season of the paych 3 weeks a first paych and a season of the paych 4 weeks a first paych and a season of the paych 4 weeks a first paych and a season of the paych 5 weeks a first paych and a season of the paych 5 weeks a first paych 5 weeks a

a, sysb S narff even not ables, parave at some site on an enter and services, parameter or uniformed or working, a commence or white most promote a beautile to be allowed by the working or the commence of t

panultuoo) story four

besvors with nasses and worming occur, consults decided between with nasses and worming occur, consults a second between several managements as the best as the second several links.

If several management is a second several links as several sement in the several several management in the several sements where the several sements where the several sements where the several sements in the several several management in the several several management in the several several management in the several s

Reys's syn in me. Children and teanagers who have or are recover mit from failer prox out will the symp but the should not use the product. When tening his product, if changes in behavior with nauses and voriming occur, consults aboth *<u>вбидшем</u>* 

e motors like lieves these symptoms of the common cold:

■ lever me sees that a messal consection ≡ sore throat

■ lever me are the messal consection ≡ sore throat

■ lever messal and bressal is

■ sore throat

■ so

Burb yotammelini - Bris lebioratanovi eouber revel/everler nish ... erim skirithnik... (seech effervescent tablet) Purpose

Active ingredients гроеу блид



# **Effervescent** Cold Pus

Chlorpheniramine Maleate / Antihistamine Phenylephrine Bitartrate / Nasal Decongestant Aspirin (NSAID) / Pain Reliever/Fever Reducer

Cold

Drug Facts (continued)

Seek medical help right away.

pain or nasal congestion gets
worse or lasts more than 7 days. worse of lasts more than 7 days.

• tever gets worse or lasts more

• han 3 days. • new symptoms

occur • redness or swelling is

present • ringing in the ears or a

loss of hearing occurs ■ nervousness, dizziness or

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 compli-

cations during delivery. Keep out of reach of children. In case of

overdose, get medical help or contact a Poison Control Center

Directions

do not use more han directed (see over dose verning)
adults and children 12 years and over take 2 tablets completely desolved in 40 zof whate every 4.6 hours
do not have more than 8 tablets in 24 hours
children ander 12 years task a obder

right away.

sleeplessness occurs

#### 20 EFFERMESCENT TABLETS

Compare to Alka-Seltzer Plus® Cold Orange Zest active ingredients\*



# **Effervescent**

Chlorpheniramine Maleate / Antihistamine Phenylephrine Bitartrate / Nasal Decongestant Aspirin (NSAID) / Pain Reliever/Fever Reducer

#### Cold

#### Relief of:

- Minor Aches and Pains
- Headache
- · Runny Nose
- Nasal Congestion
- · Sore Throat
- Orange Flavor

#### 20 EFFERVESCENT TABLETS

#### Drug Facts (continued)

Other information

- each tablet contains:
  sodium 464 mg
  phenyketonurics:contains
  phenylalanine 9 mg per tablet
  store at room temperature
- (59°-86°F)

inactive ingredients acesultare potassim, aspartare, other acid, docusate sodium, FUSC, rearnibl, Dovidone, sodium benaste, sodium benaste, sodium benaste, sodium bicarbonate

Questions or comments: Call H-888-228-8937t

DO NOT USE IF PRINTED PACKETS ARE TORNOR PUNCTURED







PN: 87560 HE C2 REV: 09/17







# **EFFERVESCENT ORANGE COLD RELIEF**

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-768	

**Route of Administration** ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
PHENYLEPHRINE BITARTRATE (UNII: 2703Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	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	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
ASPARTAME (UNII: Z0H242BBR1)		
DOCUSATE SODIUM (UNII: F05Q2T2JA0)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
MANNITOL (UNII: 3OWL53L36A)		
POVIDONE K30 (UNII: U725QWY32X)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM BICARBONATE (UNII: 8MDF5V39QO)		

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-768- 20	10 in 1 CARTON	01/30/2018	
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	01/30/2018	

Labeler - H. E. Butt Grocery Company (007924756)

Revised: 4/2021 H. E. Butt Grocery Company