

FAMILY WELLNESS EFFERVESCENT COLD RELIEF ORANGE- aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent Family Dollar Services, Inc.

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.

Family Wellness Effervescent Cold Relief Tablets Orange Flavor 20 Ct.

Active ingredients

(in each effervescent tablet)

Aspirin 325 mg **(NSAID)***

Chlorpheniramine maleate 2 mg

Phenylephrine bitartrate 7.8 mg

*Nonsteroidal anti-inflammatory drug

Purpose

Aspirin 325 mg **(NSAID)***.Pain reliever/fever reducer

Chlorpheniramine maleate 2 mgAntihistamine

Phenylephrine bitartrate 7.8 mgNasal decongestant

*Nonsteroidal anti-inflammatory drug

Uses

temporarily relieves these symptoms of the common cold:

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

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

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 use if you have

Ask a doctor before use 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

Ask a doctor or pharmacist before use if 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 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

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

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 fully 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 comments?

Call 1-888-228-6937

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



Drug Facts (continued)

more than 2 days, is accompanied 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/reducer
- if you are allergic to aspirin
- if you are now taking a prescription or nonprescription drug for depression, psychiatric or monamine oxidase inhibitor (MAOI) certain drugs for depression, psychiatric or MAOI drug, if you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking the 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 use 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 ■ 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 ■ 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.

Stop use and ask a doctor if ■ you vomit blood ■ have black stools or stomach bleeding ■ feel faint ■ you experience any of the following signs or symptoms

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

■ have stomach pain that does not get better

Drug Facts

Active ingredients (in each effervescent tablet)

Aspirin 25 mg (NSAID)
Chlorpheniramine maleate 2 mg
Phenylephrine bitartrate 7.8 mg
Nonsteroidal anti-inflammatory drug

Purpose

temporarily relieves these symptoms of the common cold:
■ runny nose ■ sneezing ■ sore throat ■ nasal and sinus congestion ■ headache ■ stuffy nose ■

Warnings

Haye'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.

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 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

COMPARE TO ALKA-SELTZER PLUS® COLD ORANGE ZEST™

FAMILY wellness™

COLD RELIEF

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

For Relief of:
Nasal Congestion • Runny Nose
Headache & Body Ache
Sore Throat • Sinus Pressure

ORANGE FLAVOR

20 EFFERVESCENT TABLETS

COMPARE TO ALKA-SELTZER PLUS® COLD ORANGE ZEST™

FAMILY wellness™

NDC 55319-675-20

COLD RELIEF

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

For Relief of:
Nasal Congestion
Runny Nose • Headache &
Body Ache • Sore Throat
Sinus Pressure

ORANGE FLAVOR

20 EFFERVESCENT TABLETS

OTC network

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, FD&C red #40, FD&C Yellow #6, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

Questions or comments?
Call 1-888-228-6937

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500 VOLVO PARKWAY, CHESAPEAKE, VA 23020 USA

MANUFACTURED IN THE USA WITH DOMESTIC AND IMPORTED INGREDIENTS.

NOT 100% SATISFIED? Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.

*This product is not manufactured or distributed by Bayer, owner of the registered trademark Alka-Seltzer Plus® Cold Orange Zest.

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Drug Facts (continued)

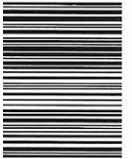
- an allergic reaction occurs. Seek medical help right away. ■ pain or nasal congestion gets worse or lasts more than 7 days. ■ fever gets worse or lasts more than 3 days. ■ new symptoms occur ■ redness or swelling is present ■ ringing in the ears or a loss of hearing occurs ■ nervousness, dizziness 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. 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)
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- children under 12 years: ask a doctor

DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED



FAMILY WELLNESS EFFERVESCENT COLD RELIEF ORANGE

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-875
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POVIDONE K30 (UNII: U725QWY32X)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

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:55319-875-20	10 in 1 CARTON	09/15/2011	
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	09/15/2011	12/31/2023

Labeler - Family Dollar Services, Inc. (024472631)

Revised: 12/2021

Family Dollar Services, Inc.