QUALITY CHOICE EFFERVESCENT COLD RELIEF - ORANGE- aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent
Chain Drug Marketing Association

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.

Quality Choice Effervescent Cold Relief Plus Orange

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 mg.....Antihistamine

Phenylephrine Bitartrate 7.8 mg.....Nasal decongestant

*Nonsteroidal anti-inflammatory drug

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.

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 ■ take more or for 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 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 ■ 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 ■ 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 ■ 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 the 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.

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)

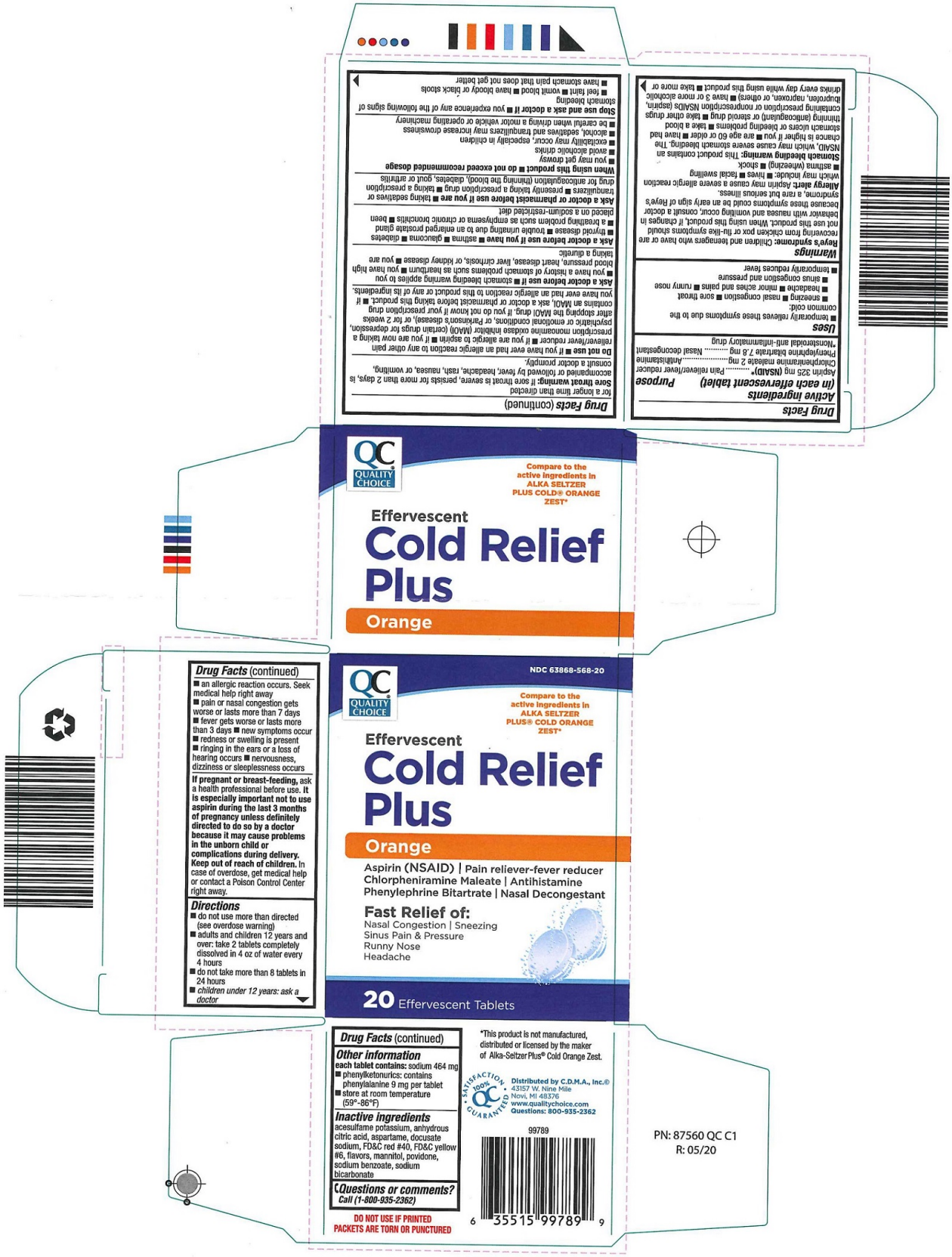
Inactive ingredients

acesulfame potassium, anhydrous citric acid, aspartame, docusate sodium, FD&C red #40, FD&C yellow #6, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

Questions or comments?

Call (1-800-935-2362)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



QUALITY CHOICE EFFERVESCENT COLD RELIEF - ORANGE

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-568
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
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	orange	**Score**	no score
Shape	ROUND	**Size**	25mm
Flavor		**Imprint Code**	CF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-568-20	10 in 1 CARTON	06/15/2020	
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	06/15/2020	

Labeler - Chain Drug Marketing Association (011920774)

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