EFFERVESCENT COLD RELIEF- as pirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, efferves cent Discount Drug Mart

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.

Drug Mart Efferves cent Cold Relief Tablets

Active ingredients

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 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

- 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

- 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 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 fully 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:

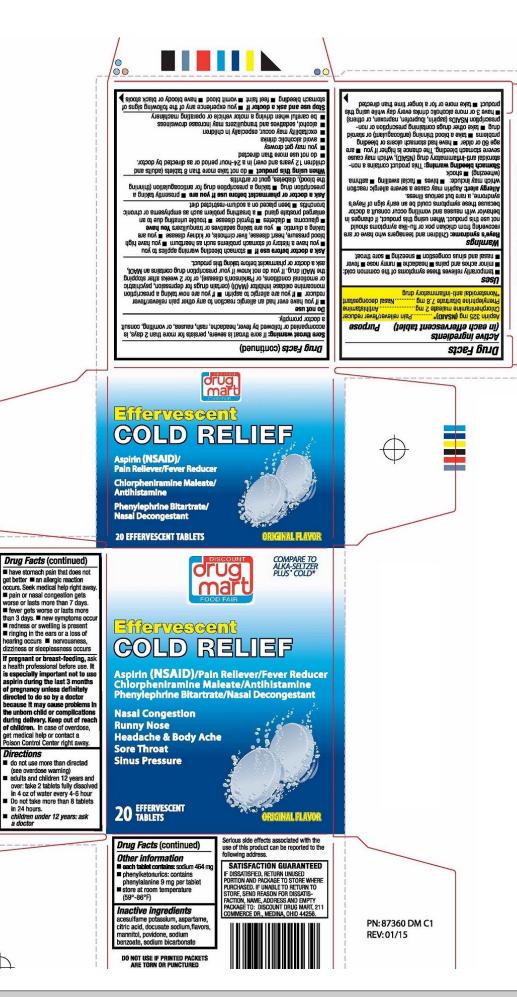
sodium 464 mg

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

Inactive ingredients

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

Package Label.Principle Display Panel



Directions

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-873
Route of Administration	ORAL		

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

Inactive Ingredients		
Ingredient Name	Strength	
SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO)		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
MANNITOL (UNII: 30WL53L36A)		
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)		
PO VIDO NE K30 (UNII: U725QWY32X)		
DOCUSATE SODIUM (UNII: F05Q2T2JA0)		
SO DIUM BENZO ATE (UNII: OJ245FE5EU)		
ASPARTAME (UNII: Z0H242BBR1)		

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

II	Packaging				
II	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:53943-873-20	20 in 1 CARTON	0 1/30/20 15		
	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	01/30/2015	

Revised: 12/2018 Discount Drug Mart