

EFFERVESCENT COLD RELIEF - aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent
Cardinal Health, 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.

Drug Facts

Active Ingredients (in each effervescent tablet)

	<i>Purpose</i>
Aspirin 325 mg NSAID*	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Phenylephrine Bitartrate 7.8 mg	Nasal decongestant

*Nonsteroidal anti-inflammatory drug

Warnings

Reye's syndrome: Children and teenagers should not use this drug for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy alert: Aspirin may cause a server 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.

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

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.

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 - glaucome - diabetes - thyroid disease - trouble urinating due to an enlarged prostate gland - a breathing problem such as emphysema or chronic bronchitis - you are taking a diuretic - 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.

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.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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.

Fast Relief of: Nasal Congestion, Runny Nose, Sneezing, Headache, Sinus Pain 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

Stop use and ask a doctor if - you experience any of the following signs of stomach bleeding - feel faint - vomit blood - have bloody 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 loss of hearing occurs - nervousness, dizziness or sleeplessness occurs.

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

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

Inactive ingredients:

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

Drug Facts (continued)

Aspirin may cause stomach bleeding. 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/reducer • If you are allergic to aspirin • If you are now taking a prescription monooxygenase 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 • 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.

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 or have stomach pain that does not get better • an allergic reaction occurs 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

Drug Facts

Active Ingredients (in each effervescent tablet)

Aspirin 325 mg NSAID • Chlorpheniramine maleate 2 mg • Phenylephrine bitartrate 7.5 mg

Purpose

Temporarily relieves these symptoms of the common cold: • fever • minor aches and pains • headache • runny nose • sneezing • sore throat

Uses

Temporarily relieves these symptoms of the common cold: • fever • minor aches and pains • headache • runny nose • sneezing • sore throat

Warnings

Hayfe's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Hayfe's syndrome, a rare but serious illness reported to be associated with aspirin. **Allergy alert:** Aspirin may cause a severe allergic reaction which may include: • asthma (wheezing) • shock • hives • facial swelling

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

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers.

LEADER®

EFFERVESCENT

Cold Relief Plus

Pain reliever/Fever Reducer
Antihistamine/Nasal Decongestant



Drug Facts (continued)

When using this product • 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

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 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

CODE AREA

No color allowed in this area



NDC 37205-218-60

LEADER®

EFFERVESCENT

Cold Relief Plus

Aspirin/Pain reliever-fever reducer
Chlorpheniramine maleate/Antihistamine
Phenylephrine bitartrate/Nasal Decongestant

Other information that may be placed on carton:
Fast Relief of: Nasal Congestion, Runny Nose, Sneezing, Headache, Sinus Pain & Pressure

20 EFFERVESCENT TABLETS

SATISFACTION GUARANTEED

Compare to Alka-Seltzer Plus® Cold active ingredients*

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, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 3000742
www.myleader.com
1-800-200-6313

All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.



*This product is not manufactured, distributed or licensed by the maker of Alka-Seltzer Plus® Cold Medicine.

DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED

PN: 87360 UE C1
REV: 07/10

EFFERVESCENT COLD RELIEF

aspirin, chlorpheniramine maleate, phenylephrine bitartrate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-218
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: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE BITARTRATE	7.8 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
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	LEMON (N&A Lemon Lime Flavor FAKP193)	Imprint Code	CF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-218-60	20 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2010	

Labeler - Cardinal Health, Inc (097537435)

Registrant - United Exchange Corporation (840130579)

Establishment

Name	Address	ID/FEI	Business Operations
Tower Laboratories Ltd		869024500	manufacture(37205-218)

Revised: 9/2012

Cardinal Health, Inc