

DOLLAR GENERAL EFFERVESCENT COLD RELIEF- aspirin, chlorpheniramine maleate, phylephrine bitartrate tablet, effervescent DOLGENCORP, LLC

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.

Dollar General Effervescent Cold Relief

Active ingredients

Active ingredients

(in each effervescent tablet) 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

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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 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 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 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.

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Drug Facts (continued)

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
- you are taking a diuretic
- you are taking sedatives or tranquilizers
- you have 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 a prescription drug for anticoagulation (thinning the blood), diabetes, gout or arthritis
- 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
- have stomach pain that does not get better
- an allergic reaction occurs.

and tranquilizers may increase drowsiness. Be careful when driving a motor vehicle or operating machinery.

Drug Facts

Active ingredients (in each effervescent tablet)

Purpose

Aspirin 325 mg (NSAID)
 Chlorpheniramine maleate 2 mg
 Phenylephrine bitartrate 7.5 mg
 Nonsteroidal anti-inflammatory drug

Uses

temporarily relieves these symptoms of the common cold:

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

Warnings

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.

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- hives
- facial swelling
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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

DG health

Compare to active ingredients in Alka-Seltzer Plus® Cold*

Effervescent Cold Relief

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

Original Flavor

Relieves:

- Nasal congestion & headache
- Sinus pain & pressure
- Runny nose & sneezing

20 Tablets

DG health

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Drug Facts (continued)

Seek medical help right away.

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- fever gets worse or lasts more than 3 days
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Drug Facts (continued)

Other information

each tablet contains:

- sodium 464 mg
- phenylketonurics: contains phenylalanine 9 mg per tablet
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Inactive Ingredients

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

Serious side effects associated with the use of this product can be reported to the following address or by calling the following telephone number.

100% SATISFACTION GUARANTEED
 (888) 309-9030

DISTRIBUTED BY DOLGENCORP, LLC
 100 MISSION RIDGE
 GOODLETTSVILLE, TN 37072
 MADE IN U.S.A. AO481



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

DO NOT USE IF PRINTED PACKETS ARE TORN OR PUNCTURED

PN:87360 DH C2
 REV: 08/15



DOLLAR GENERAL EFFERVESCENT COLD RELIEF

aspirin, chlorpheniramine maleate, phylephrine bitartrate tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-873
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
MANNITOL (UNII: 3OWL53L36A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-873-20	10 in 1 CARTON	09/14/2015	
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
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Labeler - DOLGENCORP, LLC (068331990)

Revised: 4/2021

DOLGENCORP, LLC