

**PAIN RELIEVER FEVER REDUCER - acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, chlorpheniramine maleate tablet, effervescent Velocity Pharma**

*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.*

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**Acetaminophen, Chlorpheniramine maleate, Dextromethorphan HBr and Phenylephrine HCl**

**Active Ingredient**

**(in each tablet)**

Acetaminophen 250 mg

Chlorpheniramine Maleate 2mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Purpose**

pain reliever/fever reducer

Antihistamine

Cough Suppressant

Nasal decongestant

**Uses**

Temporarily relieves these symptoms due to cold or flu:

- Minor aches and pains
- Headaches
- Cough
- Sore throat
- Runny nose
- Sneezing
- Nasal and sinus congestion
- Temporarily reduces fever

**Warnings**

**Liver Warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 tablets in 24 hours which is maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

**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 to sedate children.**

**do not use:**

- with any other drug containing acetaminophen (prescription or not prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- 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 you have**

- liver disease
- Heart disease
- Thyroid disease
- Diabetes
- High blood pressure
- Glaucoma
- Cough with excessive phlegm (mucus)
- A breathing problem such as emphysema or chronic bronchitis
- Difficulty in urinating due to enlargement of prostate gland
- Persistent or chronic cough such as occurs with smoking, asthma or emphysema
- A sodium restricted diet

#### **ask your doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin.
- taking sedative or tranquilizers

#### **when using this product**

- do not exceed recommended dosage
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedative and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur especially in children

#### **Stop use and ask a doctor if**

- pain, cough or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. **These could be signs of serious condition.**
- Nervousness, dizziness, or sleeplessness occurs
- **If pregnant or breast-feeding, ask a health professional before use**

#### **Keep out of reach of children.**

**Overdose warning: Taking more than recommended dose (overdose) may cause liver damage.** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Direction**

- **do not take more than the recommended dose**
- **Adults and children 12 years and over:** 2 tablets fully dissolved in 4 oz of water every 4 hours, Do not exceed 8 tablets in 24 hours or as directed by a doctor
- **children under 12 years: do not use**

**Other Information**

- phenylketonurics: contains phenylalanine 15 mg per tablet
- store at room temperature , avoid excessive heat.

Total sodium : 415 mg/tablet  
Total potassium: 1mg/tablet

**INACTIVE INGREDIENT**

acesulfame potassium, aspartame, citric acid anhydrous, color ponceau 4r, isopropyl alcohol, mannitol, orange flavor, pvp k-30, Simethicone, sodium benzoate, sodium bicarbonate, sodium saccharin, tween 80.

**QUESTIONS**

**Call toll free 1-855-314-1850**

**Distributed by Velocity Pharma Llc**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

# PAIN RELIEVER FEVER REDUCER

## Drug Facts

Active ingredients (in each tablet)	Purposes
Acetaminophen 250 mg	Pain reliever/fever reducer
Chlorpheniramine maleate 2 mg	Antihistamine
Dextromethorphan hydrobromide 10 mg	Cough suppressant
Phenylephrine hydrochloride 5 mg	Nasal decongestant

**Dosage:** temporarily relieves these symptoms due to a cold or flu:  
 ■ minor aches and pain ■ headache ■ cough ■ sore throat ■ runny nose ■ sneezing ■ nasal and sinus congestion ■ temporarily reduces fever

**Warnings:** **Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 8 tablets in 24 hours, which is the maximum daily amount for this product ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product.

**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 to sedate children.**

**Do not use** ■ with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ 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 have ever had an allergic reaction to this product or any of its ingredients ■ in children under 12 years of age  
**Ask a doctor before use if you have:** ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ glaucoma ■ cough with excessive phlegm (mucus) ■ a breathing problem such as emphysema or chronic bronchitis ■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema ■ a sodium restricted diet

**Ask a doctor or pharmacist before use if you are:**  
 ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers

**When using this product** ■ do not exceed recommended dosage ■ may cause marked drowsiness ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children.

**Stop use and ask a doctor if**  
 ■ pain, cough, or nasal congestion gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with rash or headache that lasts. **These could be signs of a serious condition.** ■ nervousness, dizziness, or sleeplessness occurs

**If pregnant or breast-feeding, ask a health professional before use.**  
 ■ **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions:**  
 ■ do not take more than the recommended dose  
 ■ adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water every 4 hours.  
 Do not exceed 8 tablets in 24 hours or as directed by a doctor  
 ■ children under 12 years: do not use

**Other information**  
 ■ **Phenylephrine:** Contains Phenylephrine 15 mg/Per Tablet  
 ■ store at room temperature. Avoid excessive heat.  
 Total Sodium: 415 mg/tablet  
 Total Potassium: 1 mg/tablet

**Inactive ingredients:** acacia/ume potassium, aspartame, citric acid anhydrous, color point/4, isopropyl alcohol, mannitol, orange flavor, pvp k-30, simethicone, sodium benzoate, sodium bicarbonate, sodium saccharin, tween 80.

Code No. : GUU-DRUGS/6/25/1878

Lot :   
 Mfg. Date :   
 Exp. Date :   
 Unvarnished Area (90 x 18 mm) for Batch Coding & 2D Barcode



Note - This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Alka Seltzer® Plus severe cold and cough.

Distributed by Velocity Pharma LLC  
 Farmingdale NY 11735  
**Questions or comments?**  
 call toll free 1-855-314-1850

REV.5/14  
 ALKA6CT

# PAIN RELIEVER FEVER REDUCER

NDC 76168-021-13

COMPARE TO THE ACTIVE INGREDIENTS IN ALKA-SELTZER® PLUS SEVERE COLD & FLU

# PAIN RELIEVER FEVER REDUCER

PAIN RELIEVER FEVER REDUCER

PAIN RELIEVER FEVER REDUCER



CITRUS

6 EFFERVESCENT TABLETS

FEVER SORE THROAT NASAL CONGESTION BODY ACHES • RUNNY NOSE

Acetaminophen/ Pain reliever fever reducer • Chlorpheniramine maleate/ Antihistamine • Dextromethorphan hydrobromide/ Cough Suppressant • Phenylephrine hydrochloride/ Nasal decongestant

NDC: 76168-021-13 6 tablets

## PAIN RELIEVER FEVER REDUCER

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, chlorpheniramine maleate tablet, effervescent

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76168-021
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ASPARTAME (UNII: Z0H242BBR1)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PONCEAU 4R (UNII: Z525CBK9PG)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MANNITOL (UNII: 3OWL53L36A)	
ORANGE (UNII: 5EVU04N5QU)	
POVIDONE K30 (UNII: U725QWY32X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

**Product Characteristics**

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	25mm
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-021-13	6 in 1 BLISTER PACK		
1		1 in 1 CARTON		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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**Labeler** - Velocity Pharma (962198409)

**Registrant** - Velocity Pharma (962198409)

Revised: 8/2014

Velocity Pharma