COLD A - acetaminophen, chlorpheniramine maleate, ephedrine hcl, guaifenesin in syrup
Daewon Pharmaceutical Co., Ltd.

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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ACTIVE INGREDIENTS

Active ingredients (in each 20 mL pouch) Purpose

- Acetaminophen 300 mg
- Chlorpheniramine Maleate 2.5 mg
- Ephedrine HCl 18 mg
- Guaifenesin 42 mg

INACTIVE INGREDIENT

Inactive ingredients:
- xanthan gum, stevion 100s, acesulfame potassium, concentrated glycerin, sucralose, d-sorbitol solution, xylitol, sodium chloride, povidone k30, propylene glycol, ethanol, disodium edetate hydrate, citric acid, sodium citrate hydrate, sodium benzoate, lemon essence, apple mint flavor 514165, red no. 40, purified water

PURPOSE

Purpose
- Pain reliever/fever reducer
- Antihistamine/immunosuppressant
- Nasal decongestant
- Expectorant

WARNINGS

Warnings:

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
- more than 8 doses 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

Allergy Alert: If you have ever experienced allergic reactions induced by drugs. Symptoms may include:
- Skin reddening
- Blisters
- Rash
If a skin reaction occurs, stop use and seek medical help right away.

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.

Reye’s syndrome: a chickenpox or influenza-suspected infant or child under 15 years of age If it is accompanied by nausea or vomit, it may be early symptoms of Reye’s syndrome, rare but serious, consult a doctor promptly.
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 conditions an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have
• liver disease • heart disease • renal disease • high blood pressure • thyroid disease • diabetes • glaucoma • dysuria • weak condition • high fever
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, pulmonary emphysema, and excessive sputum production
• trouble urinating due to enlarged prostate gland
• a sodium-restricted diet

Ask a doctor or pharmacist before use if you are
• taking sedatives or tranquilizer
• taking blood thinning drug warfarin

When using this product
• observe usage and dosage instructions.
• do not take this drug for a long term.
• children should take this drug under the guardians’ supervision.
• do not drink alcohol while you are taking this drug.
• tends to cause drowsiness, avoid driving cars and operating machinery while taking this drug.
• patients, administered with barbital drugs, tricyclic antidepressants, or alcohol, tend to lack the ability to metabolize lots of acetaminophen, their plasma elimination half-life may increase.

Stop use and ask a doctor if
• cough and pain gets worse or persist for more than a week and accompanied by rash, flare, itching, nausea, vomiting, edema (swelling), dysuria, or insomnia.
• fever gets worse or lasts more than 3 days.
• new symptoms occur.
• cough come back or occurs with rash or headache that lasts.
These could be signs of a serious condition.

If pregnant, potentially-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.

Uses
Uses temporarily relieves common cold/flu symptoms:
• runny nose • sneezing • nasal congestion • sore throat • cough due to minor throat and bronchial irritation • fever • headache • minor pains and aches

Directions
Directions:
• take only as directed • do not exceed 8 doses per 24 hours
One dose 30 minutes after meals, three times a day
adults & children 12 yrs & over --------- 20 mL/dose
children under 12 yrs --------- do not use

OTHER INFORMATION

Other information
• each 20 ml contains: sodium 27 mg
• store between 20~25°C (68~77°F).
• protect from direct sunlight and keep in a low-humidity and cool place.
• do not store in a different container to prevent misuse and preserve quality.

QUESTIONS
Questions? 1-562-281-5888

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 20mL Pouch

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - Carton
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<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
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<th>Basis of Strength</th>
<th>Strength</th>
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<td>ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)</td>
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<td>Guaifenesin (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)</td>
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Labeler - Daewon Pharmaceutical Co., Ltd. (689275501)

Registrant - Daewon Pharmaceutical Co., Ltd. (689275501)

Establishment

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<th>Name</th>
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