

COLD RELIEF SEVERE PAIN COUGH - acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hydrobromide tablet

Select Corporation

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

Acetaminophen 325 mg. Guaifenesin 200 mg Phenylephrine HCl 5 mg

Pain Reliever, Fever Reducer, Expectorant, Nasal Decongestant, Cough Suppressant

Directions: adults and children 12 years of age and over • take 2 tablets with water every 6-8 hours, as needed • do not take more than 8 tablets in 24 hours children under 12 years of age • do not give to children under 12 years of age

Uses: or the temporary relief of the following cold symptoms: • minor aches and pains • headache • sore throat • nasal congestion • cough • helps loose phlegm (mucus) and thin bronchial secretions to make coughs more productive • 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 • with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. • with any other product containing any of the above active ingredients • 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 • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema • cough that occurs with too much phlegm (mucus) 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 • excitability may occur, especially in children • marked drowsiness may occur • alcohol, sedatives and tranquilizers may increase the drowsiness effect • avoid alcoholic drinks • be careful when driving a motor vehicle or operating machinery Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • pain or nasal congestion or cough 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.

If pregnant or breast-feeding baby, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN.

Inactive ingredients:

Maltodextrin, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid

MM1

OSGCRLIGHHCH

PACKAGING NOT CHILD RESISTANT



Manufactured for Select Corporation, Carrollton, TX 75007

Contains 2 Tablets

Active Ingredients (in each tablet)

Purposes

Acetaminophen 325mg.....Pain Reliever/Fever Reducer
 Dextromethorphan HBr 15mg.....Cough suppressant
 Guaifenesin 200 mg.....Expectorant
 Phenylephrine HCl 5 mg.....Nasal decongestant

Uses • for the temporary relief of the following cold symptoms:
 • minor aches and pains • headache • sore throat • nasal congestion
 • cough • helps loose phlegm (mucus) and thin bronchial secretions to
 make coughs more productive • **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** • with any other drug containing
 acetaminophen (prescription or nonprescription). If you are not sure
 whether a drug contains acetaminophen, ask a doctor or pharmacist.
 • with any other product containing any of the above active ingredients
 • 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 prescripion drug contains an
 MAOI, ask a doctor or pharmacis before taking this product.

Ask a doctor before use if you have • liver
 disease • heart disease • high blood pressure • thyroid
 disease • diabetes • trouble urinating due to an
 enlarged prostate gland • persistent or chronic cough
 such as occurs with smoking, asthma, chronic bronchitis or
 emphysema • cough that occurs with too much phlegm (mucus)

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
 • excitability may occur, especially in children • marked drowsiness
 may occur • alcohol, sedatives and tranquilizers may increase the
 drowsiness effect • avoid alcoholic drinks • be careful when driving a
 motor vehicle or operating machinery **Stop use and ask a doctor if** •
 nervousness, dizziness, or sleeplessness occur • pain or nasal congestion
 or cough 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. **If pregnant or breast feeding, ask a
 health professional before use, Keep out of reach of children,**

Overdose warning: In case of overdose, contact a Poison Control
 Center immediately. Prompt medical attention is critical for adults as well
 as for children even if you do not notice any signs or symptoms.

Directions • adults and children 12 years of age and over • take 2
 tablets with water every 6-8 hours, as needed • do not take more than 8
 tablets in 24 hours **children under 12 years of age** • do not give to
 children under 12 years of age **Other information** • store between
 59-86°F (15°-30°C) • avoid excessive heat and humidity • **do not use if
 pouch is opened or torn** • see below for lot number and expiration date

Inactive Ingredients maltodextrin, microcrystalline cellulose, povidone,
 sodium starch glycolate, starch, stearic acid **Questions or Comments?**
 call 877-433-4489 M-F: 9am-5pm CST

COLD RELIEF SEVERE PAIN COUGH

acetaminophen, guaifenesin, phenylephrine hcl, dextromethorphan hydrobromide tablet

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52904-456 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 15 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| POVIDONE K29/32 (UNII: 390RMW2PEQ) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |

Product Characteristics

| | | | |
|-----------------|--------------------|---------------------|----------|
| Color | white (snow white) | Score | no score |
| Shape | ROUND (FR12) | Size | 12mm |
| Flavor | | Imprint Code | FR12 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:52904-456-02 | 2 in 1 PACKET | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 10/15/2012 | |

Labeler - Select Corporation (053805599)

Revised: 10/2012

Select Corporation