COUGH MULTI SYMPTOM- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl liquid
Kinray 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.

Cough and Sore Throat Drug Facts

Active ingredients (in each 15 mL tablespoon)

Acetaminophen 500 mg

Dextromethorphan HBr 15 mg

Doxylamine Succinate 6.25 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever / Fever reducer

Cough suppressant

Antihistamine

Nasal Decongestant

Uses

temporarily relieves common cold/flu symptoms:

- sore throat
- headache
- minor aches and pains
- nasal congestion
- runny nose and sneezing
- cough
- sinus congestion and pressure helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

Warnings

Alcohol Warning: if you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take Acetaminophen or oter pain releivers/ fever reducers.

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

- more than 4 doses in 24 hours, which is the maximum daily amount of 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.
- 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.
- to make a child sleep
- if you are allergic to acetaminophen or any of the ingredients in this product.

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product do not use more than directed

- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when operating machinery

Stop use and ask a doctor if

- pain 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: taking more than recommended dose can cause serious health problems. 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.

Directions

- take only as recommended - see overdose warning
- use dose cup or Tabelspoon (TBSP)
- do not take more than 10 tablespoons (tbsp) or 150 mL in 24-hours period

Adults and children 12 years of age and over	• take 2 tablespoons (tbsp) 30 ml in dose cup provided every 6 hours as needed

Children under 12 years	• do not use this product in children under 12 years of age: this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- Store at room temperature 15°- 30°C (59° - 86°F)
- Protect from freezing
- each tablespoon contains: sodium 21 mg

TAMPER EVIDENT: DO NOT USE IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING

Inactive ingredients

carboxy methyl cellulose sodium, citric acid, FD&C Blue #1, flavor, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol and sucrose

Questions or comments?

1-845-692-5799

Principal Display Panel

Cold Multi-Symptom

Drug Facts

Active Ingredients (in each 15 mL tablespoon)	Purpose
Acetaminophen 325 mg	Pain reliever / Fever reducer
Dextromethorphan HBr, 10 mg	Cough Suppressant
Doxylamine Succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal Decongestant

Uses temporarily relieves common cold/flu symptoms: ■ sore throat ■ headache ■ minor aches and pain ■ nasal congestion ■ runny nose and sneezing ■ cough ■ sinus congestion and pressure helps clear nasal passages ■ relieves cough to help you sleep ■ temporarily reduces fever

Warnings: **Alcohol Warning:** if you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take Acetaminophen or other pain relievers/ fever reducers.

Liver Warning: this product contains Acetaminophen. Severe liver damage may occur if you take: more than 6 doses in 24 hours, which is the maximum daily amount of 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 drugs 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 ■ to make a child sleep ■ if you are allergic to acetaminophen or any of the ingredients in 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 ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ cough that occurs with too much phlegm (mucus) ■ 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 sedatives or tranquilizers ■ taking the blood thinning drug warfarin

When using this product do not use more than directed ■ excitability may occur, especially in children ■ marked drowsiness may occur ■ alcohol, sedatives and tranquilizers may increase drowsiness ■ 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, 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: Taking more than the recommended dose can cause serious health problems. 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.

Directions: take only as recommended - see overdose warning ■ Use dose cup or Tablespoon (TBSP) ■ do not take more than 10 tablespoons (tbsp) or 150 mL in 24-hours period

Adults and children 12 years of age and over	take 2 tablespoons (tbsp) or 30 ml in dose cup provided every 4 hours
Children under 12 years	do not use this product in children under 12 years of age: this will provide more than the recommended dose (overdose) and may cause liver damage

Other information ■ Store at room temperature 15° - 30°C (59° - 86°F) ■ Protect from freezing ■ each tablespoons (15 mL) contains: sodium 21 mg

TAMPER EVIDENT: DO NOT USE IF PRINTED INNER CAP SEAL IS BROKEN OR MISSING.

Inactive Ingredients: carboxy methyl cellulose sodium, citric acid, FD&C Blue #1, flavor, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium saccharin, sorbitol and sucrose

Questions or comments? 1-845-692-5799

Cold Multi-Symptom

COUGH MULTI SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61715-074

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 15 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MENTHOL (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	BLUE (clear)	**Score**	
Shape		**Size**	
Flavor	MENTHOL	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-074-08	236 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/28/2006	

Labeler - Kinray LLC (012574513)