PREFERRED PLUS CHEST CONGESTION RELIEF PE- guaifenesin and phenylephrine hydrochloride tablet
Kinray

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 ingredient - (per tablet)

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purpose

Guaifenesin.....Expectorant

Phenylephrine HCl.....Nasal decongestant

Uses

Temporarily relieves symptoms associated with a cough ,the common cold,hay fever or other upper respiratory allergies.

- helps loosen phlegm (mucus)
- clear nasal passageways
- loosens nasal congestion
- drain bronchial tubes
- shrinks swollen membranes
- clears stuffy nose
- makes coughs more productive

Warnings

Do not exceed recommended dosage

Do not use

- this product 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 are uncertain whether your prescription drug contains an MAOI, ask a health professional.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease

■ diabetes
■ excessive phlegm;mucus
■ difficulty in urination due to an enlarged prostate gland
■ persistent or chronic cough such as occurs with smoking,asthma,chronic bronchitis or emphysema

Stop use and ask a doctor if

■ nervousness, dizziness or sleeplessness occurs
■ symptoms are accompanied by fever, rash,
persistent headache or excessive phlegm (mucus)
■ cough and congestion do not improve within 7 days
or tend to recur.
These could be signs of a serious condition.

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

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

■ adults and children 12 years and over:
take 1 caplet every 4 hours as needed
■ children 6 to under 12 years:
take 1/2 caplet every 4 hours as needed
■ children under 6 years: consult a doctor
Do not exceed 6 doses in a 24 hour period or as directed by a doctor.

Inactive ingredients

lactose, magnesium silicate,
croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin,
microcrystalline cellulose, mineral oil, povidone, silica, sodium lauryl sulfate, stearic acid,
titanium dioxide and triacetin

PREFERRED PLUS CHEST CONGESTION RELIEF PE

guaifenesin/phenylephrine tablet

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:61715-014
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (Guaifenesin)	Guaifenesin	400 mg
PHENYLEPHRINE HYDROCHLORIDE (PHENYLEPHRINE)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM	
LACTOSE	
MALTODEXTRIN	
CELLULOSE, MICROCRYSTALLINE	
MINERAL OIL	
POVIDONE	
MAGNESIUM SILICATE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	RCCGPE;C27
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61715-014-01	1 in 1 CARTON		
1	NDC:61715-014-50	50 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/05/2006	

Labeler - Kinray (012574513)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(61715-014), repack(61715-014)