DECONEX IR- guaifenesin and phenylephrine hydrochloride tablet
Poly Pharmaceuticals

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.

DECONEX IR TABLETS

Drug Facts
Active ingredients
(in each tablet)
Guaifenesin 380 mg
Phenylephrine HCl 10 mg

Purpose
Expectorant
Nasal Decongestant

Uses
Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- nasal congestion
- reduces swelling of nasal passage

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 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
- a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- a cough that occurs with too much phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.
- new symptoms occur

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.

Directions
Do not exceed recommended dosage.

Adults and children 12 years of age and over:	1 tablet every 4 hours, not to exceed 6 tablets in 24 hours.
Children 6 to under 12 years of age:	1/2 tablet every 4 hours, not to exceed 3 tablets in 24 hours.
Children under 6 years of age:	Consult a physician.

Other information
Store at controlled room temperature between 15°- 30°C (59°- 86°F).
Supplied in a tight, light-resistant container with a child-resistant cap.
Contains color additives including FD&C Yellow No. 5 (tartrazine).
Deconex IR Tablets are green, oval-shaped, scored tablets, debossed "POLY" bisect "716" on one side, and plain on the other side.

Inactive ingredients
colloidal silicon dioxide, croscarmellose sodium, FD&C Blue #1 aluminum lake, FD&C Yellow #5 aluminum lake, hypromellose, maltodextrin, povidone, silicified microcrystalline cellulose, and stearic acid.

Questions? Comments?
Call 1-800-882-1041

Manufactured for:
Poly Pharmaceuticals
Quitman, MS 39355
1 (800) 882-1041

Rev. 02/12

Product Packaging
The packaging below represents the labeling currently used.

Principal display panel and side panel for 60 tablets label:

NDC 50991-716-60

DECONEX IR

TABLETS

EXPECTORANT · NASAL DECONGESTANT

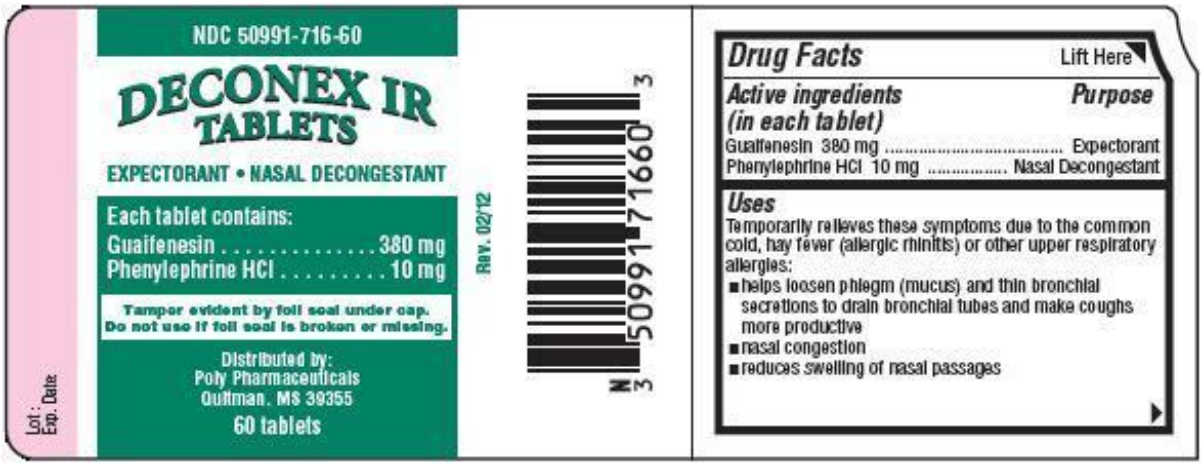
Each tablet contains:
Guaifenesin.....380 mg
Phenylephrine HCl.....10 mg

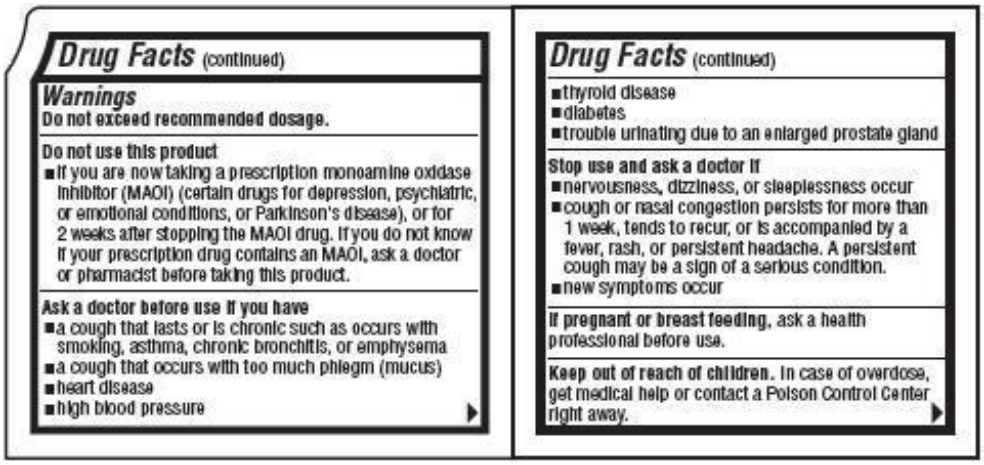
Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.

Distributed by:
Poly Pharmaceuticals
Quitman, MS 39355

60 tablets

Rev. 02/12





Drug Facts (continued)

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	1 tablet every 4 hours, not to exceed 6 tablets in 24 hours.
Children 6 to under 12 years of age:	½ tablet every 4 hours, not to exceed 3 tablets in 24 hours.
Children under 6 years of age:	Consult a physician.

Other information

Store at controlled room temperature between 15°-30°C (59°-86°F).

Supplied in a tight, light-resistant container with a child-resistant cap.

Contains color additives including FD&C Yellow No. 5 (tartrazine).

Drug Facts (continued)

Deconex IR Tablets are green, oval-shaped, scored tablets, debossed "POLY" bisect "716" on one side, and plain on the other side.

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DECONEX IR

guaifenesin, phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:50991-716
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (Guaifenesin)	Guaifenesin	380 mg
Phenylephrine Hydrochloride (Phenylephrine)	Phenylephrine Hydrochloride	10 mg

Inactive Ingredients

Ingredient Name	Strength
Croscarmellose Sodium	
Hypromelloses	
Maltodextrin	
Povidone	
Silicon Dioxide	
Cellulose, Microcrystalline	
Stearic Acid	

Product Characteristics

Color	green	**Score**	2 pieces
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	POLY;716
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-716-60	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/25/2012	

Labeler - Poly Pharmaceuticals (198449894)

Registrant - Pernix Manufacturing, LLC (078641814)

Establishment

Name	Address	ID/FEI	Business Operations
Pernix Manufacturing, LLC dba Great Southern Laboratories		078641814	manufacture(50991-716)

Revised: 10/2012 Poly Pharmaceuticals