GLENTUSS- dextromethorphan hydrobromide, pseudoephedrine hydrochloride, and doxylamine succinate syrup
Glendale Inc

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.

Glentuss

Drug Facts

Active ingredients (in each teaspoonful)	***Purpose***
Dextromethorphan Hydrobromide 15 mg	Antitussive (cough suppressant)
Pseudoephedrine Hydrochloride 30 mg	Nasal Decongestant
Doxylamine Succinate 6.25 mg	Antihistamine

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- temporarily restores freer breathing through the nose congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

- to sedate a child or make a child sleepy
- 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

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

Ask a doctor or pharmacist before use if you are

- taking any other nasal decongestant or stimulant
- taking sedatives or tranquilizers

When using this product

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

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. 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.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not exceed 4 dosage in a 24-hour period.

Adults and children 12 years of age and over:	2 teaspoonfuls every 6 hours
Children under 12 years of age:	Consult a physician

Other information

Store at 59°-86°F (15°-30°C) [see USP for Controlled Room Temperature]

Inactive ingredients

Apple candy flavor, citric acid, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol.

Questions? Comments?

To report a serious adverse event or obtain product information, Call 1-630-530-7000.

Distributed by:
Glendale Inc
Villa, Park, IL 60181

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 70147-0233-16

Glentuss

Antitussive

Nasal Decongestant
Antihistamine

Each teaspoonful for oral administration contains:
Dextromethorphan HBr 15 mg
Pseudoephedrine HCl 30 mg
Doxylamine Succinate 6.25 mg

SUGAR FREE / DYE FREE
ALCOHOL FREE

Apple Candy Flavored Liquid

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

Distributed by:
Glendale Inc
Villa Park, IL 60181

16 fl oz. (473 mL)

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Drug Facts (continued)

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Rev. 10/15

GLENTUSS

dextromethorphan hydrobromide, pseudoephedrine hydrochloride, and doxylamine succinate syrup

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70147-233
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	APPLE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70147-233-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/05/2015	

Labeler - Glendale Inc (079987961)

Revised: 12/2015 Glendale Inc