

PHENAGIL- chlorpheniramine maleate, dextromethorphan hbr and phenylephrine hcl tablet
Syntho Pharmaceuticals, 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.

PHENAGIL® CH

ANTI-HISTAMINE, NASAL DECONGESTANT AND ANTITUSSIVE

DYE FREE

PRESERVATIVE FREE

SODIUM FREE

SUGAR FREE

Drug Facts

Active ingredients

(in each tablet)

Chlorpheniramine maleate 3.5 mg

Dextromethorphan HBr 29 mg

Phenylephrine HCl 10 mg

Purposes

Antihistamine

Cough suppressant

Nasal decongestant

Uses

Temporarily relieves:

- cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants.
- nasal congestion due to the common cold, hay fever or other upper respiratory allergies.
- temporarily relieves these symptoms due to hay fever (allergic rhinitis):
 - runny nose.
 - sneezing.
 - itchy, watery eyes.
 - itching of the nose or throat.
- temporarily restores freer breathing through the nose.

Warnings

Do not use

- to sedate a child or to 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.
- trouble urinating due to an enlarged prostate gland.
- glaucoma.
- cough that occurs with too much phlegm (mucus).
- a breathing problem or persistent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Ask a doctor or pharmacist before use if you are

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

When using this product

- **do not use more than directed.**
- may cause drowsiness.
- avoid alcoholic beverages.
- 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

- you get nervous, dizzy, or sleepless.
- symptoms do not get better within 7 days or are accompanied by fever.
- cough lasts more than 7 days, comes back, or is accompanied by 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

- **Adults and Children 12 years and over.** : Take one tablet every 6-8 hours.
Do not take more than 4 tablets in a 24 hour period.
- **Children 6 to 12 years of age** : Take 1/2 tablet every 6-8 hours.
Do not take more than 2 tablets in a 24 hour period.
- **Children under 6 years**: Consult a doctor.

Other information

- store at room temperature.
- do not use if safety seal is broken or missing.

Inactive ingredients

Hydroxypropyl Methylcellulose, Lactose Monohydrate, Microcrystalline Cellulose, Magnesium Stearate and Polyethylene Glycol.

Questions or comments?

Call **1-787-848-9114**, Monday–Friday 9AM–5PM EST. Call your doctor for medical advice in the event of side effects.

Manufactured for:

GIL PHARMACEUTICAL CORP.,
Ponce, Puerto Rico 00716

Manufactured by:
 Syntho Pharmaceuticals, Inc.
 Farmingdale, New York (NY) 11735
 Label revised: 04/22

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL
PHENAGIL® CH - NDC 66576-337-01 - 100's Bottle Label.

PHENAGIL
 chlorpheniramine maleate, dextromethorphan hbr and phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66576-337
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	3.5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	29 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	3mm
Flavor		Imprint Code	323;Gil
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66576-337-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/26/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/26/2022	

Labeler - Syntho Pharmaceuticals, Inc. (088797407)

