PHENAGIL- chlorpheniramine maleate,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.

Relieve Allergy and Congestion with:

PHENAGIL ®ANTIHISTAMINE AND NASAL DECONGESTANT

DYE FREE

PRESERVATIVE FREE

SODIUM FREE

SUGAR FREE

Drug Facts

Active Ingredients (in each tablet)

Chlorpheniramine Maleate 3.5 mg

Phenylephrine HCl 10 mg

Purposes

Antihistamine

Nasal Decongestant

Uses

Temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper-respiratory allergies:

• runny nose.

• sneezing.

• itchy, watery eyes.

• nasal congestion.

• itching of the nose or throat.

• sinus congestion and pressure.

Warnings

Do not use 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.
• a breathing problem such as emphysema or chronic bronchitis.
• glaucoma.

Ask a doctor or pharmacist before you use if you are taking sedatives or tranquilizers.

When using this product

- do not exceed recommended dose.
- excitability may occur, especially in children.
- 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 occurs.
• symptoms do not improve within 7 days or occur with a fever.

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 (1-800-222-1222).

Directions

- **Adults and children 12 years and over.**
  Take 1 tablet every 4 hours.
  Do not take more than 6 tablets in a 24 hours.
- **Children 6 to 12 years of age::** Take 1/2 tablet every 4 hours, Do not to exceed 3 tablets in a 24 hour period.
- **Do not use this product children under 6 years of age.**

Other information

• store at room temperature, USP.
• do not use if safety seal is broken or missing.

Inactive Ingredients

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

Questions? Call 787-848-9114

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- NDC- 66576-322-01- 100's Bottle Label.

Drug Facts

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Chlorpheniramine Maleate 3.5 mg .....Antihistamine
Phenylephrine HCl 10 mg .....Nasal Decongestant

Uses

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• runny nose • sneezing • itchy, watery eyes • nasal congestion • itching of the nose or throat • sinus congestion and pressure

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• heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • a breathing problem such as emphysema or chronic bronchitis • glaucoma

Label revised: 04/22

PEEL HERE FOR MORE INFORMATION

Drug Facts (continued)

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Manufactured for: GIL PHARMACEUTICAL CORP., Ponce, Puerto Rico 00716

Label revised: 04/22

PHENAGIL

chlorpheniramine maleate,phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66576-322
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	322;Gil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66576-322-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2022	

Labeler - Syntho Pharmaceuticals, Inc. (088797407)

Revised: 6/2022 Syntho Pharmaceuticals, Inc.