POLY HIST FORTE- doxylamine succinate and phenylephrine hydrochloride tablet
Poly Pharmaceuticals, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Poly Hist Forte

Drug Facts

Active ingredients

(in each tablet)

Doxylamine Succinate 10.5mg

Purpose

Antihistamine

Active ingredients

(in each tablet)

Phenylephrine HCl 10 mg

Purpose

Nasal Decongestant

Uses

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

- nasal congestion
- reduces swelling of nasal passages
- runny nose
- sneezing
- itching of nose or throat
- itchy, watery eyes

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor before use if

you are taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by 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.

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 12 years of age:	1/2 tablet every 4 hours, not to exceed 3 tablets in 24 hours.
Children 6 years of age and younger:	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.

Poly Hist Forte Tablets are blue, caplet-shaped, scored tablets, debossed "Poly" bisect "216" on one side and plain on the other.

Inactive ingredients

FD&C Blue # 2, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

Questions? Comments?

Call 1-800-882-1041

Manufactured for:

Poly Pharmaceuticals, Inc.

Huntsville, AL Rev. 4/16

PRINCIPAL DISPLAY PANEL

NDC 50991-626-01

POLY HIST FORTE ®

TABLETS

Nasal Decongestant • Antihistamine

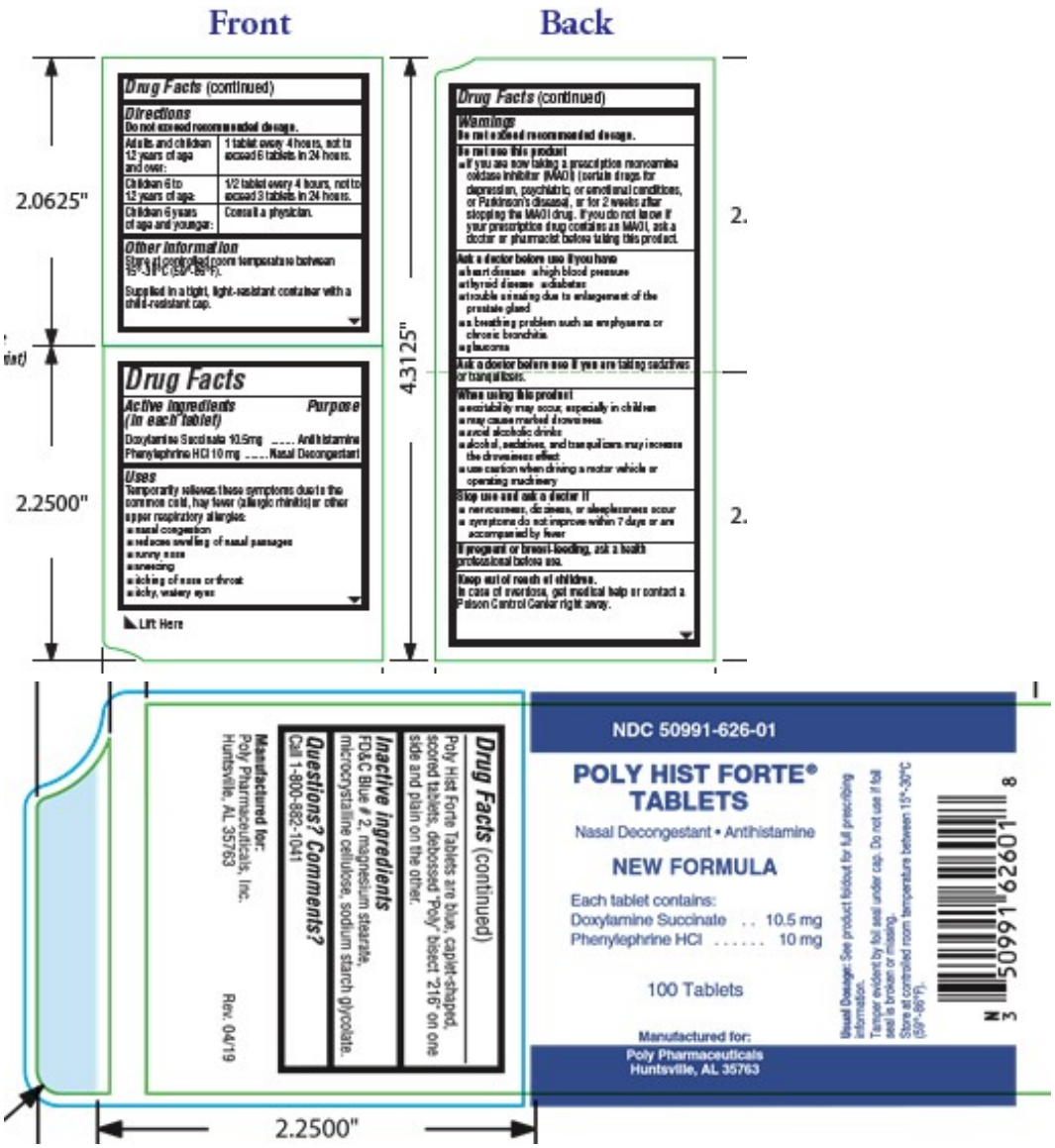
NEW FORMULA

Each tablet contains:

Doxylamine Succinate . . . 10.5 mg

Phenylephrine HCl . . . . . 10 mg

100 Tablets



POLY HIST FORTE

doxylamine succinate and phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50991-626
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	10.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	blue	**Score**	2 pieces
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	Poly;216
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-626-02	12 in 1 CARTON	06/01/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50991-626-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2019	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 1/2024 Poly Pharmaceuticals, Inc.