

DURAHIST- dexbrompheniramine maleate, pseudoephedrine hcl tablet
Poly Pharmaceuticals, Inc.

Durahist

Purpose

Dexbrompheniramine Maleate Antihistamine

Pseudoephedrine HCl Nasal Decongestant

Active ingredients

(in each tablet)

Dexbrompheniramine Maleate 2mg

Pseudoephedrine HCl 60mg

Uses

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

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

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

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

When using this product

- excitability may occur, especially in children
- may cause 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

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

Other information

Store at 15° - 30°C (59° - 86°F).

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

Durahist Tablets are pink caplet shaped, scored tablets, debossed "Poly" bisect "865" on one side and plain on the other.

Inactive ingredients

Lake Blend Red, Magnesium Stearate, Microcrystalline Cellulose and Sodium Starch Glycolate.

Questions?

Call 1-800-882-1041

Manufactured for:

Poly Pharmaceuticals
Quitman, MS 39355

Rev. 09/2024

Product Packaging

The packaging below represents the labeling currently used.

Principal display panel for 90 tablets label:

NDC 50991-865-90



DURAHIST

dexbrompheniramine maleate, pseudoephedrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50991-865
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	2 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	pink	Score	2 pieces
Shape	OVAL	Size	11mm
Flavor		Imprint Code	Poly;865

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-865-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2025	
2	NDC:50991-865-02	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/29/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/22/2025	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 12/2025

Poly Pharmaceuticals, Inc.