

ALA-HIST IR- dexbrompheniramine maleate tablet
Poly Pharmaceuticals, Inc.

ALA-HIST IR 2 mg Tablets

Drug Facts

Active ingredients

(in each tablet)

Dexbrompheniramine Maleate 2 mg

Purpose

Antihistamine

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

Warnings

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

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

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

Contains color additives including FD&C Yellow No. 5 (tartrazine).

Ala-Hist IR Tablets are dark green caplet shaped, scored tablets, debossed "Poly" bisect "783" on one side and plain on the other.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C Blue #1 aluminum lake, FD&C Yellow #5 aluminum lake, magnesium stearate, and silicified microcrystalline cellulose.

Questions?

Call 1-800-882-1041

Manufactured for:

Poly Pharmaceuticals
Quitman, MS 39355

Rev. 02/12

Product Packaging

The packaging below represents the labeling currently used.

Principal display panel and side panel for 60 tablets label:

NDC 50991-783-60

ALA-HIST IR

2 mg Tablets

Antihistamine

Each tablet contains:

Dexbrompheniramine Maleate.....2 mg

60 Tablets

Usual Dosage: See product foldout for full

prescribing information

Tamper evident by foil seal under cap. Do not

use if foil seal is broken or missing.

KEEP THIS AND ALL DRUGS OUT OF

REACH OF CHILDREN.

Store at controlled room temperature 15°-30°C

(59°-86°F).

Manufactured for:

Poly Pharmaceuticals

Rev. 02/12

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Store at controlled room temperature between 15°-30°C (59°-86°F).

Manufactured for:
Poly Pharmaceuticals
Huntsville, AL 35763

Rev. 02/17

NDC 50991-783-60

ALA-HIST IR

2 mg Tablets

Antihistamine

Each tablet contains:
Dexbrompheniramine Maleate .. 2 mg

60 Tablets

Usual Dosage: See product foldout for full prescribing information.
Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.



N 3 50991 78360 5

Lot : _____
Exp. Date: _____

<p>KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.</p> <p>ALA-HIST IR 2 mg Tablets</p> <p>Each tablet contains: Dexbrompheniramine Maleate .. 2 mg</p> <p>60 Tablets</p>	<p>Drug Facts (continued)</p> <p>Active ingredients (in each tablet) Dexbrompheniramine Maleate 2 mg</p> <p>Purpose Antihistamine</p>	<p>Drug Facts (continued)</p> <p>Uses Temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes</p>	<p>Drug Facts (continued)</p> <p>Warnings 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</p>	<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p> <p>When using this product ■ excitability may occur, especially in children ■ may cause drowsiness ■ avoid alcoholic drinks</p>	<p>Drug Facts (continued)</p> <p>■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect ■ use caution when driving a motor vehicle or operating machinery</p> <p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>If pregnant or breast feeding, ask a health professional before use.</p>
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<p>Directions Adults and children 12 years of age and over: 1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours, or as directed by a doctor.</p>	<p>Drug Facts (continued)</p> <p>Directions Children 6 to under 12 years of age: 1/2 tablet every 4 to 6 hours, not to exceed 3 tablets in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.</p>	<p>Drug Facts (continued)</p> <p>Other information Store at 15°-30°C (59°-86°F). Supplied in a tight, light-resistant container with a child-resistant cap.</p>	<p>Drug Facts (continued)</p> <p>ALA-HIST IR Tablets are dark green caplet shaped, scored tablets, debossed "Poly" bisect "783" on one side and plain on the other.</p>	<p>Drug Facts (continued)</p> <p>Inactive ingredients D&C Yellow #10, D&C Blue #1, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate.</p>	<p>Drug Facts (continued)</p> <p>Questions? Comments? Call 1-800-952-1541</p> <p>Manufactured for: Poly Pharmaceuticals Huntsville, AL 35893 Rev. 02/12</p>

ALA-HIST IR
dexbrompheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50991-783
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII: 75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	2 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	green (dark green)	Score	2 pieces
Shape	OVAL	Size	11mm
Flavor		Imprint Code	Poly;783
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-783-02	12 in 1 CARTON	08/22/2011	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50991-783-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/22/2011	

Labeler - Poly Pharmaceuticals, Inc. (198449894)