FEXOFENADINE HYDROCHLORIDE- fexofenadine hcl tablet
Denton Pharma, Inc. DBA Northwind Pharmaceuticals

Major Pharmaceuticals

Active ingredient (in each film-coated tablet)

Fexofenadine HCL 180 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings

Do not use

if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

kidney disease. Your doctor should determine if you need a different dose.

When using this product

- do not take more than directed
- do not take at the same time as aluminum or magnesium antacids
- do not take with fruit juices (see Directions)

Stop use and ask a doctor if

an allergic reaction to this product occurs. Seek medical help right away.

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 of age and over	take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours
children under 12 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information

- **each tablet contain**: sodium 8 mg
- store between 20 to 25°C (68 to 77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 2

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol, pregelatinized starch (maize), red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide

Questions or comments?

Call: **1-800-616-2471**

Principal Display Panel

COMPARE TO the active ingredient in ALLEGRA® ALLERGY 24 HOUR*

FEXOFENADINE HYDROCHLORIDE USP 180 mg

Antihistamine

ALLERGY RELIEF

24-HOUR Relief of:

- sneezing
- Runny nose
- Itchy, watery eyes
- Itchy nose or throat

Indoor and Outdoor

Allergy Relief

Non-Drowsy

Capsule Shaped Tablets

*This product is not manufactured or distributed by Chattem Inc., distributor of Allegra® Allergy 24 hour

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by:

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

Product Label

NDC: 70934-629-90

FEXOFENADINE HYDROCHLORIDE

fexofenadine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70934-629(NDC:0904-7050)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	SG;202
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70934-629-90	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/18/2022	03/31/2025
2	NDC:70934-629-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/11/2022	01/31/2025

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	08/11/2022	03/31/2025

Labeler - Denton Pharma, Inc. DBA Northwind Pharmaceuticals (080355546)

Registrant - Denton Pharma, Inc. DBA Northwind Pharmaceuticals (080355546)

Establishment

Name	Address	ID/FEI	Business Operations
Denton Pharma, Inc. DBA Northwind Pharmaceuticals		080355546	repack(70934-629)