

FEXOFENADINE HCL - fexofenadine hcl tablet
NorthStar RxLLC

Fexofenadine Hydrochloride Tablets USP, 180 mg

ACTIVE INGREDIENT(S) in each tablet

Fexofenadine hydrochloride USP, 180 mg

PURPOSE

Antihistamine

USE(S)

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

§ runny nose

§ sneezing

§ itchy, watery eyes

§ 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.

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

- Tamper-Evident: Do not use if printed foil seal under cap is missing
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

Inactive ingredients

Colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

Questions?

Call **1-800-206-7821**

Manufactured for:
Northstar Rx LLC
Memphis, TN 38141.

Manufactured by:
Hetero Labs Limited,
Unit V, Polepally, Jadcherla,
Mahabubnagar - 509 301, India.

Mfg. Lic. No.: 50/MN/AP/2009/F/R

Issued: 04/2019

PRINCIPAL DISPLAY PANEL

Fexofenadine Hydrochloride Tablets USP, 180 mg - 30s container label

NDC 16714-899-01 **NON-DROWSY**

Original Prescription Strength

Fexofenadine Hydrochloride

Tablets USP, 180 mg

Antihistamine

INDOOR / OUTDOOR ✓ Sneezing
ALLERGY RELIEF ✓ Runny Nose
 ✓ Itchy, Watery Eyes
 ✓ Itchy Nose or Throat

 **24HR**

30 Tablets



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Issued: 04/2019

Mfg. Lic. No.: 50/MN/AP/2009/F/R

Manufactured for: Northstar Rx LLC
 Memphis, TN 38141.

2051368

Manufactured by:
 Hetero Labs Limited,
 Unit V, Polepally, Jadcherla,
 Mahabubnagar - 509 301, India.

VARNISH FREE AREA

Open here to learn more



Drug Facts

Active ingredient (in each tablet)	Purpose
Fexofenadine hydrochloride USP, 180 mg.....	Antihistamine

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

■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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.

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Drug Facts (continued)

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

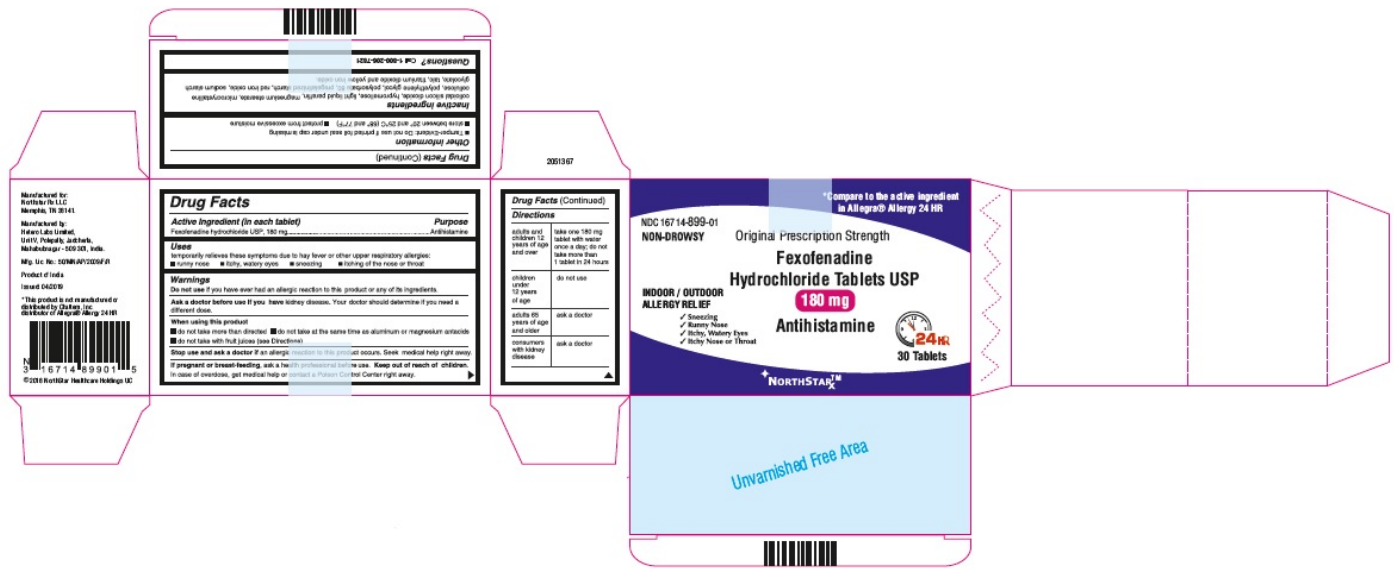
Other information ■ Tamper-Evident: Do not use if printed foil seal under cap is missing.
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Questions? Call 1-800-206-7821

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Fexofenadine Hydrochloride Tablets USP, 180 mg - 30s container carton



Fexofenadine Hydrochloride Tablets USP, 180 mg - 100s container label

NDC 16714-899-02 **NON-DROWSY**

Original Prescription Strength

Fexofenadine Hydrochloride
Tablets USP, 180 mg

Antihistamine

INDOOR / OUTDOOR ALLERGY RELIEF

- ✓ Sneezing
- ✓ Runny Nose
- ✓ Itchy, Watery Eyes
- ✓ Itchy Nose or Throat

 **24HR**

100 Tablets

 NORTHSTAR™

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Issued: 04/2019

VARNISH FREE AREA

Mfg. Lic. No.: 50/MN/AP/2009/F/R

Manufactured for: Northstar Rx LLC
 Memphis, TN 38141.

2051379

Manufactured by: Hetero Labs Limited,
 Unit V, Polepally, Jadcherla,
 Mahabubnagar - 509 301, India.

Open here to learn more

Drug Facts

Active ingredient (in each tablet)	Purpose
Fexofenadine hydrochloride USP, 180 mg.....	Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 runny nose sneezing itchy, watery eyes 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**

Drug Facts (continued)

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
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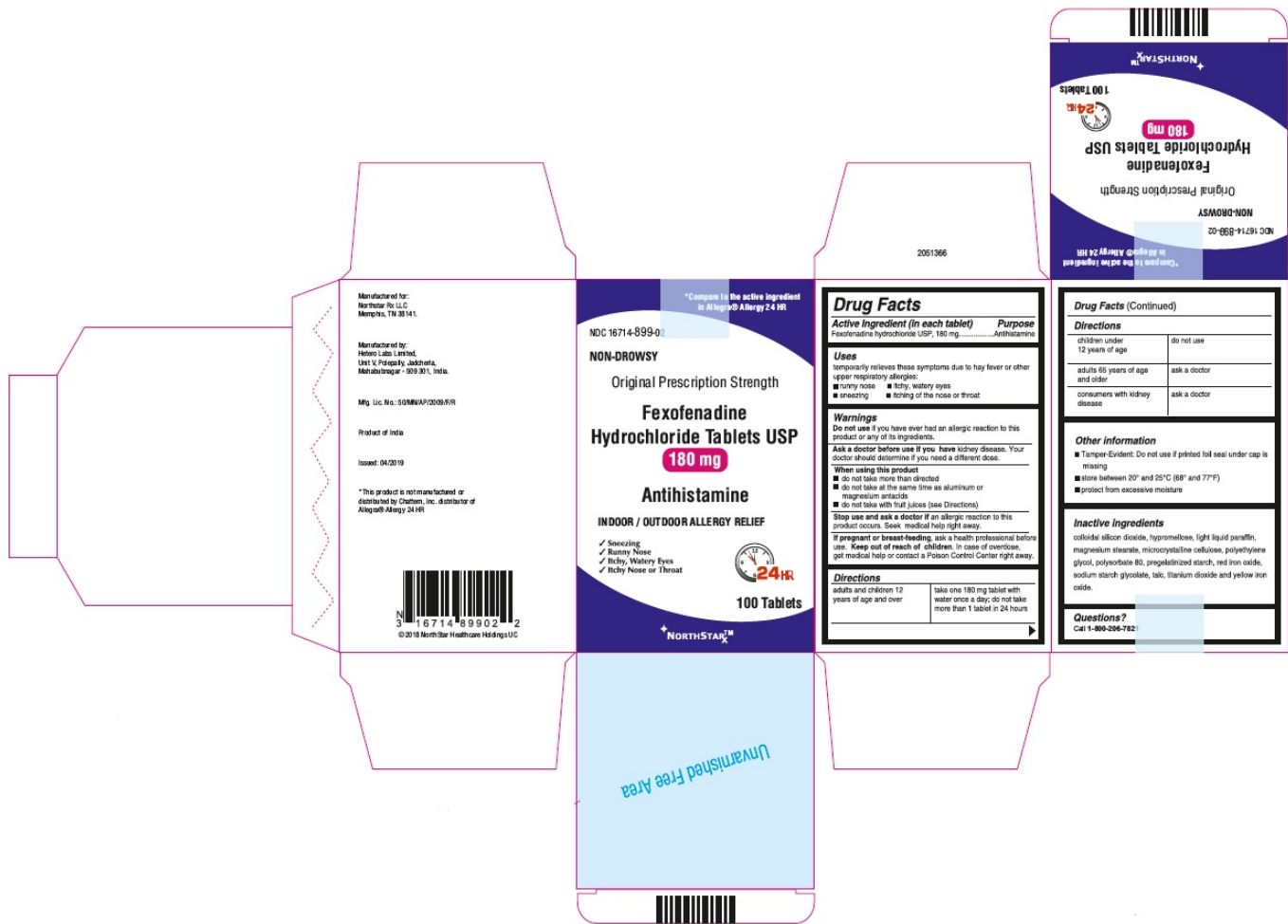
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Questions? Call **1-800-206-7821**

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Fexofenadine Hydrochloride Tablets USP, 180 mg - 100s container carton



FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16714-899
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

MAGNESIUM STEARATE (UNII: 70097M6I30)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
STARCH, CORN (UNII: O8232NY3SJ)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	J;44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16714-899-01	1 in 1 CARTON	02/18/2019	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:16714-899-02	1 in 1 CARTON	02/18/2019	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204097	02/18/2019	

Labeler - NorthStar RxLLC (830546433)

Establishment

Name	Address	ID/FEI	Business Operations
Hetero Labs Limited Unit V		650452530	ANALYSIS(16714-899) , MANUFACTURE(16714-899)