FEXOFENADINE HCL- fexofenadine hcl tablet
Proficient Rx LP

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

60 mg

adults and children 12 years of age and over	take one 60 mg tablet with water every 12 hours; do not take more than 2 tablets 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

180 mg

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

- □ Safety Sealed: do not use if carton is opened or if printed foil inner seal on the bottle is torn or missing.
- □ store between 20° and 25°C (68° and 77°F)
- □ protect from excessive moisture

INACTIVE INGREDIENTS

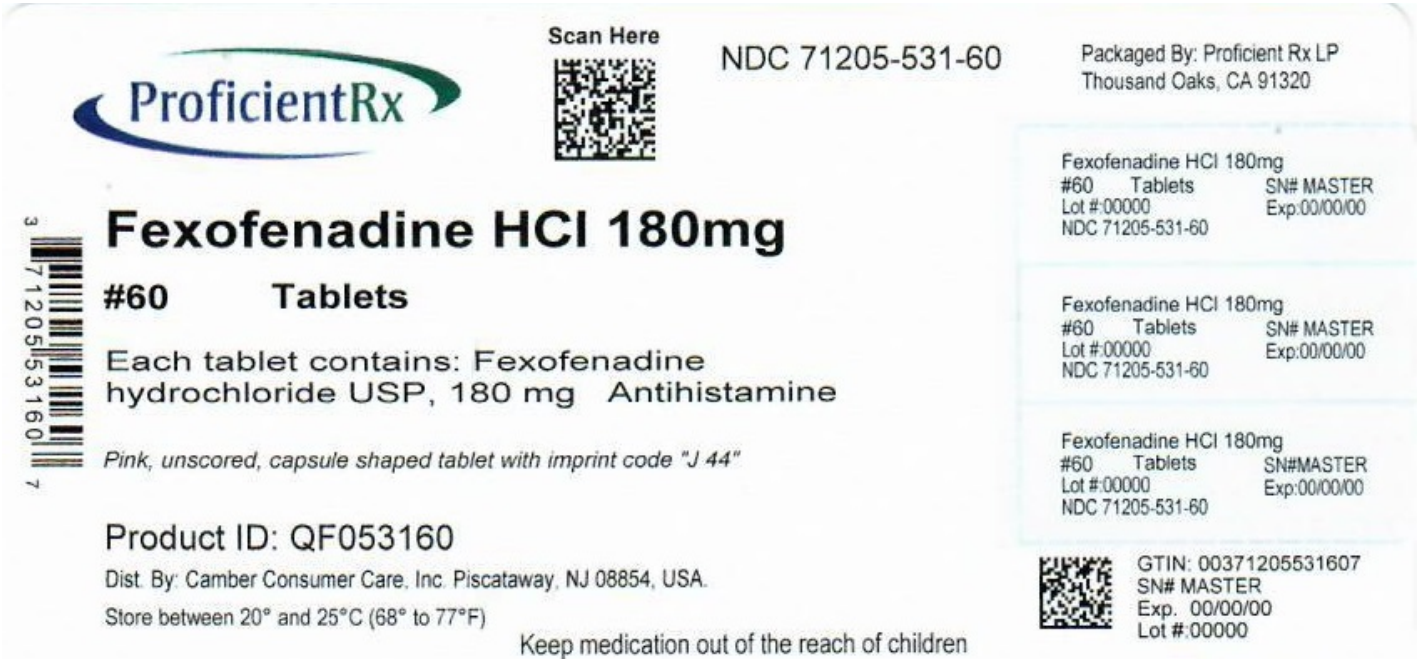
Colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

QUESTIONS OR COMMENTS

call toll-free weekdays 9 AM to 5 PM EST at **1-888-588-1418**

PRINCIPAL DISPLAY PANEL

Fexofenadine Hydrochloride Tablets, USP 180 mg 60s Container Label



FEXOFENADINE HCL

fexofenadine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71205-531(NDC:69230-300)
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)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
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)	

POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	

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:71205-531-10	10 in 1 BOTTLE; Type 0: Not a Combination Product	03/11/2024	
2	NDC:71205-531-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	03/11/2024	
3	NDC:71205-531-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/11/2024	
4	NDC:71205-531-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2021	
5	NDC:71205-531-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2021	
6	NDC:71205-531-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/03/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204097	08/19/2016	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-531) , RELABEL(71205-531)