

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated

Padagis Israel Pharmaceuticals Ltd

Fexofenadine Hydrochloride Tablets, 180 mg Drug Facts

Active ingredient (in each 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

- do not use if printed foil under cap is broken or missing
- store between 20° -25°C (68° -77°F)
- protect from excessive moisture
- this product meets the requirements of USP *Dissolution Test 2*

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Allegra® Allergy active ingredient

Fexofenadine Hydrochloride Tablets, 180 mg

Antihistamine

24 HR

Indoor/Outdoor Allergy Relief

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

NON-DROWSY

Allergy

actual size

100 TABLETS

Padagis™



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-847

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	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	PINK	Score	no score	
Shape	OVAL	Size	18mm	
Flavor		Imprint Code	L847	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-847-78	1 in 1 CARTON	01/07/2022	
1		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	ANDA212971		01/07/2022	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

