

TOPCARE FEXOFENADINE HYDROCHLORIDE- fexofenadine hcl tablet, film coated
Topco Associates LLC

Topco Associates LLC. Fexofenadine Hydrochloride Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCl 60 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 60 mg tablet with water every 12 hours; do not take more than 2 tablets in 24 hours
children under 12 years of	do not use

age	
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information

- do not use if blister unit is broken or torn
- store at 20°-25°C (68°-77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 3

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

ORIGINAL PRESCRIPTION STRENGTH

12-HOUR

Fexofenadine Hydrochloride Tablets, 60 mg

ANTIHISTAMINE

Allergy

INDOOR & OUTDOOR ALLERGIES

Relief of:

Sneezing

Runny nose

Itchy, watery eyes

Itchy nose or throat

NON-DROWSY

actual size

COMPARE TO ALLEGRA® ALLERGY active ingredient

60 mg EACH



TopCare®

12-HOUR

Fexofenadine Hydrochloride

Tablets, 60 mg

ANTIHISTAMINE

Allergy



NDC 36800-425-53

ORIGINAL PRESCRIPTION STRENGTH

12-HOUR

Fexofenadine Hydrochloride

Tablets, 60 mg

ANTIHISTAMINE

Allergy

INDOOR & OUTDOOR ALLERGIES

Relief of:

- Sneezing • Runny nose • Itchy, watery eyes
- Itchy nose or throat

NON-DROWSY



actual size



COMPARE TO ALLEGRA® ALLERGY active ingredient*

12 TABLETS • 60 mg EACH

42553 AB C1

Code Area

TopCare®

CONVENIENT RECLOSING TAB



This TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

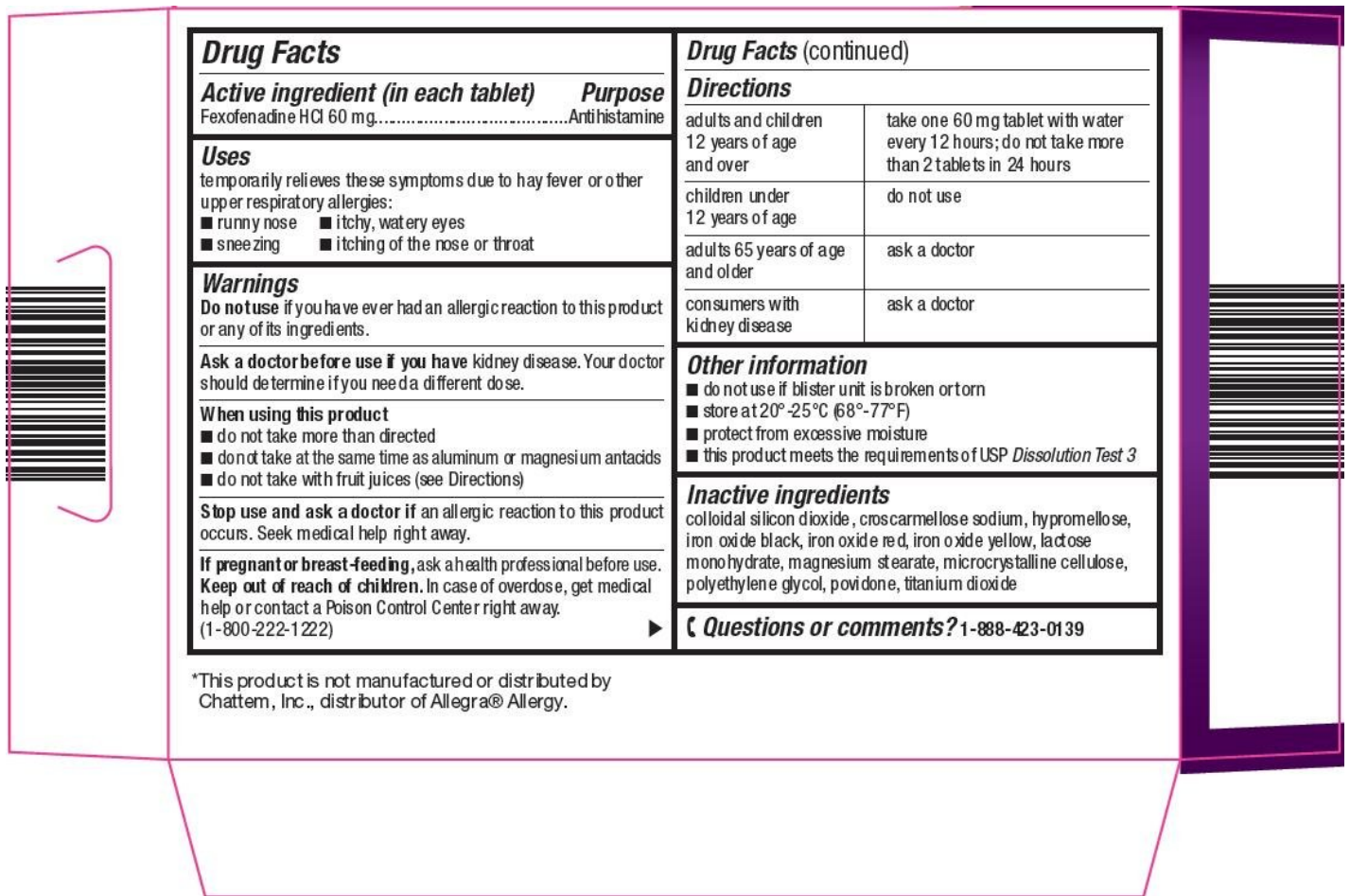
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Fexofenadine Hydrochloride Carton Image 1



Fexofenadine Hydrochloride Carton Image 2

TOPCARE FEXOFENADINE HYDROCHLORIDE

fexofenadine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-425
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	60 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSO FERRIC O XIDE (UNII: XM0M87F357)	
FERRIC O XIDE RED (UNII: 1K09F3G675)	
FERRIC O XIDE YELLOW (UNII: EX438O2MRT)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	ORANGE (Peach)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	93;7252
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-425-53	2 in 1 CARTON		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076447	09/02/2011	

Labeler - Topco Associates LLC (006935977)