

**FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet  
Granules India Ltd**

-----  
**Fexofenadine HCl Tablets USP, 60 mg and 180 mg**

**ACTIVE INGREDIENT(S)**

Fexofenadine HCl USP 60 mg (for 60 mg)

Fexofenadine HCl USP 180 mg (for 180 mg)

**PURPOSE**

Antihistamine

**USE(S)**

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

- runny nose
- itchy, water 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.

## 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 (for 60 mg) take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours (for 180 mg)
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 foil printed with granules logo under bottle cap is opened or torn.
- Do not use if carton is opened or if individual blister units are torn or opened.
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

## INACTIVE INGREDIENTS

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide.

## QUESTIONS OR COMMENTS

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

Manufactured By:

**Granules India Limited**

Hyderabad-500 081, India

**MADE IN INDIA**

Distributed By:

**Granules USA, Inc.**

Parsippany, NJ 07054

## PRINCIPAL DISPLAY PANEL

# Fexofenadine Hydrochloride Tablets USP, 180 mg

Each Film coated Tablet contains

Fexofenadine Hydrochloride USP 180 mg.

Batch No. : 7660001A

Mfg. Dt. : 07/2020

Exp. Dt. : 06/2022

Mfg.Lic.No.: 37/RR/AP/2003/F/R

NDC No. : 62207-766-35

No. of Units : 5 x 5000

Gross Wt. : 00.000 Kg

Tare Wt. : 00.000 Kg

Net Wt. : 00.000 Kg

Box No. : 000

Storage : Store between 20° and 25°C (68° and 77° F) protective from excessive moisture

Caution : For repacking only.



(01)50362207766352(17)220600(10)7660001A

Country of Origin: INDIA



(00)18903832000000004

GIL/PL/041C



Manufactured by:

**Granules India Limited**

Sy.No.160/A, 161/E, 162, & 174/A, Gagillapur Village,  
Dundigal-Gandimaisamma Mandal, Medchal-Malkajgiri District - 500043,  
Telangana, INDIA

FG Code: 700000002249

LOT:  
EXP: Un Varnish area

NDC 62207-765-51

NON-DROWSY

# Fexofenadine HCl Tablets, USP

60 mg

## Antihistamine

INDOOR / OUTDOOR ALLERGY  
RELIEF

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



10 Tablets



\*Compare to the active ingredient in  
ALLEGRA® ALLERGY 12 HOUR

### Drug Facts

**Active ingredient.....Purpose**  
(in each tablet)  
Fexofenadine HCl USP, 60 mg....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.

### Drug Facts (continued)

#### 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 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 foil printed with granules logo under bottle cap is opened or torn.
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

#### Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide.

#### Questions or comments?

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

Manufactured By:  
**Granules India Limited**  
Hyderabad – 500 081, India

**MADE IN INDIA**

Distributed By:  
**Granules USA, Inc.**  
Parsippany, NJ 07054

\*This product is not manufactured or distributed by Chattem, Inc., distributor of Allegra® Allergy 12 Hour

XXXXXXXXXXXX  
M. L. No.: 37/RR/AP/2003/F/R



Labeling Format Information	
Format	Description
Font Style	Helvetica Norm., Bold, Italic
Drug Facts	10 pt
Drug Facts (continued)	9 pt
Headings	8 pt
Body Text	7 pt
Bullet (solid square)	5 pt
Barline	2 pt
Headline	6.5 pt
Drug Title	18.5 pt
Justification	Left

Un Varnish area

EXP:  
LOT:

NDC 62207-766-51

NON-DROWSY

# Fexofenadine HCl Tablets, USP 180 mg



## Antihistamine

INDOOR / OUTDOOR ALLERGY  
RELIEF

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

10 Tablets



\*Compare to the active ingredient in ALLEGRA®  
ALLERGY 24 HOUR

### Drug Facts

**Active ingredient.....Purpose  
(in each tablet)**  
Fexofenadine HCl USP, 180 mg..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.

### 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

- safety sealed: do not use if foil printed with granules logo under bottle cap is opened or torn.
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

#### Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide.

#### Questions or comments?

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

Manufactured By:  
**Granules India Limited**  
Hyderabad – 500 081, India

**MADE IN INDIA**

Distributed By:  
**Granules USA, Inc.**  
Parsippany, NJ 07054

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

XXXXXXXXXXXX

M. L. No.: 37/RR/AP/2003/F/R



Labeling Format Information	
Format	Description
Font Style	Helvetica Norm., Bold, Italic
Drug Facts	10 pt
Drug Facts (continued)	9 pt
Headings	8 pt
Body Text	7 pt
Bullet (solid square)	5 pt
Barline	2 pt
Barline	1.5 pt
Drug Title	15.5 pt
Justification	Left

# Fexofenadine Hydrochloride Tablets USP, 60 mg

Each Film Coated Tablet Contains  
Fexofenadine Hydrochloride USP, 60 mg.

Batch No. : XXXXXXXX No. of Units : 10000

Mfg. Dt. : MM/YYYY

Exp. Dt. : MM/YYYY

Mfg.Lic.No. : 37/RR/AP/2003/F/R

NDC No. : 62207-765-88

Storage : Store between 20° and 25°C (68° and 77° F) protect from excessive moisture

Caution :For repacking only.

Country of Origin: INDIA

FD Code: 7/0101012803

# Fexofenadine Hydrochloride Tablets USP, 60 mg

Each Film Coated Tablet Contains  
Fexofenadine Hydrochloride USP, 60 mg.

Batch No. : XXXXXXXX No. of Units : 5 x 10000

Mfg. Dt. : MM/YYYY Gross Wt. : 00.000 Kg

Exp. Dt. : MM/YYYY Tare Wt. : 00.000 Kg

Mfg.Lic.No. : 37/RR/AP/2003/F/R Net Wt. : 00.000 Kg

NDC No. : 62207-765-88 Box No. : 000

Storage : Store between 20° and 25°C (68° and 77° F) protect from excessive moisture

Caution :For repacking only.



(01)5030220776581(17)090010(10)XXXXXX

Country of Origin: INDIA



(01)189323200000334

FD Code: 7/0101012803

## FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62207-765
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FEXOFENADINE HYDROCHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX43802MRT)	
<b>HYPROMELLOSE 2910 (15 MPA.S)</b> (UNII: 36SFW2JZ0W)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	orange (PEACH)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	G5
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-765-51	1 in 1 CARTON	12/18/2020	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62207-765-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	
3	NDC:62207-765-60	8 in 1 CARTON	12/18/2020	
3		9 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:62207-765-88	5 in 1 BOX	11/17/2021	
4		10000 in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211075	12/18/2020	

## FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62207-766
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FEXOFENADINE HYDROCHLORIDE</b> (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYPROMELLOSE 2910 (15 MPA.S)</b> (UNII: 36SFW2JZ0W)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	orange (PEACH)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Capsule-shaped)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	G6
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-766-51	1 in 1 CARTON	12/18/2020	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62207-766-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	
3	NDC:62207-766-58	7 in 1 CARTON	12/18/2020	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:62207-766-35	25000 in 1 BOX; Type 0: Not a Combination Product	12/18/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------



ANDA	ANDA211075	12/18/2020	
------	------------	------------	--

**Labeler** - Granules India Ltd (915000087)

Revised: 1/2023

Granules India Ltd