

**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

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?

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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	10.5 pt
Justification	Left

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
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children under 12 years of age	do not use
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adults 65 years of age and older	ask a doctor
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consumers with kidney disease	ask a doctor
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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?

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Parsippany, NJ 07054

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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

Fexofenadine Hydrochloride Tablets USP, 60 mg

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

Batch No. : XXXXXXX	No. of Units : 5 x 10000
Mfg. Dt. : YYYY/MM	Gross Wt. : 00.000 Kg
Exp. Dt. : YYYY/MM	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° - 25°C (68° - 77° F) protect from excessive moisture

Caution :For repacking only.



(01)50362207765881(17)YYMMDD(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

FG Code: 700000002803

Fexofenadine Hydrochloride Tablets USP, 180 mg

Each Film coated Tablet contains
Fexofenadine Hydrochloride USP 180 mg.

Batch No. : XXXXXXX	No. of Units : 5 x 5000
Mfg. Dt. : YYYY/MM	Gross Wt. : 00.000 Kg
Exp. Dt. : YYYY/MM	Tare Wt. : 00.000 Kg
Mfg.Lic.No. : 37/RR/AP/2003/F/R	Net Wt. : 00.000 Kg
NDC No. : 62207-766-35	Box No. : 000

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

Caution : For repacking only.



(01)50362207766352(17)YYMMDD(10)XXXXXXX

Country of Origin: INDIA



(00)189038320000000004

FG Code: 700000002249

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3S)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

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		
	NDC:62207-765			

4	NDC:62207-766-88	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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-766
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

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: 8/2025

Granules India Ltd