

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

Fexofenadine HCl Tablets USP, 60 mg and 180 mg

Active ingredient (in each tablet)

Fexofenadine HCl USP, 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.

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 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

ammonium hydroxide, colloidal silicon dioxide, croscarmellose sodium, D & C Red 33, ferrousferic oxide, FD & C blue 1, FD & C yellow 6, gelatin, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac, 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 180 mg - 24s Container Label

NDC 62207-623-41

NON-DROWSY

Fexofenadine HCl

Tablets USP, 180 mg

Allergy

Antihistamine

INDOOR / OUTDOOR ALLERGY RELIEF 24HR

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

24 GELCAPS

Gel Coated Tablets

***Compare to the active ingredient in**

Allegra[®] Allergy 24 HOUR

NDC 62207-623-41

NON-DROWSY

Fexofenadine HCl
Tablets USP, 180 mg

Allergy

Antihistamine
INDOOR / OUTDOOR ALLERGY
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- Sneezing
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24 GELCAPS
Gel Coated 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

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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



N 3 16 2 2 0 7 1 6 2 3 4 1 4

LOT:
EXP:



Glue area
20 mm

Drug Facts (continued)

Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.

When using this product

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- do not take at the same time as aluminum or magnesium antacids
- do not take with fruit juices (see Directions)

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Drug Facts (continued)

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 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours
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Glue area
20 mm

Drug Facts (continued)

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)

Drug Facts (continued)

- protect from excessive moisture

Inactive ingredients

ammonium hydroxide, colloidal silicon dioxide, croscarmellose sodium, D & C Red 33, ferrousferic oxide, FD & C blue 1, FD & C yellow 6, gelatin, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, propylene glycol, shellac, titanium dioxide.

Questions or comments?

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Mon-Fri 8:00 AM EST to 5:00 PM PST.

PRINCIPAL DISPLAY PANEL 180 mg -24s Container Carton

NDC 62207-623-41
NON-DROWSY

**Fexofenadine HCl
Tablets, USP**

180 mg

Allergy

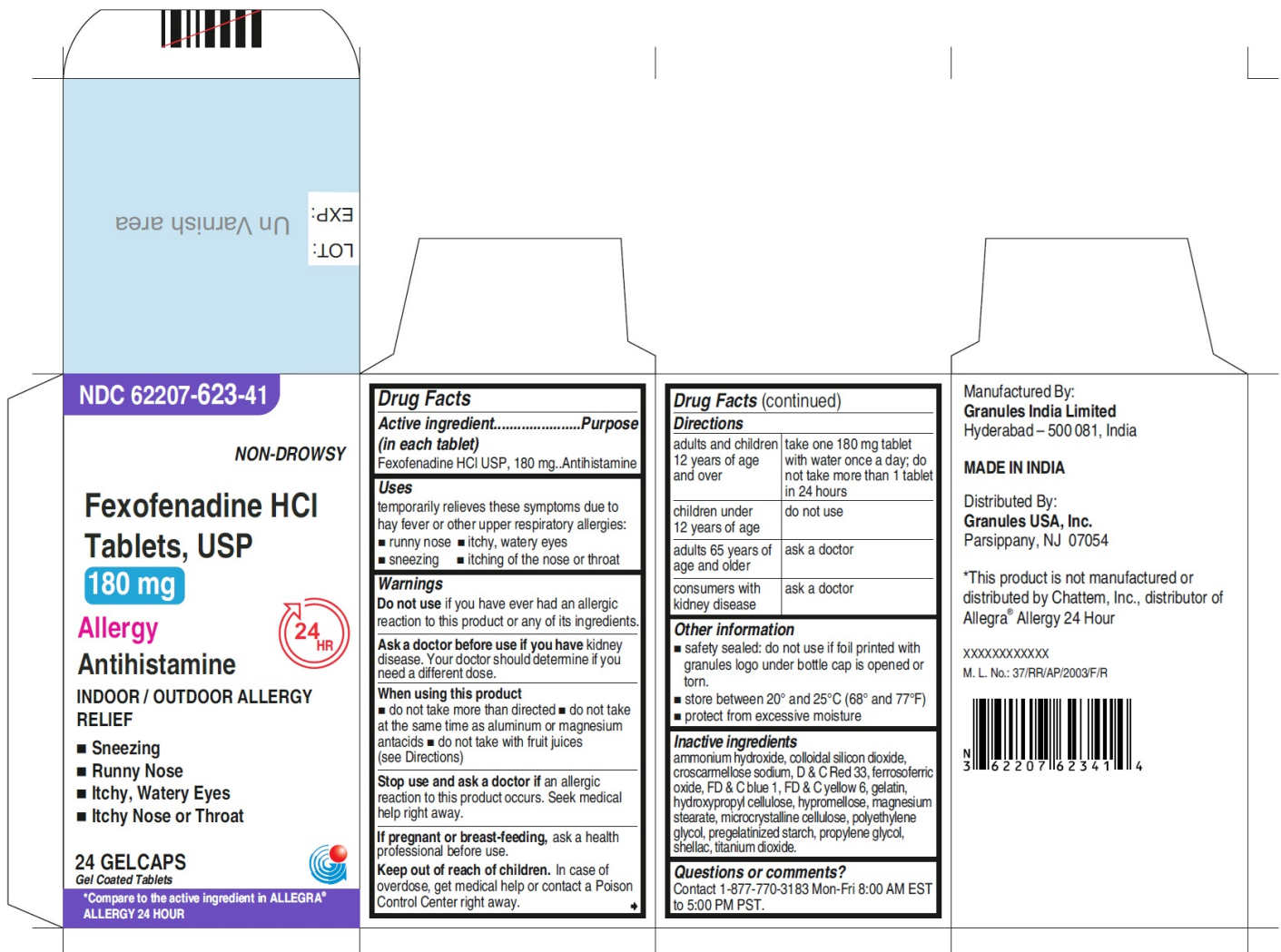
**Antihistamine
INDOOR / OUTDOOR ALLERGY
RELIEF 24 HR**

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

**24 GELCAPS
Gel Coated Tablets**

***Compare to the active ingredient in Allegra®**

Allergy 24 HOUR



PRINCIPAL DISPLAY PANEL 180 mg - Blister Carton

NDC 62207-623-71

NON-DROWSY

Fexofenadine HCl Tablets USP, 180 mg

Allergy

Antihistamine

INDOOR / OUTDOOR ALLERGY

RELIEF 24 HR

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

70 (7x10) GELCAPS

Gel Coated Tablets

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

NDC 62207-623-71

NON-DROWSY

Fexofenadine HCl Tablets USP, 180 mg

Allergy

Antihistamine

INDOOR / OUTDOOR ALLERGY RELIEF



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

70 (7 x 10) GELCAPS
Gel Coated Tablets

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

LOT:
EXP:

Un varnish area

Drug Facts

Active ingredient (in each tablet).....	Purpose
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

XXXXXXXXXX

Drug Facts (continued)

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
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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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Other information

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Drug Facts (continued)

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Drug Facts (continued)

Questions or comments ?

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



N 31 62207 162371 1

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 Chatham, Inc., distributor of Allegra® Allergy 24 Hour

M.L.No.: 37/R/RAP/2003/F/R

PRINCIPAL DISPLAY PANEL 180 mg - Blister Foil

NDC 62207-623-71
Fexofenadine HCl
Tablet USP, 180 mg
Allergy

Antihistamine (GELCAP)
Mfg. by: Granules India Limited
Made in India

M.L.No.: 37/RR/AP/2003/F/R **24 HR**
Push tablet through foil

LOT#

EXP. DATE:

NDC 62207-623-71

Fexofenadine HCl
Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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

Push tablet through foil



LOT#

EXP. DATE:

NDC 62207-623-71

Fexofenadine HCl
Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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

Push tablet through foil



LOT#

EXP. DATE:

NDC 62207-623-71

Fexofenadine HCl
Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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

Push tablet through foil



LOT#

EXP. DATE:

NDC 62207-623-71

Fexofenadine HCl
Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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

Push tablet through foil



LOT#

EXP. DATE:

NDC 62207-623-71

Fexofenadine HCl
Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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

Push tablet through foil



LOT#

EXP. DATE:

NDC 62207-623-71

Fexofenadine HCl
Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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

Push tablet through foil



LOT#

EXP. DATE:

NDC 62207-623-71

Fexofenadine HCl



NDC 62207-623-71

Fexofenadine HCl



Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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

Push tablet through foil

LOT#

EXP. DATE:



Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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Push tablet through foil

LOT#

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NDC 62207-623-71

Fexofenadine HCl

Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

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Made in India

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

Push tablet through foil

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NDC 62207-623-71

Fexofenadine HCl

Tablet USP, 180 mg

Allergy

Antihistamine (GELCAP)

Mfg. by: Granules India Limited

Made in India

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

Push tablet through foil

LOT#

EXP. DATE:



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-623
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STARCH, CORN (UNII: O8232NY3SJ)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
SHELLAC (UNII: 46N107B71O)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
AMMONIA (UNII: 5138Q19F1X)

Product Characteristics

Color	gray (WHITE BAND IN THE MIDDLE)	Score	no score
Shape	OVAL (capsule shaped)	Size	20mm
Flavor		Imprint Code	G18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-623-71	7 in 1 CARTON	01/02/2024	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:62207-623-41	24 in 1 CONTAINER; Type 0: Not a Combination Product	01/02/2024	
3	NDC:62207-623-57	90 in 1 CONTAINER; Type 0: Not a Combination Product	01/02/2024	
4	NDC:62207-623-45	225 in 1 CONTAINER; Type 0: Not a Combination Product	01/02/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211075	01/02/2024	

Labeler - Granules India Limited (915000087)