

FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet, film coated
Granules India Limited

Fexofenadine HCl Tablets USP, 60 mg and 180 mg

Active ingredient (in each tablet)

Fexofenadine HCl USP, 60 mg (for 60 mg)

Fexofenadine HCl USP, 180 mg (for 180 mg)

Purpose

Antihistamine

Uses

reduces hives and relieves itching due to hives (urticaria). This product will not prevent hives or an allergic skin reaction from occurring.

Warnings

Severe Allergy Warning:Get emergency help **immediately** if you have hives along with any of the following symptoms:

- trouble swallowing
- dizziness or loss of consciousness
- swelling of tongue
- swelling in or around mouth
- trouble speaking
- wheezing or problems breathing
- drooling

These symptoms may be signs of anaphylactic shock. This condition can be life threatening if not treated by a health professional **immediately**. Symptoms of anaphylactic shock may occur when hives first appear or up to a few hours later.

Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for “anaphylaxis” or severe allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. If you have been prescribed an epinephrine injector, you should carry it with you at all times.

Do not use

- to **prevent** hives from any known cause such as:
 - foods
 - insect stings
 - medicines

- latex or rubber gloves

because this product will not stop hives from occurring. Avoiding the cause of your hives is the only way to prevent them. Hives can sometimes be serious. If you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you find a cause.

- 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.
- hives that are an unusual color, look bruised or blistered
- hives that do not itch

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.
- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

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.
- 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 60 mg - 10s Container Label

NDC 62207-889-51

New!

NON-DROWSY

Fexofenadine HCl

Tablets, USP 60 mg

Hives

Antihistamine

REDUCES HIVES and

12 HR

RELIEVES ITCHING

due to hives

10 Tablets

***Compare to the active ingredient in**

Allegra[®] Hives 12 HOUR

NDC 62207-889-51

New!

NON-DROWSY

Fexofenadine HCl
Tablets, USP 60 mg

Hives

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Allegra® Hives 12 HOUR

Drug Facts

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XXXXXXXXXXXX

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



LOT:
EXP:

Drug Facts (continued)

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Drug Facts (continued)

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- hives that are an unusual color, look bruised or blistered
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Glue area
20 mm

Drug Facts (continued)

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- symptoms do not improve after 3 days of treatment
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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
children under 12 years of age	do not use

Drug Facts (continued)

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

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Glue area
20 mm

PRINCIPAL DISPLAY PANEL 60 mg - 10s Container Carton

NDC 62207-889-51

New!

NON-DROWSY

Fexofenadine HCl

Tablets, USP

60 mg

Hives

Antihistamine

REDUCES HIVES and

RELIEVES ITCHING

due to hives

12 HR

10 Tablets

***Compare to the active ingredient in**

Allegra ® Hives 12 HOUR



PRINCIPAL DISPLAY PANEL 60 mg - Blister Carton

NDC 62207-889-60

New!

NON-DROWSY

Fexofenadine HCl Tablets USP, 60 mg

Hives

Antihistamine

REDUCES HIVES and

12 HR

RELIEVES ITCHING

due to hives

72 (8 x 9) Tablets

***Compare to the active ingredient in Allegra® Hives 12 HOUR**

NDC 62207-889-60

New!

NON-DROWSY

Fexofenadine HCl Tablets USP, 60 mg

Hives

Antihistamine

REDUCES HIVES and
RELIEVES ITCHING due to hives



72 (8 x 9) Tablets



* Compare to the active ingredient in Allegra® Hives 12 HOUR

Un varnish area

LOT:
EXP:

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Drug Facts (continued)	<ul style="list-style-type: none"> do not use if you have had an allergic reaction to this product or any of its ingredients if you have ever had an allergic reaction to this product help you find a cause if you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you prevent them. Hives can sometimes be serious. Avoiding the cause of your hives is the only way to prevent them. Avoiding the cause of your hives is the only way to prevent them. Avoiding the cause of your hives is the only way to prevent them. if you have had an allergic reaction to this product or any of its ingredients if you have ever had an allergic reaction to this product help you find a cause if you do not know the cause of your hives, see your doctor for a medical exam. Your doctor may be able to help you prevent them. Hives can sometimes be serious. Avoiding the cause of your hives is the only way to prevent them. Avoiding the cause of your hives is the only way to prevent them.
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Drug Facts (continued)

Manufactured by: Granules India Limited
Hyderabad - 500 081, India
MADE IN INDIA
Distributed By: Granules USA, Inc.
Paraspandy, NJ 07054
* This product is not manufactured or distributed by Chatten, Inc., distributor of Allegra® Hives 12 Hour

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

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NON-DROWSY

Fexofenadine HCl

Tablets, USP 180 mg

Hives

Antihistamine

REDUCES HIVES and 24 HR

RELIEVES ITCHING

due to hives

10 Tablets

***Compare to the active ingredient in**

Allegra ® Hives 24 HOUR

NDC 62207-891-51

New!

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



N 3 6 2 2 0 7 1 8 9 1 5 1 6

LOT:
EXP:



Drug Facts (continued)

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Glue area
20 mm

Drug Facts (continued)

- an allergic reaction to this product occurs. Seek medical help right away.

- symptoms do not improve after 3 days of treatment
- the hives have lasted more than 6 weeks

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 every once a day; do not take more than 1 tablet in 24 hours
children under 12 years of age	do not use

Drug Facts (continued)

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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Glue area
20 mm

PRINCIPAL DISPLAY PANEL 180 mg - 10s Container Carton

NDC 62207-891-51

New!

PRINCIPAL DISPLAY PANEL 180 mg - Blister Carton

NDC 62207-891-58

New!

NON-DROWSY

Fexofenadine HCl Tablets USP, 180 mg

Hives

Antihistamine

REDUCES HIVES and

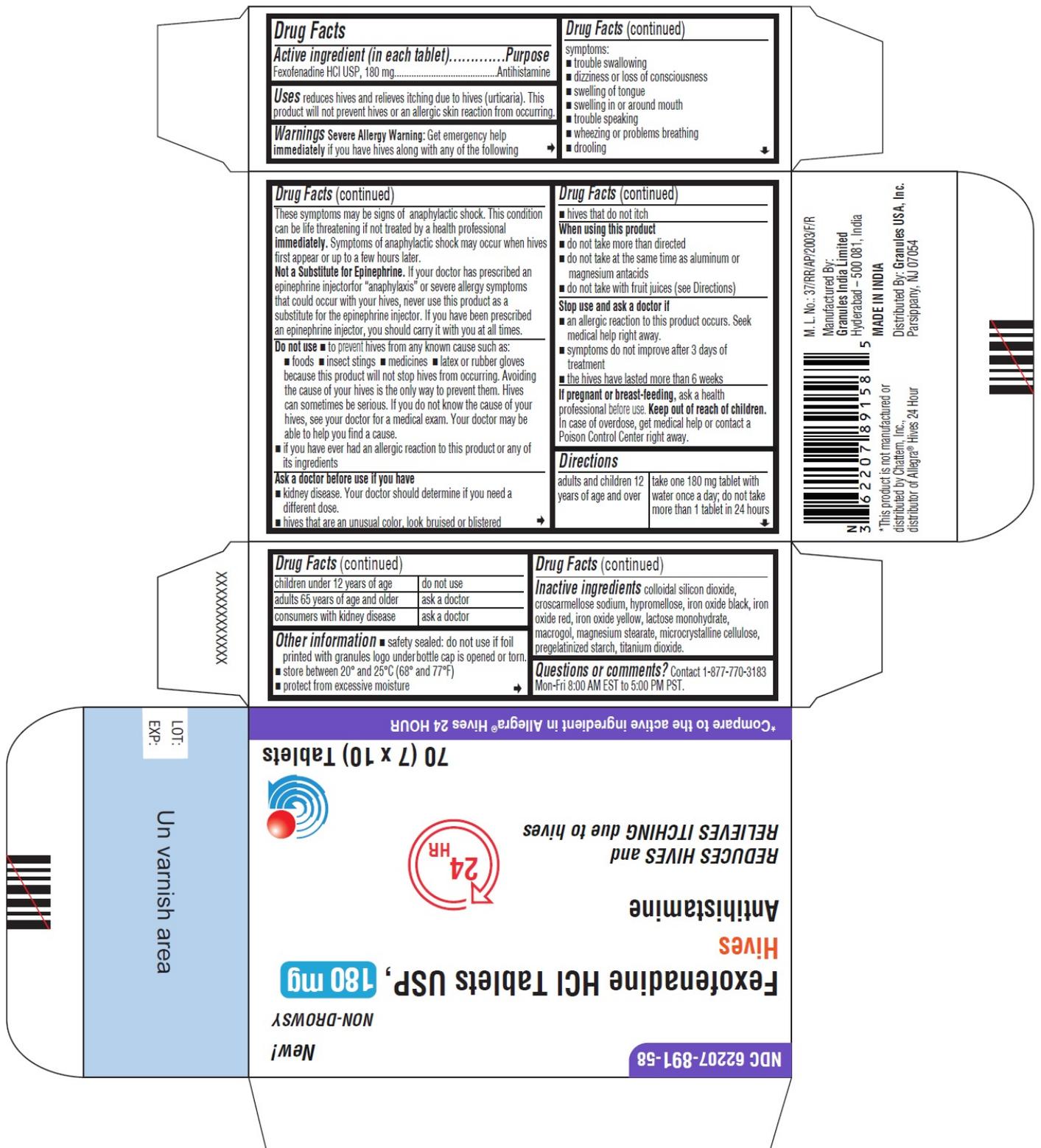
24 HR

RELIEVES ITCHING

due to hives

70 (7 x 10) Tablets

***Compare to the active ingredient in Allegra ® Hives 24 HOUR**



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-889
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: 365FW2JZ0W)	
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	Size	12mm
Flavor		Imprint Code	G5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-889-51	1 in 1 CARTON	11/07/2023	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62207-889-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/07/2023	
3	NDC:62207-889-60	8 in 1 CARTON	11/07/2023	
3		9 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211075	11/07/2023	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62207-891
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)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 365FW2JZ0W)	
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	CAPSULE (CAPSULE)	Size	17mm
Flavor		Imprint Code	G6
Contains			

Packaging

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1	NDC:62207-891-51	1 in 1 CARTON	11/07/2023	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62207-891-49	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/07/2023	
3	NDC:62207-891-58	7 in 1 CARTON	11/07/2023	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination		

Product			
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211075	11/07/2023	

Labeler - Granules India Limited (915000087)

Revised: 11/2023

Granules India Limited