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

Fexofenadine HCI Tablets USP, 60 mg and 180 mg

Active ingredient (in each tablet)

Fexofenadine HCI USP, 60 mg (for 60 mg)

Fexofenadine HCI 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 preventhives 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^o and 25^oC (68^o and 77^oF)

• 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

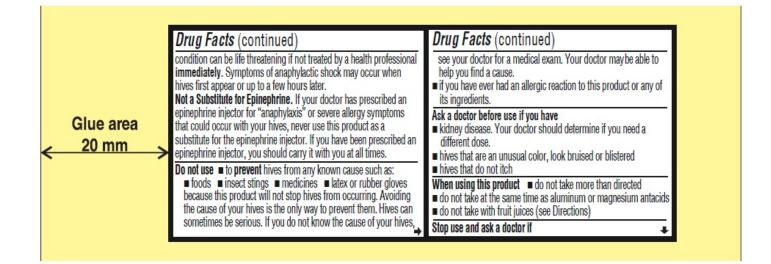
Distributed By: **Granules USA, Inc.** Parsippany, NJ 07054

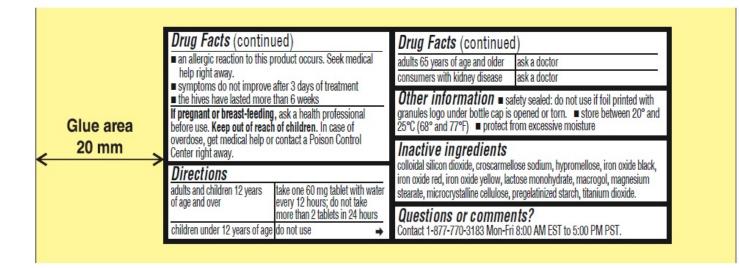
PRINCIPAL DISPLAY PANEL 60 mg - 10s Container Label

NDC 62207-889-51	New!
	NON-DROWSY
Fexofenadine HCI	
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







PRINCIPAL DISPLAY PANEL 60 mg - 10s Container Carton NDC 62207-889-51

New!

NON-DROWSY

Fexofenadine HCI 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

12 HR

Fexofenadine HCI 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

	NDC 62207-889-60 New!		
	NON-DROWSY Fexofenadine HCI Tablets USP, 60 mg Hives Antihistamine REDUCES HIVES and RELIEVES ITCHING due to hives	Un varnish area	
	N 3 4 5 5 72 (8 x 9) Tablets *Compare to the active ingredient in Allegra® Hives 12 HOUR	LOT: EXP: Ur	
	Drug Facts (continued) Drug Facts (continued) adults and children 12 years Of not use Offher information vears of age and over implements Dirug Facts (continued) Dirug Facts (continued) vears of age and over implements Dirug Facts (continued) Dirug Facts (continued) vears of age and over implements Dirug Facts (continued) Dirug Facts (continued) of adults 65 years of age and actor = stely sealed on trace = stely sealed in trace of adults 65 years of age and actor = stely sealed in trace = stely sealed in trace of adults 66 years of age and actor = stely sealed in trace = stely sealed in trace of adults 66 years of age and actor = stely sealed in trace = stely sealed in trace of adults 66 years of age and actor = stely sealed in trace = stely sealed in trace of adults 66 years of age and actor = stely sealed in trace = stely sealed in trace of adults 66 years of age and actor = stely sealed in trace = stely sealed in trace of adults 66 years of age and actor = stely sealed in trace = stely sealed in trace of adults 66 years of age and actor = stely sealed in trace = stely sealed in trace of adults 66 years of ade adu		
Drug Facts (continued) M. L. No.: 37/RR/AP/2003/F/R hypromeloss, iron oxide back, iron oxide red, iron oxide peak, iron oxide red, iron oxide	 condition can be life threated by a health product any confessional immediately. Symptoms of anaphylacis show for use its does not account when hives that could occur with your does that any its account of the product index o		
WFFR XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	Drug Facts Drug Facts Continued Drug Facts Drug Facts Drug Facts Drug Facts Active ingredient (in each tablet) Punpace Punpace Factorea hives ingredient (in each tablet) Punpace Punpace Factorea hives income Ponug Facts Pace solong Uss of und control Pace solong Punpace Uss of und control Pace solong Punpace Uss of und control Punpace Pace solong Uss of und control Punpace Pace solong Uss of und control Punpace Punpace Punpace Punpace		

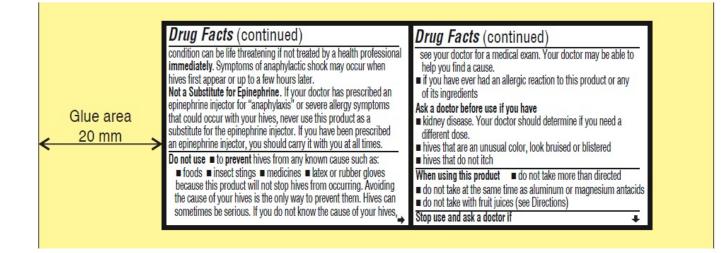
PRINCIPAL DISPLAY PANEL 180 mg - 10s Container Label

NDC 62207-891-51

NON-DROWSY

Fexofenadine HCI 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





	Drug Facts (continued) an allergic reaction to this product occurs. Seek medical help right away.	Drug Facts (continued) adults 65 years of age and older ask a doctor consumers with kidney disease ask a doctor	
Glue area 20 mm	 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 	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	
	overdose, get medical help or contact a Poison Control Center right away. Directions adults and children 12 years [take one 180 mg tablet with water]	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.	
	of age and over every once a day; do not take more than 1 tablet in 24 hours children under 12 years of age do not use	Questions or comments? Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.	

PRINCIPAL DISPLAY PANEL 180 mg - 10s Container Carton NDC 62207-891-51

New!

NON-DROWSY

- Fexofenadine HCI Tablets, USP 180 mg Hives Antihistamine *REDUCES HIVES and* 24 HR *RELIEVES ITCHING due to hives*
- **10 Tablets**

*Compare to the active ingredient in

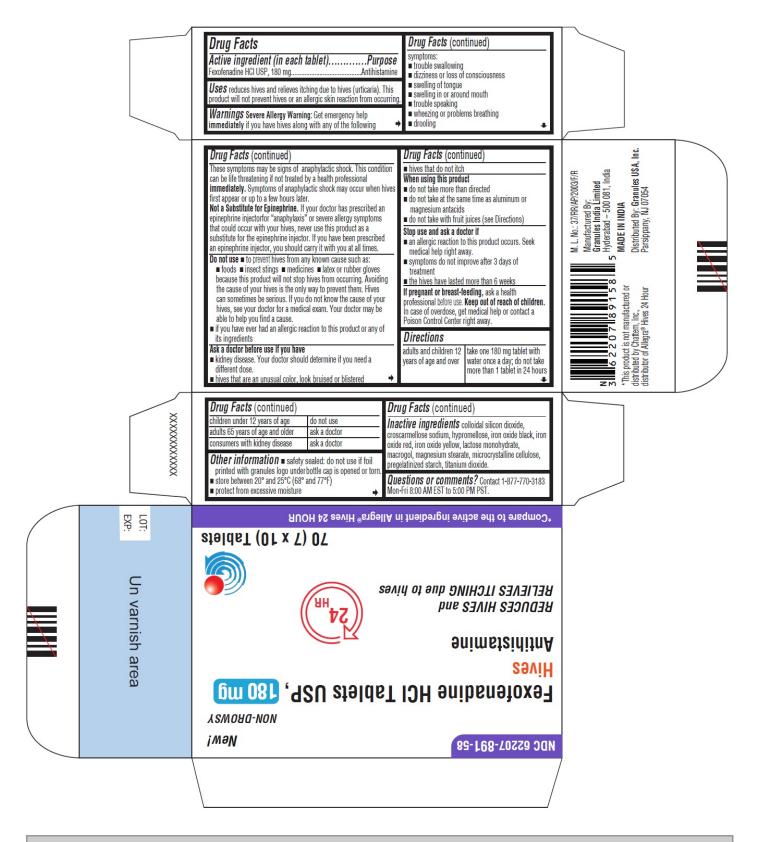
Allegra ® Hives 24 HOUR

נסד: ExP: Un Varnish агеа		
NDC 62207-891-51 New! NON-DROWSY	Drug Facts Active ingredient (in each tablet)Purpose Feorenadine HCI USP, 180 mgAntihistamine Uses reduces hives and relieves itching due to hives (urticaria). This product	Drug Facts (continued) inves that are an unusual color, look bruised or blistered inves that on thich When using this product do not take more than directed do not take at the same time as aluminum or magnesium antacids
Fexofenadine HCI	will not prevent hives or an allergic skin reaction from occurring.	do not take with fruit juices (see Directions) sop use and ask a defort if an alleric reaction to this product occurs. Seek medical help Hyderabad - 500 081, India
Tablets, USP	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	right arway.
180 mg	 swelling of tongue swelling in or around mouth trouble speaking wheezing or problems breathing drooling 	If pregnant or breast-feeding, ask a health professional before use. Keep out of reash of children. In case of overdoes, get medical help or contast A children. In case of overdoes, get medical Granules USA, Inc.
Hives (24 _{HR})	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	Parsippany, NJ 07054 <u>Directions</u> adults and children 12 years take one 180 mg tablet with water every *This product is not manufactured or distributed by
Antihistamine	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	of age and over once a day do not take more than 1 tablet in 24 hours. Chattern, Inc., distributor of Allegra® Hives 24 Hour Chattern, Inc., distributor of Allegra® Hives 24 Hour
REDUCES HIVES and RELIEVES ITCHING due to hives	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.	adjet adults 65 years of age ask a doctor and older M. L. No.: 37/RR/AP/2003/F/R
	Do not use to prevent hives from any known cause such as: foods in insect stings in medicines in latex or rubber gloves	consumers with ask a doctor kidney disease
	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 hele you find a cause.	Other information stafely scalad: do not used for printed with granules logo under bottle cap is operated or torn. store between 20° and 25°C (60° and 72°F) protect from excessive moisture
10 Tablets 🕑	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	Inactive ingredients colloidal silicon dioxide, croscammellose sodium, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, lactose monohydrate, macropol,
*Compare to the active ingredient in Allegra® Hives 24 HOUR	■ kidney disease. Your doctor should determine if you need a different dose.	magnesium stearate, microcrystalline cellulose, pregelatinized starch, titanium dioxide.

PRINCIPAL DISPLAY PANEL 180 mg - Blister Carton NDC 62207-891-58 New! NON-DROWSY Fexofenadine HCI 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					

	Ingredient Name			Basis of St	renath	Strength
FEXOFENADINE HYDRC UNII:E6582LOH6V)	CHLORIDE (UNII: 2S068B75ZU) (I	EXOFENAD		FEXOFENADINE HYDROCHLORIDE	•	60 mg
Inactive Ingredie	ate					
mactive mgreater	Ingredient Name	•			St	rength
CROSCARMELLOSE SO	DIUM (UNII: M28OL1HH48)	•				lengen
FERROSOFERRIC OXID						
FERRIC OXIDE RED (UN						
FERRIC OXIDE YELLOW	(UNII: EX43802MRT)					
HYPROMELLOSE 2910	(15 MPA.S) (UNII: 36SFW2JZ0W)					
LACTOSE MONOHYDRA	TE (UNII: EWQ57Q8I5X)					
MAGNESIUM STEARATE	E (UNII: 70097M6I30)					
MICROCRYSTALLINE C	ELLULOSE (UNII: OP1R32D61U)					
POLYETHYLENE GLYCO	L 6000 (UNII: 30IQX730WE)					
SILICON DIOXIDE (UNII:	ETJ7Z6XBU4)					
STARCH, CORN (UNII: O	8232NY3SJ)					
TITANIUM DIOXIDE (UN	II: 15FIX9V2JP)					
Product Characte	ristics					
Color	orange (PEACH)	Score			no scor	e
Shape	OVAL	Size			12mm	
Flavor		Imprint	t Code		G5	
Contains						
Packaging						
Packaging # Item Code	Package Description			eting Start Date		ting End

I					
	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		
I					

Marketing Information

U.

Category	Citation	Marketing Start Date	Marketing End Date
ANDA ANDA211075		11/07/2023	

			ROCHLORIDE blet, film coated						
Ρ	roduct Infor	mation							
Ρ	roduct Type HUMAN OTC DRUG Item Code (Source) NDC:62207-891)7-891	
		istration	ORAL		• • • •				
	Route of Administration ORAL								
Α	ctive Inared	ient/Active	Moietv						
	Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength								
FF		•	E (UNII: 2S068B75ZU) (FE)		INF -	FEXOFENADINE	lengti		
	NII:E6582LOH6V)					HYDROCHLORID	E	180 mg	
Ir	active Ingre	edients							
			Ingredient Name				St	rength	
С	ROSCARMELLOS	E SODIUM (UN	II: M28OL1HH48)						
FE	RROSOFERRIC	OXIDE (UNII: XM	10M87F357)						
	RRIC OXIDE RE								
	RRIC OXIDE YE								
			S) (UNII: 36SFW2JZOW)						
LA	CTOSE MONOH	IYDRATE (UNII:	EWQ57Q8I5X)						
	AGNESIUM STEA								
			(UNII: OP1R32D61U)						
			JNII: 30IQX730WE)						
	LICON DIOXIDE	-							
	TARCH, CORN (U		~						
TI	TANIUM DIOXID	E (UNII: 15FIX9V	2JP)						
Ρ	roduct Chara	acteristics							
С	olor	orange (PE	ACH)	Sco	re		no sco	ore	
SI	паре	CAPSULE (CAPSULE)	Size	e		17mm		
FI	avor			Imp	rint Co	de	G6		
С	ontains								
P	ackaging								
#	ltem Code	Pa	ckage Description		Mark	eting Start Date		ting End ate	
1	NDC:62207- 891-51	1 in 1 CARTON			11/07/2	023			
1		10 in 1 BOTTLE Product	; Type 0: Not a Combinatio	'n					
2	NDC:62207- 891-49	1000 in 1 BOTT Product	LE; Type 0: Not a Combina	tion	11/07/2	023			
3	NDC:62207- 891-58								
			R PACK; Type 0: Not a Com						

3	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