

FEXOFENADINE- fexofenadine tablet, film coated
Wockhardt USA LLC.

Fexofenadine Tablets

Active ingredient (in each tablet)

For 30 mg:

Fexofenadine HCl 30 mg

For 60 mg:

Fexofenadine HCl 60 mg

For 180 mg:

Fexofenadine HCl 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
- drooling
- wheezing or problems breathing

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

For 30 mg:

adults and children 12 years of age and over	take two 30 mg tablets with water every 12 hours; do not take more than 4 tablets in 24 hours
children 6 to under 12 years of age	take one 30 mg tablet with water every 12 hours; do not take more than 2 tablets in 24 hours
children under 6 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

For 60 mg:

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

For 180 mg:

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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 open or if individual blister unit is torn or open
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone K-30, talc, titanium dioxide

Questions or comments?

Call toll-free **1-800-346-6854**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 64679-744-06

Children's
Fexofenadine HCl Tablet, USP

30 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

TEAR



NDC 64679-744-06

Children's
Fexofenadine HCl Tablet, USP

30 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

TEAR

NDC 64679-744-06

Children's
Fexofenadine HCl Tablet, USP

30 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

TEAR



NDC 64679-744-06

Children's
Fexofenadine HCl Tablet, USP

30 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-744-06

Children's
Fexofenadine HCl Tablet, USP

30 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-744-06

Children's
Fexofenadine HCl Tablet, USP

30 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCl 30 mgAntihistamine

Purpose

Uses

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

Drug Facts (continued)

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
 - drooling
 - wheezing or problems breathing
- 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 two 30 mg tablets with water every 12 hours; do not take more than 4 tablets in 24 hours
children 6 to under 12 years of age	take one 30 mg tablet with water every 12 hours; do not take more than 2 tablets in 24 hours
children under 6 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 open or if individual blister unit is torn or open
- store at 20° to 25°C (68° to 77°F) ■ protect from excessive moisture



Non Varnish Area

Lot:
Exp.:

Drug Facts (continued)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone K-30, talc, titanium dioxide

Questions or comments?

Call toll-free 1-800-346-6854

DO NOT USE IF CARTON IS OPEN OR IF
INDIVIDUAL BLISTER UNIT IS TORN OR OPEN

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

NDC 64679-744-07

Children's

Fexofenadine HCl Tablets, USP

30 mg/antihistamine

HIVES

12HOUR

Ages 6 Years

Manufactured by:
Wockhardt
Mumbai, India
Iss. 151211

red by:
Distributed by:
Wockhardt USA LLC.
20 Waterview Blvd.
Parsippany, NJ 07054
USA.

and Older

RELIEF OF
ITCHING DUE
TO HIVES



6 Tablets 30 mg each

NDC 64679-982-06

Fexofenadine HCl Tablet, USP

60 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-982-06

Fexofenadine HCl Tablet, USP

60 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-982-06

Fexofenadine HCl Tablet, USP

60 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-982-06

Fexofenadine HCl Tablet, USP

60 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-982-06

Fexofenadine HCl Tablet, USP

60 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-982-06

Fexofenadine HCl Tablet, USP

60 mg 12 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR



TEAR



Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCl 60 mgAntihistamine

Purpose

Uses

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

Drug Facts (continued)

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
 - drooling
 - wheezing or problems breathing
- 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 glovesbecause 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
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 open or if individual blister unit is torn or open
- store at 20° to 25°C (68° to 77°F)
- protect from excessive moisture



Non Varnish Area

Lot:
Exp.:

Drug Facts (continued)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone K-30, talc, titanium dioxide

Questions or comments?

Call toll-free 1-800-346-6854

DO NOT USE IF CARTON IS OPEN OR IF
INDIVIDUAL BLISTER UNIT IS TORN OR OPEN

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

NDC 64679-982-07

Fexofenadine HCl Tablets, USP

60 mg/antihistamine

HIVES

12HOUR

RELIEF OF

Manufactured by:
Wockhardt
Mumbai, India
Iss. 151211

red by: **Distributed by:**
Wockhardt USA LLC.
20 Waterview Blvd.
Parsippany, NJ 07054
USA.

ITCHING
DUE TO
HIVES



12 Tablets 60 mg each

NDC 64679-987-07

Fexofenadine HCl Tablet, USP

180 mg 24 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

TEAR



NDC 64679-987-07

Fexofenadine HCl Tablet, USP

180 mg 24 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-987-07

Fexofenadine HCl Tablet, USP

180 mg 24 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

TEAR

NDC 64679-987-07

Fexofenadine HCl Tablet, USP

180 mg 24 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

NDC 64679-987-07

Fexofenadine HCl Tablet, USP

180 mg 24 Hour

HIVES

Distributed by: Wockhardt USA LLC.
Parsippany, NJ 07054, USA.

Lot : Exp.:

TEAR

TEAR



Drug Facts

Active ingredient (in each tablet)

Fexofenadine HCl 180 mgAntihistamine

Purpose

Uses

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

Drug Facts (continued)

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
 - drooling
 - wheezing or problems breathing
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 - insect stings
 - medicines
 - latex or rubber glovesbecause 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.
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- 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

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- 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 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 open or if individual blister unit is torn or open
- store at 20° to 25°C (68° to 77°F)
- protect from excessive moisture



Non Varnish Area

Lot:
Exp.:

Drug Facts (continued)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone K-30, talc, titanium dioxide

Questions or comments?

Call toll-free 1-800-346-6854

DO NOT USE IF CARTON IS OPEN OR IF
INDIVIDUAL BLISTER UNIT IS TORN OR OPEN

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

NDC 64679-987-08

Fexofenadine HCl Tablets, USP

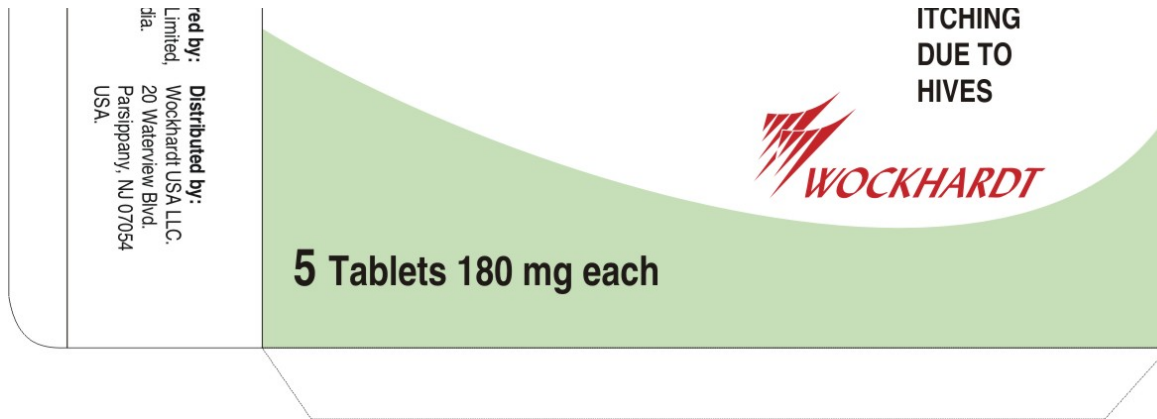
180 mg/antihistamine

HIVES

24HOUR

RELIEF OF

Manufactured by
Wockhardt
Mumbai, India
Iss. 151211



FEXOFENADINE			
fexofenadine tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64679-744
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
FEXO FENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)		FEXOFENADINE HYDROCHLORIDE	30 mg
Inactive Ingredients			
Ingredient Name			Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)			
POVIDONE K30 (UNII: U725QWY32X)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND (round)	Size	7mm
Flavor		Imprint Code	W;30
Contains			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64679-744-07	1 in 1 CARTON		
1	NDC:64679-744-06	6 in 1 BLISTER PACK		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA079112	02/08/2012	

FEXOFENADINE

fexofenadine tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64679-982	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)		FEXO FENADINE HYDROCHLORIDE	60 mg	
Inactive Ingredients				
Ingredient Name			Strength	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
POVIDONE K30 (UNII: U725QWY32X)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE	Score	no score	
Shape	CAPSULE (Capsule)	Size	11mm	
Flavor		Imprint Code	W;982	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:64679-987-07	5 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA079112	02/08/2012		

Labeler - Wockhardt USA LLC. (170508365)

Registrant - Wockhardt USA LLC. (170508365)

Establishment			
Name	Address	ID/FEI	Business Operations
Wockhardt Limited		676257570	Manufacture

Revised: 3/2012

Wockhardt USA LLC.