### FEXOFENADINE- fexofenadine tablet, film coated Wockhardt USA LLC.

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#### **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:

	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**

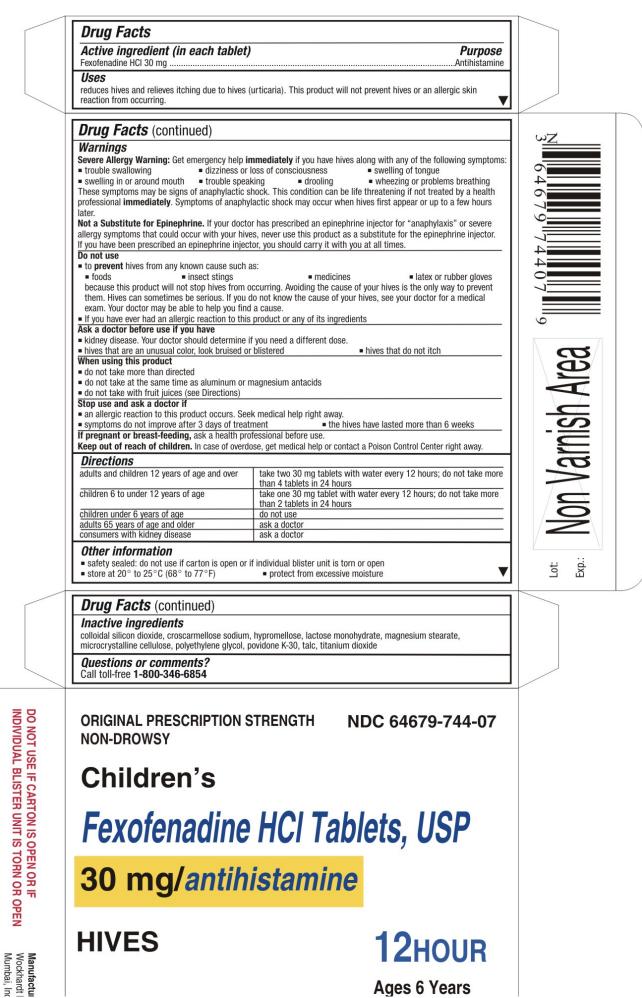
colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone K-30, talc, titanium dioxide

#### Questions or comments?

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

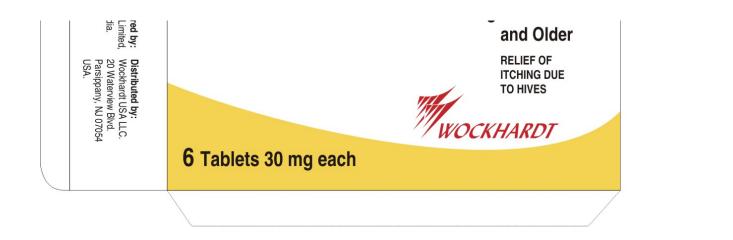
#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 64679-74 Children's Fexofenadi	ne HCI Tablet, USP		NDC 64679-744-06 Children's Fexofenadine HCI Tablet, USP
30 mg	12 Hour	H	<b>30 mg</b> 12 Hour
HIVES		TEAR	HIVES
Distributed by: W Parsippany, NJ 07	/ockhardt USA LLC. 054, USA.		Distributed by: Wockhardt USA LLC. Parsippany, NJ 07054, USA.
Lot : TEAR	Exp.:		Lot : Exp.: TEAR
NDC 64679-74	14-06	ALC MAR	NDC 64679-744-06
Children's Fexofenadi	ne HCI Tablet, USP		Children's Fexofenadine HCI Tablet, USP
30 mg	12 Hour		<b>30 mg</b> 12 Hour
HIVES Distributed by: W Parsippany, NJ 07	/ockhardt USA LLC. 054, USA.	TEAR	HIVES Distributed by: Wockhardt USA LLC. Parsippany, NJ 07054, USA.
Lot : TEAR	Exp.:		Lot : Exp.: TEAR
NDC 64679-74	14-06		NDC 64679-744-06
Children's	na HCI Tablat USD		Children's
	ne HCI Tablet, USP	_	Fexofenadine HCI Tablet, USP
30 mg	12 Hour	TEAR	<b>30 mg</b> 12 Hour
HIVES Distributed by: W Parsippany, NJ 07	/ockhardt USA LLC. 054, USA.		HIVES Distributed by: Wockhardt USA LLC. Parsippany, NJ 07054, USA.
Lot : TEAR	Exp.:		Lot : Exp.: TEAR



Ages 6 Years

lss.151211



NDC 64679-98 Fexofenadii	2-06 ne HCI Tablet, USP		NDC 64679-98	<sup>32-06</sup> ne HCI Tablet, USP
60 mg	12 Hour		60 mg	12 Hour
HIVES		TEAR	HIVES	
Distributed by: W Parsippany, NJ 07	/ockhardt USA LLC. 054, USA.		<b>Distributed by:</b> V Parsippany, NJ 0	Vockhardt USA LLC. 7054, USA.
Lot :	Exp.:	HT AR	Lot :	Exp.:
TEAR				TEAR
NDC 64679-98	2-06		NDC 64679-98	82-06
Fexofenadi	ne HCI Tablet, USP		Fexofenadi	ne HCI Tablet, USP
60 mg	12 Hour		60 mg	12 Hour
HIVES		TEAR	HIVES	
Distributed by: W Parsippany, NJ 07	/ockhardt USA LLC. 054, USA.	AR	Distributed by: V Parsippany, NJ 0	Vockhardt USA LLC. 7054, USA.
Lot : TEAR	Exp.:		Lot :	Exp.: TEAF
NDC 64679-98	2-06		NDC 64679-98	82-06
Fexofenadi	ne HCI Tablet, USP		Fexofenadi	ne HCI Tablet, USP
60 mg	12 Hour	н	60 mg	12 Hour
HIVES		TEAR	HIVES	
Distributed by: W Parsippany, NJ 07	/ockhardt USA LLC. 054, USA.		Distributed by: V Parsippany, NJ 0	Vockhardt USA LLC. 7054, USA.
Lot :	Exp.:	ALL ALL	Lot :	Exp.:

#### **Drug Facts**

Active ingredient (in each tablet) Fexofenadine HCI 60 mg

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: dizziness or loss of consciousness trouble swallowing swelling of tongue swelling in or around mouth trouble speaking drooling wheezing or problems breathing 6 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 9 later. Not a Substitute for Epinephrine. If your doctor has prescribed an epinephrine injector for "anaphylaxis" or severe 5 allergy symptoms that could occur with your hives, never use this product as a substitute for the epinephrine injector. $\infty$ 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: insect stings foods 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. amish Area 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 Exp. Lot: store at 20° to 25°C (68° to 77°F) protect from excessive moisture 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

> Manufactui Wockhardt I Mumbai, Inc

lss.151211

ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY

NDC 64679-982-07

Purpose

Antihistamine

# Fexofenadine HCI Tablets, USP

## 60 mg/antihistamine

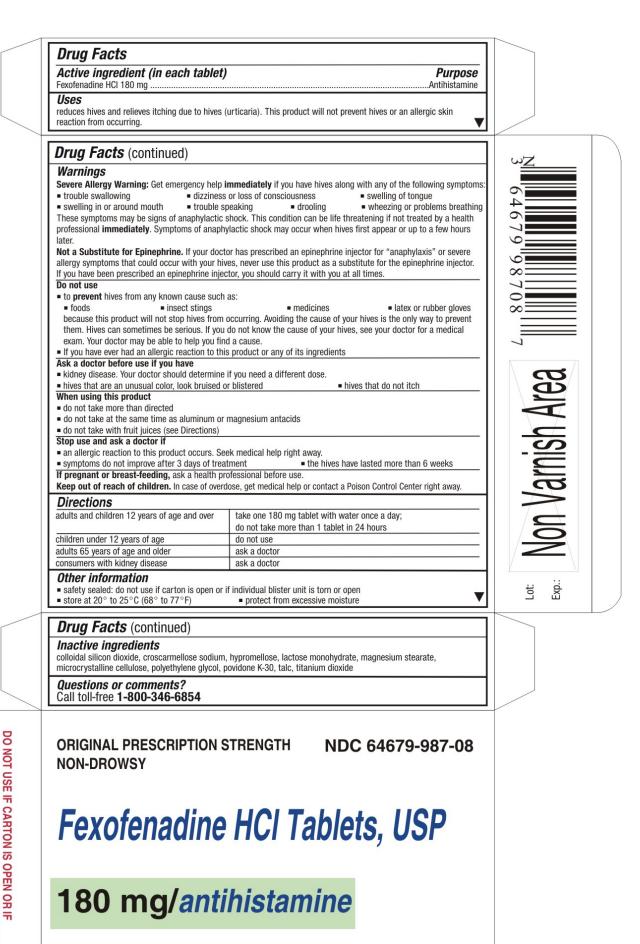
HIVES

# 12HOUR

RELIEF OF

<b>red by: Distributed by:</b> Limited, Wockhardt USA LLC. Jia. 20 Waterview Blvd. Parsippany, NJ 07054 USA.	ITCHING DUE TO HIVES WOCKHARDT
	12 Tablets 60 mg each

NDC 64679-987 Fexofenadin	-07 e HCI Tablet, USP		NDC 64679-9 Fexofenadi	<sup>87-07</sup> i <b>ne HCI Tablet, USP</b>
180 mg	24 Hour		180 mg	24 Hour
HIVES		TEAR	HIVES	
Distributed by: Wo Parsippany, NJ 070			Distributed by: N Parsippany, NJ 0	Wockhardt USA LLC. 7054, USA.
Lot :	Exp.:	ALL PR	Lot :	Exp.:
TEAR				TEAR
NDC 64679-987	-07		NDC 64679-9	87-07
Fexofenadin	e HCI Tablet, USP		Fexofenadi	ine HCI Tablet, USP
180 mg	24 Hour		180 mg	24 Hour
HIVES		TEAR	HIVES	
Distributed by: Wo Parsippany, NJ 070		AR	Distributed by: N Parsippany, NJ 0	Wockhardt USA LLC. 7054, USA.
Lot : TEAR	Exp.:		Lot :	Exp.: TEAF
NDC 64679-987	-07			
Fexofenadin	e HCI Tablet, USP			
180 mg	24 Hour	Ħ		
HIVES		TEAR		
Distributed by: Wo				
Parsippany, NJ 070				



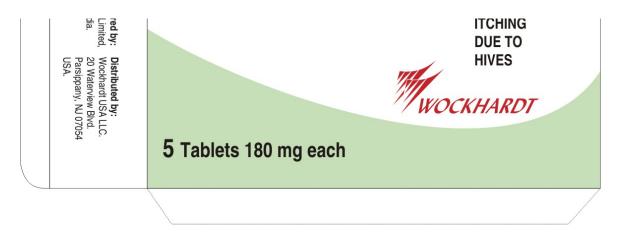
HIVES

RELIEF OF

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Manufactui Wockhardt I Mumbai, Inc Iss. 151211

INDIVIDUAL BLISTER UNIT IS TORN OR OPEN



Product Information					
Product Type	HUMAN OTC DI	RUG Item Code (	Source)	NDC:64679	9-744
Route of Administration	ORAL				
Active Ingredient/Act	ive Moiety				
	Ingredient Name		Basis	of Strength	Strength
FEXOFENADINE HYDROCH UNII:E6582LOH6V)	HLORIDE (UNII: 2S068B75	ZU) (FEXOFENADINE -	FEXOFENAD HYDROCHLO		30 mg
Inactive Ingredients					
	Ingredie			S	trength
CELLULOSE, MICROCRYS	,	1U)			
CROSCARMELLOSE SODI	<b>UM</b> (UNII: M280L1HH48)				
HYPROMELLOSES (UNII: 3	NXW29V3WO)				
LACTOSE MONOHYDRAT					
MAGNESIUM STEARATE (U					
POLYETHYLENE GLYCOL					
POVIDONE K30 (UNII: U725					
SILICON DIO XIDE (UNII: ET	TJ7Z6XBU4)				
TALC (UNII: 7SEV7J4R1U)					
TITANIUM DIO XIDE (UNII:	15FIX9 V2JP)				
Product Characteristi	ics				
Color V	VHITE	Score		no score	
Shape F	ROUND (round)	Size		7mm	
		Imprint Code		W;30	
Flavor		-			

Packaging

Item Code	Package Description	Marketii	ng Start Date	M	arketing End Date
NDC:64679-744-07	1 in 1 CARTON				
NDC:64679-744-06	6 in 1 BLISTER PACK				
Iarketing Infor	mation				
Aarketing Category	Application Number or Monogra	ph Citation	Marketing Start	Date	Marketing End Date
NDA A	ANDA0 79 112		02/08/2012		
	NDC:64679-744-07 NDC:64679-744-06 Marketing Infor Marketing Category	NDC:64679-744-07 1 in 1 CARTON   NDC:64679-744-06 6 in 1 BLISTER PACK   Iarketing Information   Marketing Category Application Number or Monogram	NDC:64679-744-07 1 in 1 CARTON   NDC:64679-744-06 6 in 1 BLISTER PACK   Image: Comparison of the state of the stat	NDC:64679-744-07 1 in 1 CARTON   NDC:64679-744-06 6 in 1 BLISTER PACK   Image: State of the state of	NDC:64679-744-07 1 in 1 CARTON Image: Carter of the second s

FEXOFENA						
exofenadine ta	blet, film coated					
-						
Product Info	rmation					
Product Type		HUMAN OTC DRUG	Item Code (So	ource)	NDC:64679	-982
Route of Admir	nistration	ORAL				
Active Ingre	dient/Active Moi	ety				
	Ingr	edient Name		Basis of S	trength	Strengt
FEXOFENADINE HYDRO CHLO RIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII: E6582LOH6V) FEXOFENADINE - HYDRO CHLO RIDE					E	60 mg
Inactive Ingr	edients					
		Ingredient Name			St	trength
CELLULOSE, M	ICRO CRYSTALL INE	(UNII: OP1R32D61U)				
CROSCARMELI	LOSE SODIUM (UNII:	M28OL1HH48)				
HYPRO MELLOS	<b>SES</b> (UNII: 3NXW29V3	WO)				
LACTOSE MON	OHYDRATE (UNII: EV	WQ57Q8I5X)				
MAGNESIUM ST	<b>EARATE</b> (UNII: 7009	7M6I30)				
POLYETHYLEN	EGLYCOL (UNII: 3W	JQ0SDW1A)				
POVIDONE K30	(UNII: U725QWY32X)					
SILICON DIO XI	<b>DE</b> (UNII: ETJ7Z6 XBU	4)				
TALC (UNII: 7SE	V7J4R1U)					
TITANIUM DIO 2	<b>KIDE</b> (UNII: 15FIX9V2J	P)				
Product Cha	racteristics					
Color	or WHITE Score				no scor	e
Shape	CAPSULE (C	apsule)	Size		11mm	
Flavor			Imprint Cod	e	W;982	
Contains						
Packaging						

112

# Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:64679-982-07	2 in 1 CA							
1 NDC:64679-982-06	6 in 1 BI	LISTER PACK						
Marketing Info	rmation							
Marketing Category		on Number or Monogra	oh Citation	Marke	eting Start Date	Marketin	g End Date	
ANDA	ANDA079112			02/08/2	-		5 2.114 2 4 10	
FEXOFENADIN	Ē							
fexofenadine tablet, fi	Im coated							
<b>Product Information</b>	on							
Product Type		HUMAN OTC DRUG	Ite m C	ode (So	urce)	NDC:64679-	987	
Route of Administration	on	ORAL						
Active Ingredient//	Active Moi	otv						
Active Ingrediend		-			Dasis of S	tuonath	Strongt	
FEVO FENADINE IN/DD	-	edient Name	OFENADINE		<b>Basis of S</b> FEXOFENADINE	_	Strengt	
UNII:E6582LOH6V)	UCHLURIDE	(UNII: 2S068B75ZU) (FEX	OFENADINE -		HYDROCHLORID		180 mg	
,								
Inactive Ingredien	ts							
	•••	Ingredient Name	<b>`</b>			St	rength	
CELLULOSE, MICROC	RVSTALLINF		-			50	rengen	
CROSCARMELLOSE S		, ,						
HYPROMELLOSES (UN								
LACTOSE MONOHYDE								
MAGNESIUM STEARAT								
POLYETHYLENE GLYC								
POVIDONE K30 (UNII: U								
SILICON DIO XIDE (UNI								
TALC (UNII: 7SEV7J4R1								
TITANIUM DIO XIDE (U		P)						
<b>Product Character</b>	istics							
Color	WHITE		Scor	re		no score	2	
				Size		17mm		
	CAPSULE (C	apsule)	5126					
Shape	CAPSULE (C	apsule)			e	W;987		
Shape Flavor	CAPSULE (C	apsule)		rint Cod	2	W;987		
Shape	CAPSULE (C	apsule)			e	W;987		
Shape Flavor	CAPSULE (C	apsule)			2	W;987		
Shape Flavor Contains	CAPSULE (C	apsule)			2	W;987		
Shape Flavor		apsule) :kage Description		rint Cod		W;987 Marketing E	d P :	

1 NDC:64679-987-07	5 in 1 BLISTER PACK		
Marketing Info	rmation		
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.