ALLERGY 24-HR - fexofenadine hydrochloride tablet, film coated
Wockhardt USA LLC.

ALLERGY 24-HOUR FEXOFENADINE HYDROCHLORIDE TABLETS

OTC - ACTIVE INGREDIENT SECTION

For 30 mg:

Fexofenadine HCl 30 mg

For 60 mg:

Fexofenadine HCl 60 mg

For 180 mg:

Fexofenadine HCl 180 mg

OTC - PURPOSE SECTION

Antihistamine

USAGE

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- 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.

OTC - KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

DOSAGE AND ADMINISTRATION

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:

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 inner seal imprinted with "Sealed for Your Protection" is missing or torn
- safety sealed: do not use if carton is opened or if individual blister unit is torn or open
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

INACTIVE INGREDIENT

For 30 mg

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate,

magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone K-30, talc, titanium dioxide

For 60 mg

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

For 180 mg

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

Questions or comments?

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

Manufactured by:

Patheon Puerto Rico, Inc.,

Manati, PR 00674

Distributed by:

Wockhardt USA LLC

20 Waterview Blvd.

Parippany, NJ 07054

USA.

Rev.06-15

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Fexofenadine hydrochloride

Film-coated Tablets

Indoor and Outdoor Allergies – 24 hours

180 mg

30 tablets bottle pack

Fexofenadine hydrochloride

Film-coated Tablets

Indoor and Outdoor Allergies – 24 hours

180 mg

90 tablets bottle pack

Fexofenadine hydrochloride

Film-coated Tablets

Indoor and Outdoor Allergies – 24 hours

180 mg

5 tablets blister carton

ALLERGY 24-HR

fexofenadine hydrochloride 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**
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	30 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	W;30
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64679-744-09	1 in 1 CARTON	02/08/2012	
1	NDC:64679-744-08	6 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	ANDA079112	02/08/2012	

ALLERGY 24-HR

fexofenadine hydrochloride 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**
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown (light peach to peach)	**Score**	no score
Shape	CAPSULE	**Size**	11mm
Flavor		**Imprint Code**	W982
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64679-982-09	2 in 1 CARTON	02/08/2012	
1	NDC:64679-982-08	6 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	ANDA079112	02/08/2012	

ALLERGY 24-HR

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64679-987
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown (light peach to peach)	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	W987
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64679-987-10	1 in 1 CARTON	02/08/2012	
1	NDC:64679-987-09	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:64679-987-11	3 in 1 CARTON	02/08/2012	
2	NDC:64679-987-09	5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:64679-987-05	2000 in 1 POUCH; Type 0: Not a Combination Product	02/08/2012	
4	NDC:64679-987-20	1 in 1 CARTON	02/08/2012	
4	NDC:64679-987-12	30 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:64679-987-24	1 in 1 CARTON	02/08/2012	
5	NDC:64679-987-16	90 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:64679-987-14	2 in 1 CARTON	02/08/2012	
6	NDC:64679-987-13	45 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:64679-987-17	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/08/2012	
8	NDC:64679-987-22	1 in 1 CARTON	02/08/2012	
8	NDC:64679-987-13	45 in 1 BOTTLE; Type 0: Not a Combination Product		

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 Limited (650069115)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Puerto Rico, Inc.		143814544	analysis(64679-982, 64679-987, 64679-744) , label(64679-982, 64679-987, 64679-744) , manufacture(64679-982, 64679-987, 64679-744) , pack(64679-982, 64679-987, 64679-744)

Revised: 12/2022 Wockhardt USA LLC.