

FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet, film coated
Sun Pharmaceutical Industries, Inc.

Fexofenadine Hydrochloride Tablets, USP

Active ingredient (in each tablet)

For 30 mg:

Fexofenadine HCl, USP 30 mg

For 60 mg:

Fexofenadine HCl, USP 60 mg

For 180 mg:

Fexofenadine HCl, USP 180 mg

Purpose

Antihistamine

Uses

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 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.

Keep out of reach of children.

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

Directions**For 30mg:**

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 60mg:

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 180mg:

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 inner safety seal is open or torn
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

crospovidone, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide

Questions?

Call toll free **1-800-818-4555** weekdays

Principal Display Panel

For 30 mg Allergy:

ORIGINAL PRESCRIPTION STRENGTH

NDC 62756-542-88

Children's

Fexofenadine Hydrochloride Tablets, USP

30 mg

ALLERGY

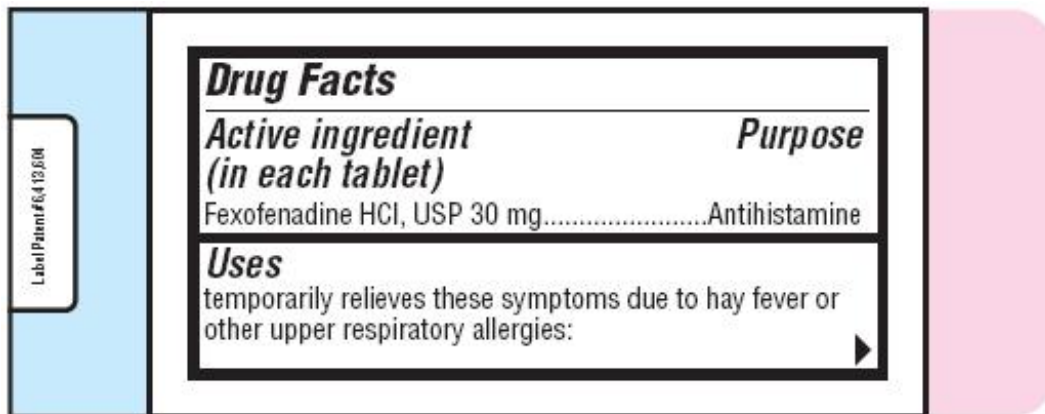
(12 Hour)

Antihistamine

Indoor and Outdoor Allergies

100 Tablets 30 mg each

SUN PHARMA



Back

Drug Facts (continued)

- 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. ▶

Insert 1 Top

Drug Facts (continued)

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) ▶

Insert 1 Back

Drug Facts (continued)

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.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ▶

Insert 2 Top

Drug Facts (continued)

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 ▶

Insert 2 Back

Drug Facts (continued)

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 ▶

Insert 3 Top

Drug Facts (continued)

Other information

- safety sealed; do not use if inner safety seal is open or torn
- store between 20° to 25°C (68° to 77°F)
- protect from excessive moisture

Inactive ingredients

crospovidone, hypromellose, iron oxide red, ▶

Insert 3 Back

Drug Facts (continued)

iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide

Questions? Call toll free 1-800-818-4555 weekdays

Insert 4 Top

DO NOT USE IF INNER SAFETY SEAL IMPRINTED WITH "SEALED for YOUR PROTECTION" IS TORN OR MISSING
ORIGINAL PRESCRIPTION STRENGTH
NDC 62756-542-88

Children's
**Fexofenadine Hydrochloride
Tablets, USP**

30 mg

ALLERGY Antihistamine (12 Hour)
Indoor and Outdoor Allergies
100 Tablets 30 mg each

Manufactured by:
Sun Pharmaceutical Ind., Ltd.
Acme Plaza, Andheri-Kurla Road,
SUN PHARMA, Andheri (East), Mumbai-400 059, India.




Insert 4 Back

NON-DROWSY
Ages 6 years and Older

Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

Distributed by: 
Caraco Pharmaceutical Laboratories, Ltd.
1150 Elijah McCoy Drive, Detroit, MI 48202
PGLB0811 PGLB0811 ISS. 12/2011
DNH/DRUGS/138

Batch No.:

Exp.

Open for Full Labeling

Base

For 60 mg Allergy:

NDC 62756-543-88
Fexofenadine Hydrochloride Tablets, USP
60 mg
ALLERGY
(12 Hour)
Antihistamine
Indoor and Outdoor Allergies
100 Tablets 60 mg each
SUN PHARMA

ORIGINAL PRESCRIPTION
STRENGTH
NON-DROWSY

NDC 62756-543-88

Fexofenadine Hydrochloride Tablets, USP

60 mg

ALLERGY

(12 Hour)

Antihistamine
Indoor and Outdoor Allergies

100 Tablets 60 mg each



Open for full labeling →



Distributed by:
Caraco Pharmaceutical Laboratories, Ltd.
1150 Elijah McCoy Drive, Detroit, MI 48202

Manufactured by:
Sun Pharmaceutical Industries Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

PGLB0815 PGLB0815 ISS. 12/2011
DNH/DRUGS/138

Batch No.:
Exp.:

Relief of:
• Sneezing
• Runny Nose
• Itchy, Watery Eyes
• Itchy Nose or Throat

DO NOT USE IF INNER
SAFETY SEAL IMPRINTED
WITH "SEALED for YOUR
PROTECTION" IS TORN
OR MISSING

Drug Facts	Active ingredient (in each tablet)	Purpose
	Fexofenadine HCl, USP 60 mg	Antihistamine
Uses	temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • itchy, watery eyes • sneezing • 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	<ul style="list-style-type: none"> 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. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	

Hinge PGLB0815.3125"

Hinge PGLB0815.3125"

Drug Facts (continued)	
Directions	take one 60 mg tablet with water every 12 hours; do not take more than 2 tablets in 24 hours
adults and children 12 years of age and over	do not use
children under 12 years of age	ask a doctor
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor
Other information	<ul style="list-style-type: none"> safely sealed; do not use if inner safety seal is open or torn store between 20° to 25°C (68° to 77°F) protect from excessive moisture
Inactive ingredients	crospovidone, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide
Questions?	Call toll free 1-800-818-4555 weekdays

For 180 mg Allergy:

NDC 62756-545-88
Fexofenadine Hydrochloride Tablets, USP
180 mg

ALLERGY
(24 Hour)
Antihistamine
Indoor and Outdoor Allergies
100 Tablets 180 mg each
SUN PHARMA

NDC 62756-545-88

Fexofenadine Hydrochloride
Tablets, USP

ORIGINAL PRESCRIPTION
STRENGTH
NON-DROWSY

Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

DO NOT USE IF INNER SAFETY SEAL IMPRINTED WITH "SEALED for YOUR PROTECTION" IS TORN OR MISSING

180 mg

ALLERGY (24 Hour)

Antihistamine
 Indoor and Outdoor Allergies
 100 Tablets 180 mg each





N 3 62756 54588 5

Open for full labeling →

CARACO
Pharmaceuticals

Distributed by:
 Caraco Pharmaceutical Laboratories, Ltd.
 1150 Elijah McCoy Drive, Detroit, MI 48202

Manufactured by:
 Sun Pharmaceutical Industries Ltd.
 Acme Plaza, Andheri-Kurla Road,
 Andheri (East), Mumbai-400 059, India.

PGLB0819 PGLB0819 ISS. 12/2011
 DNH/DRUGS/138

Batch No: _____

Exp.: _____

Drug Facts	<p>Active ingredient (in each tablet) Purpose Fexofenadine HCl, USP, 180 mgAntihistamine</p> <p>Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • itchy, watery eyes • sneezing • itching of the nose or throat</p> <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product</p> <ul style="list-style-type: none"> • 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) <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>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.</p> <p>Directions</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">adults and children 12 years of age and over</td> <td>take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours</td> </tr> <tr> <td>children under 12 years of age</td> <td>do not use</td> </tr> <tr> <td>adults 65 years of age and older</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with kidney disease</td> <td>ask a doctor</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> • tightly sealed; do not use if inner safety seal is open or torn • store between 20° to 25°C (68° to 77°F) • protect from excessive moisture <p>Inactive ingredients croscollon, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide</p> <p>Questions? Call toll free 1-800-818-4555 weekdays</p>	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
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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								
	PGLB0819 ↓ Hinge Area 0.315"								

Principal Display Panel

For 30 mg Allergy:

NDC 62756-542-74
ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY
Children's
Fexofenadine Hydrochloride Tablets, USP
30 mg
ALLERGY
(12 Hour)
Antihistamine

Indoor and Outdoor Allergies

Ages 6 years and Older



Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

5 (1 x 5) Tablets 30 mg each

SUN PHARMA

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN

<p>Drug Facts (continued)</p> <p>Inactive Ingredients croscarmellose, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polybutadiene starch, titanium dioxide</p> <p>Questions? Call toll free 1-800-414-4855 weekdays</p>	 <p>NDC 62756-543-74</p> <p>Manufactured by: SUN PHARMA Sun Pharmaceutical Industries Ltd., Acropolis Plaza, Annapolis Hill Road, Annapolis, MD 21403, USA 11818 Sun Pharma Drive, Laurel, MD 21050</p>	<p>NDC 62756-543-74 ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY Children's Fexofenadine Hydrochloride Tablets, USP</p> <p>30 mg</p> <p>ALLERGY Antihistamine (12 Hour) Indoor and Outdoor Allergies</p> <p>Ages 6 years and Older Relief of:</p> <ul style="list-style-type: none"> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Nose or Throat <p>5 (1 x 5) Tablets 30 mg each</p> <p>DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN</p> <p style="text-align: right;"></p>	<p>DEPARTMENT OF HEALTH & HUMAN SERVICES</p> <p>Form No. 209-101 (01/11)</p> <p>Net Content: 5 (1 x 5) Tablets, USP</p> <p style="text-align: center;">30 mg</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredient (in each tablet)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Fexofenadine HCl, USP 30 mg</td> <td>Antihistamine</td> </tr> </tbody> </table> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> • runny nose • itchy, watery eyes • sneezing • itching of the nose or throat <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product:</p> <ul style="list-style-type: none"> • do not take more than directed • do not take at the same time as aluminum or magnesium antacids • do not take with fruit juice (see Directions) <p>Stop use and ask a doctor if a allergic reaction to this product occurs. Seek medical help right away.</p>	Active Ingredient (in each tablet)	Purpose	Fexofenadine HCl, USP 30 mg	Antihistamine
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Fexofenadine HCl, USP 30 mg	Antihistamine							

<p>Drug Facts (continued)</p> <p>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.</p>											
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<p>Other information</p> <ul style="list-style-type: none"> • safety sealed, do not use if carton is opened or individual blister units are torn or opened • store between 20° to 25°C (68° to 77°F) • protect from excessive moisture 											

Principal Display Panel

For 60 mg Allergy:

NDC 62756-543-74

ORIGINAL PRESCRIPTION STRENGTH

NON-DROWSY

Fexofenadine Hydrochloride Tablets, USP

60 mg

ALLERGY

(12 Hour)

Antihistamine

Indoor and Outdoor Allergies



Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

5 (1 x 5) Tablets 60 mg each

SUN PHARMA

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN

<p>Drug Facts (continued)</p> <p>Inactive Ingredients croscarmellose, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polybutadiene starch, titanium dioxide</p> <p>Questions? Call toll free 1-800-414-4855 weekdays</p>	 <p>NDC 62756-543-74</p> <p>Manufactured by: SUN PHARMA Sun Pharmaceutical Industries Ltd., Acropolis Plaza, Annapolis Hill Road, Annapolis, MD 21403, USA 11818 Sun Pharma Drive, Laurel, MD 21050</p>	<p>NDC 62756-543-74 ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY Fexofenadine Hydrochloride Tablets, USP</p> <p>60 mg</p> <p>ALLERGY Antihistamine (12 Hour) Indoor and Outdoor Allergies</p> <p>Relief of:</p> <ul style="list-style-type: none"> • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Nose or Throat <p>5 (1 x 5) Tablets 60 mg each</p> <p>DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN</p> <p style="text-align: right;"></p>	<p>DEPARTMENT OF HEALTH & HUMAN SERVICES</p> <p>Form No. 209-101 (01/11)</p> <p>Net Content: 5 (1 x 5) Tablets, USP</p> <p style="text-align: center;">60 mg</p>	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredient (in each tablet)</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Fexofenadine HCl, USP 60 mg</td> <td>Antihistamine</td> </tr> </tbody> </table> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:</p> <ul style="list-style-type: none"> • runny nose • itchy, watery eyes • sneezing • itching of the nose or throat <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients.</p> <p>Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.</p> <p>When using this product:</p> <ul style="list-style-type: none"> • do not take more than directed • do not take at the same time as aluminum or magnesium antacids • do not take with fruit juice (see Directions) <p>Stop use and ask a doctor if a allergic reaction to this product occurs. Seek medical help right away.</p>	Active Ingredient (in each tablet)	Purpose	Fexofenadine HCl, USP 60 mg	Antihistamine
Active Ingredient (in each tablet)	Purpose							
Fexofenadine HCl, USP 60 mg	Antihistamine							

<p>Drug Facts (continued)</p> <p>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.</p>									
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consumers with kidney disease	ask a doctor								
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Principal Display Panel

For 180 mg Allergy:

NDC 62756-545-74

**ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY**

Fexofenadine Hydrochloride Tablets, USP

180 mg

ALLERGY

(24 Hour)

Antihistamine

Indoor and Outdoor Allergies


Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

5 (1 x 5) Tablets 180 mg each

SUN PHARMA

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN

<p>Drug Facts (continued)</p> <p>Inactive ingredients croscarellone, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch, titanium dioxide</p> <p>Questions? Call toll free 1-800-818-4835 weekdays</p>	 <small>6275654574</small>	<p>NDC 62756-545-74 ORIGINAL PRESCRIPTION STRENGTH NON-DROWSY Fexofenadine Hydrochloride Tablets, USP 180 mg</p> <p>ALLERGY Antihistamine Indoor and Outdoor Allergies (24 Hour)</p> <p>Relief of: • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Nose or Throat</p> <p>5 (1 x 5) Tablets 180 mg each</p> <p>DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN</p>	<small>180 mg</small> <small>180 mg</small>	<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">Active ingredient (in each tablet)</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Fexofenadine HCl, USP 180 mg</td> <td>Antihistamine</td> </tr> </table> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • itchy, watery eyes • sneezing • itching of the nose or throat</p> <p>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.</p> <p>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)</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p>	Active ingredient (in each tablet)	Purpose	Fexofenadine HCl, USP 180 mg	Antihistamine	<p>Drug Facts (continued)</p> <p>If you repeat or break through, 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.</p> <p>Directions</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td>adults and children 12 years of age and over</td> <td>take one 180 mg tablet with water once a day; do not take more than 1 tablet in 24 hours</td> </tr> <tr> <td>children under 12 years of age</td> <td>do not use</td> </tr> <tr> <td>adults 65 years of age and older</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with kidney disease</td> <td>ask a doctor</td> </tr> </table> <p>Other information • safety sealed; do not use if carton is opened or individual blister units are a torn or opened • store between 20° to 25°C (68° to 77°F) • protect from excessive moisture</p>	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
Active ingredient (in each tablet)	Purpose																
Fexofenadine HCl, USP 180 mg	Antihistamine																
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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																

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62756-542
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND (circular)	Size	6 mm
Flavor		Imprint Code	542
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62756-542-83	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2012	
2	NDC:62756-542-88	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2012	
3	NDC:62756-542-74	1 in 1 CARTON	02/06/2012	
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:62756-542-66	2 in 1 CARTON	02/06/2012	
4		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:62756-542-77	9 in 1 CARTON	02/06/2012	
5		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:62756-542-64	5 in 1 CARTON	02/06/2012	
6		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:62756-542-76	10 in 1 CARTON	02/06/2012	
7		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:62756-542-78	15 in 1 CARTON	02/06/2012	
8		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	ANDA091567	02/06/2012	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62756-543
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	543
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62756-543-83	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2012	
2	NDC:62756-543-88	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2012	
3	NDC:62756-543-74	1 in 1 CARTON	02/06/2012	
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:62756-543-66	2 in 1 CARTON	02/06/2012	
4		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:62756-543-77	9 in 1 CARTON	02/06/2012	
5		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:62756-543-64	5 in 1 CARTON	02/06/2012	
6		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:62756-543-76	10 in 1 CARTON	02/06/2012	
7		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:62756-543-78	15 in 1 CARTON	02/06/2012	
8		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	ANDA091567	02/06/2012	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62756-545
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXO FENADINE HYDRO CHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	545
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62756-545-83	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2012	
2	NDC:62756-545-88	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/06/2012	
3	NDC:62756-545-74	1 in 1 CARTON	02/06/2012	
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:62756-545-66	2 in 1 CARTON	02/06/2012	
4		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		

5	NDC:62756-545-77	9 in 1 CARTON	02/06/2012	
5		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:62756-545-64	5 in 1 CARTON	02/06/2012	
6		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:62756-545-76	10 in 1 CARTON	02/06/2012	
7		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:62756-545-78	15 in 1 CARTON	02/06/2012	
8		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	ANDA091567	02/06/2012	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(62756-542, 62756-543, 62756-545) , LABEL(62756-542, 62756-545) , MANUFACTURE(62756-542, 62756-543, 62756-545) , PACK(62756-542, 62756-545)

Revised: 10/2018

Sun Pharmaceutical Industries, Inc.