

FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride tablet, film coated
Hetero Labs Limited

Fexofenadine Hydrochloride Tablets USP, 30 mg, 60 mg and 180 mg

ACTIVE INGREDIENT(S)

(in each tablet)

Fexofenadine Hydrochloride USP, 30 mg
Fexofenadine Hydrochloride USP, 60 mg
Fexofenadine Hydrochloride USP, 180 mg

PURPOSE

Antihistamine

USE(S)

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.

PREGNANCY/BREASTFEEDING

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

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

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

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

- Tamper Evident: Do not use if printed foil seal under cap is missing
- This unit-dose package is not child-resistant
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

INACTIVE INGREDIENTS

Colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

QUESTIONS?

Call 1-866-495-1995

PRINCIPAL DISPLAY PANEL

Fexofenadine Hydrochloride Tablets USP, 30 mg - Container Carton



Fexofenadine Hydrochloride Tablets USP, 30 mg - Container Label

NDC 68554-5061-0

Children

**Fexofenadine Hydrochloride
Tablets USP, 30 mg /Antihistamine**

Allergy

Ages 6 Years and Older

INDOOR / OUTDOOR ALLERGY RELIEF

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

12HR

30 Tablets

Mfg. Lic. No.: 50MM/AP/2009/FR
Manufactured by:
HETEROTM
HETERO LABS LIMITED Unit-V, Pallepally,
Jeecherla, Mahabub Nagar - 509 301, India.
2037177

LOT: _____
EXP: _____

VARNISH FREE AREA

Open here to learn more

Active Ingredient (in each tablet)
Fexofenadine hydrochloride USP, 30 mg.....Antihistamine

Purpose
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 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.

1

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 ■ Tamper-Evident: Do not use if printed foil seal under cap is missing
 ■ store between 20° and 25°C (68° and 77°F) ■ protect from excessive moisture

Inactive ingredients colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

Questions? Call 1-866-495-1995

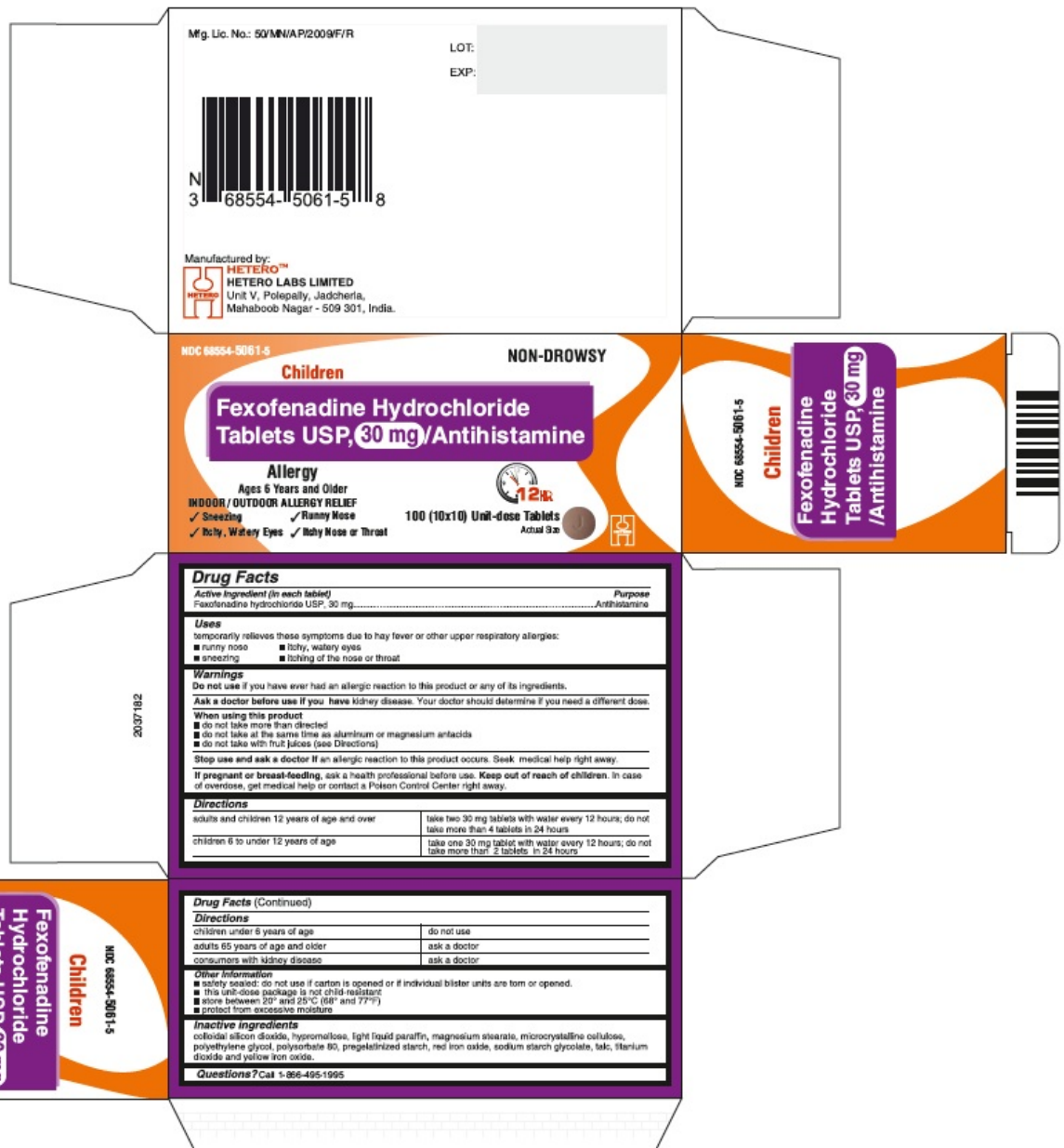
2

Fexofenadine Hydrochloride Tablets USP, 30 mg - Blister Foil

<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>	<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>	<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>	<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>	<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>
<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>	<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>	<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>	<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>	<p>NDC 68554-5061-4 Allergy <i>Children</i> Fexofenadine Hydrochloride Tablet USP, 30 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jadcherla, Mahabub Nagar - 509 301, India.</p>

Mfg. L.C. No.: 50WNIAP2004FR
2037187

Fexofenadine Hydrochloride Tablets USP, 30 mg - Blister Carton



Fexofenadine Hydrochloride Tablets USP, 60 mg - Container Carton



Fexofenadine Hydrochloride Tablets USP, 60 mg - Container Label

NDC 68554-5062-0

**Fexofenadine Hydrochloride
Tablets USP, 60 mg /Antihistamine**

Allergy

INDOOR / OUTDOOR ALLERGY RELIEF

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

12HR

30 Tablets

Mfg. Lic. No.: 50/MN/AP/2009/F/R
Manufactured by:
HETERO™
HETERO LABS LIMITED Unit V, Polepally,
Jadcherla, Mahabub Nagar - 509 301, India.
2037179

LOT:
EXP:

VARNISH FREE AREA

Open here to learn more

Active Ingredient (in each tablet)

Fexofenadine hydrochloride USP, 60 mg.....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 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.

1

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 ■ Tamper-Evident: Do not use if printed foil seal under cap is missing ■ store between 20° and 25°C (68° and 77°F) ■ protect from excessive moisture

Inactive ingredients colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

Questions? Call 1-866-495-1995

2

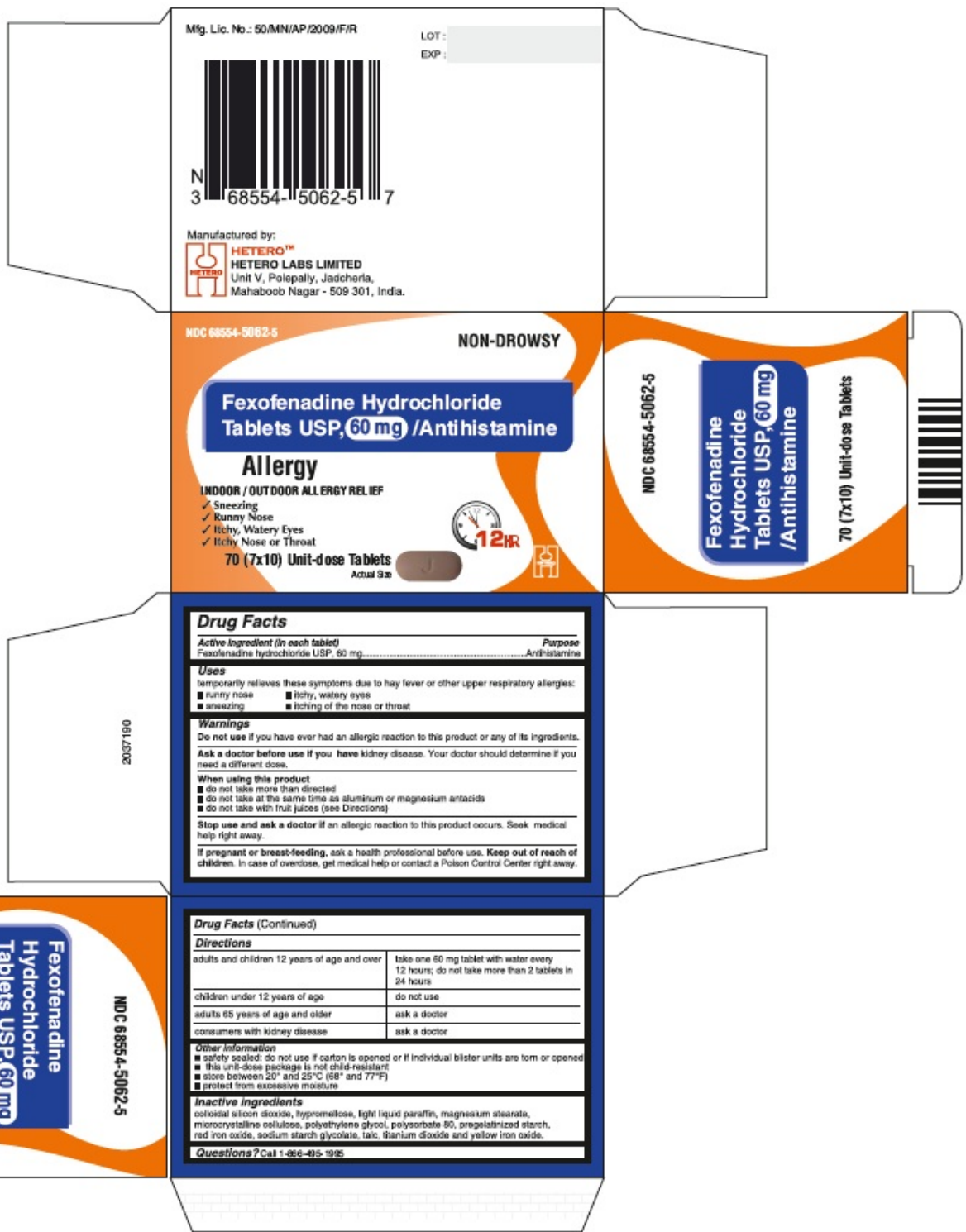
Fexofenadine Hydrochloride Tablets USP, 60 mg - Blister Foil

<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>
<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5062-4 Allergy Fexofenadine Hydrochloride Tablet USP, 60 mg 12 HOUR Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepaly, Jadcherla, Mahaboob Nagar - 509 301, India.</p>

Mfg. Lic. No.: 50MNVAP/2009FF/R

2037184

Fexofenadine Hydrochloride Tablets USP, 60 mg - Blister Carton



Fexofenadine Hydrochloride Tablets USP, 180 mg - Container Carton



Fexofenadine Hydrochloride Tablets USP, 180 mg - Container Label

NDC 68554-5063-0

**Fexofenadine Hydrochloride
Tablets USP, 180 mg /Antihistamine**

Allergy

INDOOR / OUTDOOR ALLERGY RELIEF

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

 24HR

30 Tablets 

Mfg. Lic. No.: 50/MNAP/2009/R

Manufactured by:
HETERO™
HETERO LABS LIMITED Unit V, Polepally,
Jadcherla, Mahabub Nagar - 509 301, India.

2037198

LOT:
EXP:

VARNISH FREE AREA

Open here to learn more 

Active Ingredient (in each tablet)

Fexofenadine hydrochloride USP, 180 mg.....Antihistamine

Purpose

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 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.

1

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 ■ Tamper-Evident: Do not use if printed foil seal under cap is missing ■ store between 20° and 25°C (68° and 77°F) ■ protect from excessive moisture

Inactive ingredients colloidal silicon dioxide, hypromellose, light liquid paraffin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and yellow iron oxide.

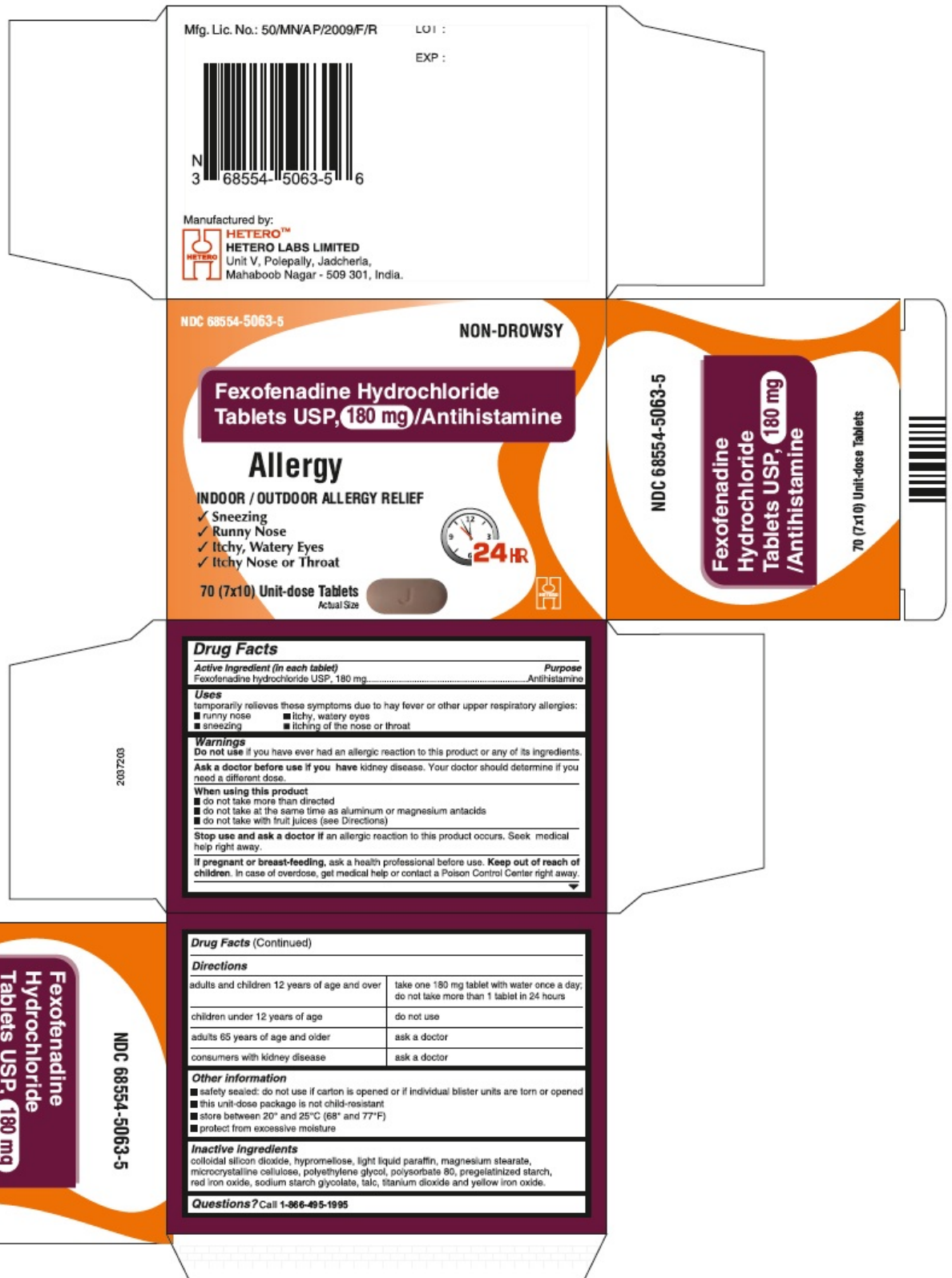
Questions? Call 1-866-495-1995

2

Fexofenadine Hydrochloride Tablets USP, 180 mg - Blister Foil

<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Mfg. Lic. No.: 50MNH/5/2008/FR</p>
<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p>	<p>NDC 68554-5063-4</p> <p>Allergy Fexofenadine Hydrochloride Tablet USP, 180 mg</p> <p>24 HOUR</p> <p>Manufactured by: HETERO™ HETERO LABS LIMITED Unit V, Polepally, Jaddhera, Mahaboob Nagar - 509 301, India.</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">2007202</p>

Fexofenadine Hydrochloride Tablets USP, 180 mg - Blister Carton



FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68554-5061
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND (biconvex)	Size	6mm
Flavor		Imprint Code	j;42
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68554-5061-0	1 in 1 CARTON	08/23/2016	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68554-5061-1	1 in 1 CARTON	08/23/2016	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68554-5061-2	1 in 1 CARTON	08/23/2016	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:68554-5061-5	10 in 1 CARTON	08/23/2016	
4	NDC:68554-5061-4	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:68554-5061-6	22 in 1 CARTON	08/23/2016	
5	NDC:68554-5061-3	10 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	ANDA204097	08/23/2016	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68554-5062
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	Score	no score
Shape	OVAL (biconvex)	Size	12mm
Flavor		Imprint Code	j;43
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68554-5062-0	1 in 1 CARTON	08/23/2016	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		

2	NDC:68554-5062-1	1 in 1 CARTON	08/23/2016	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68554-5062-2	1 in 1 CARTON	08/23/2016	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:68554-5062-5	7 in 1 CARTON	08/23/2016	
4	NDC:68554-5062-4	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:68554-5062-6	15 in 1 CARTON	08/23/2016	
5	NDC:68554-5062-3	10 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	ANDA204097	08/23/2016	

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68554-5063
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE (biconvex)	Size	18mm
Flavor		Imprint Code	j;44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68554-5063-0	1 in 1 CARTON	08/23/2016	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68554-5063-1	1 in 1 CARTON	08/23/2016	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68554-5063-2	1 in 1 CARTON	08/23/2016	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:68554-5063-5	7 in 1 CARTON	08/23/2016	
4	NDC:68554-5063-4	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:68554-5063-6	15 in 1 CARTON	08/23/2016	
5	NDC:68554-5063-3	10 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	ANDA204097	08/23/2016	

Labeler - Hetero Labs Limited (917261950)

Revised: 9/2016

Hetero Labs Limited