

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet, film coated
AvKARE, Inc.

Fexofenadine Hydrochloride Tablets USP

Active ingredient (in each tablet)

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 aluminium 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 care 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 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

- store between 20°and 25°C (68°and 77°F)
- protect from excessive moisture and light

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol 400, pregelatinized corn starch, red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide

Questions or comments?

call 1-855-361-3993

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

AvKARE

NDC 42291-296-90

Fexofenadine Hydrochloride Tablets USP

Antihistamine

60 mg

90 Tablets

Manufactured for:

AvKARE, Inc.

Pulaski, TN 38478

Mfg. Rev. LM-1239

AV 09/15 (P)

AVKARE
NDC 42291-296-90
Fexofenadine Hydrochloride Tablets USP
Antihistamine
60 mg
90 Tablets

Drug Facts

Active Ingredient	Purpose
(in each tablet) Fexofenadine HCl 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.

Peel Here

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)

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 care 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 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

Drug Facts (continued)
Other information
<ul style="list-style-type: none"> ■ Store between 20° and 25°C (68° and 77°F) ■ protect from excessive moisture and light
Inactive ingredients
anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol 400, pregelatinized corn starch, red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide.
Questions? call 1-855-361-3993

Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. LM-1239 AV 09/15 (P)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

AvKARE

NDC 42291-297-90

Fexofenadine Hydrochloride Tablets USP

Antihistamine

180 mg

90 Tablets

Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. LM-1241 AV 04/15 (P)



NDC 42291-297-90

Fexofenadine Hydrochloride Tablets USP

Antihistamine

180 mg

90 Tablets

Drug Facts

Active Ingredient	Purpose
(in each tablet) Fexofenadine HCl USP, 180 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.

Peel Here

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)

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 care 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 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

Drug Facts (continued)**Other information**

- Store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture and light

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, lactose monohydrate, polyethylene glycol 400, pregelatinized corn starch, red iron oxide, stearic acid, titanium dioxide, and yellow iron oxide.

Questions? call 1-855-361-3993

Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. LM-1241

AV 04/15 (P)

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42291-296(NDC:13107-066)
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (Peach)	Score	no score
Shape	CAPSULE (Bevel Edge, Biconvex)	Size	12mm
Flavor		Imprint Code	E;42
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-296-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2015	08/20/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202039	10/16/2015	08/20/2019

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42291-297(NDC:13107-067)
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
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ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange (Peach)	Score	no score
Shape	CAPSULE (Bevel Edge, Biconvex)	Size	17mm
Flavor		Imprint Code	E;44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-297-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	
2	NDC:42291-297-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202039	05/01/2015	

Labeler - AvKARE, Inc. (796560394)