FEXOFENADINE HCL- fexofenadine hcl tablet, film coated
ScieGen Pharmaceuticals, Inc.

HIVES

Active ingredient (in each film-coated tablet)

Fexofenadine HCl USP 60 mg

Fexofenadine HCl USP 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 profession **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 60mg)

adults and children 12 years of age and over	take one 60mg 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

Directions (for 180mg)

adults and children 12 years of age and over	take one 180mg 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
- **each tablet contains:** sodium 2.7mg(for 60 mg), sodium 8.2mg(for 180 mg)
- this product meets the requirements of USP *Dissolution Test 2*
- **Tamper Evident:** Do not use if imprinted inner safety seal is torn or missing

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate,

pregelatinized starch(maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide titanium dioxide and yellow iron oxide.

Questions or comments?

Call toll-free **1-855-724-3436**

Manufactured by:

ScieGen Pharmaceuticals, Inc.

Hauppauge, NY 11788 USA

ALLERGY

Active ingredient (in each film-coated tablet)

Fexofenadine HCl USP 60 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 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.

Directions (for 60mg)

adults and children 12 years of age and over	take one 60mg 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

Directions (for 180mg)

adults and children 12 years of age and over	take one 180mg 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
- **each tablet contains:** sodium 2.7mg(for 60 mg), sodium 8.2mg(for 180 mg)
- this product meets the requirements of USP *Dissolution Test 2*
- **Tamper Evident:** Do not use if imprinted inner safety seal is torn or missing

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch(maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide titanium dioxide and yellow iron oxide.

Questions or comments?

Call toll-free **1-855-724-3436**

Manufactured by:

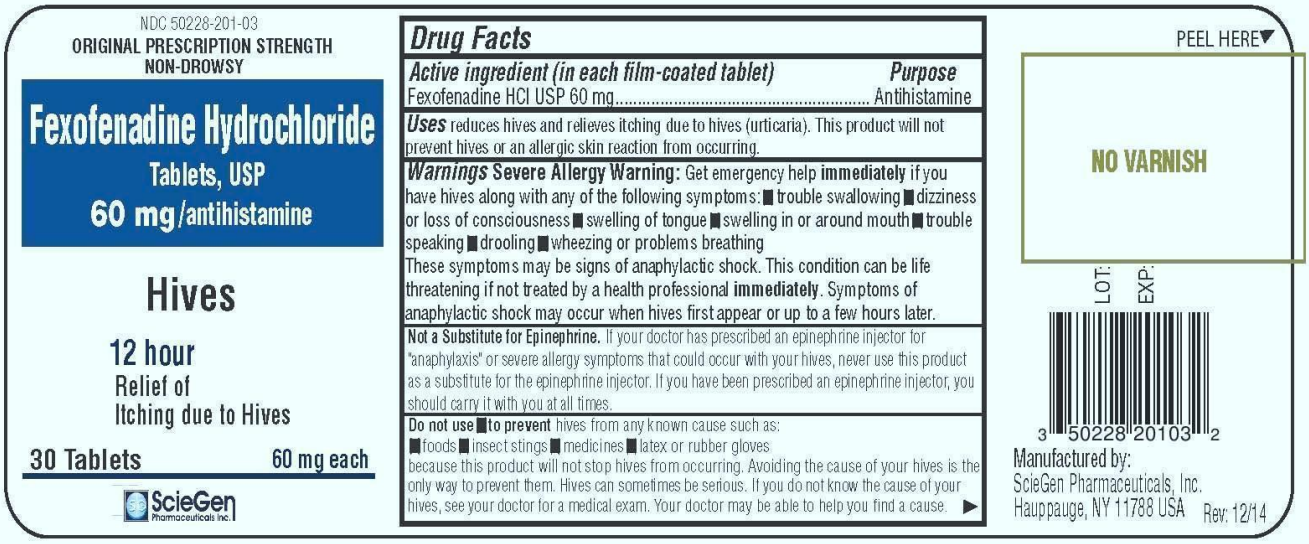
ScieGen Pharmaceuticals, Inc.

Hauppauge, NY 11788 USA

Package/Label Principal Display Panel

Fexofenadine Hydrochloride Tablets USP 60mg

FRONT



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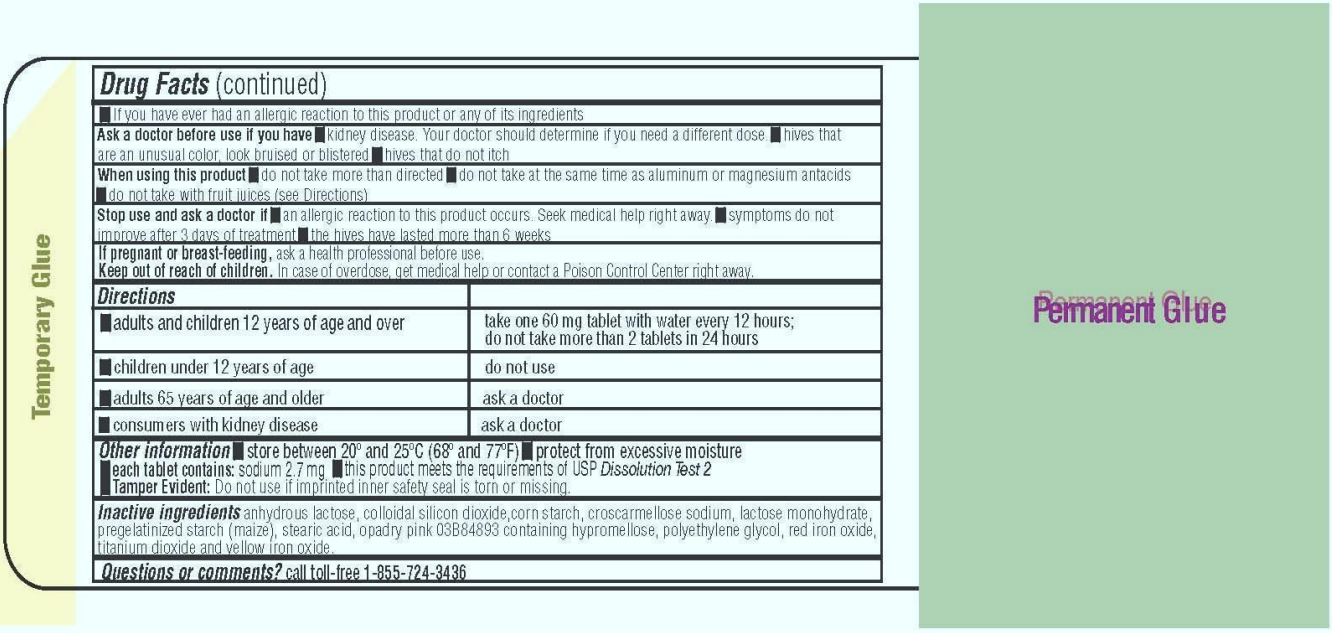
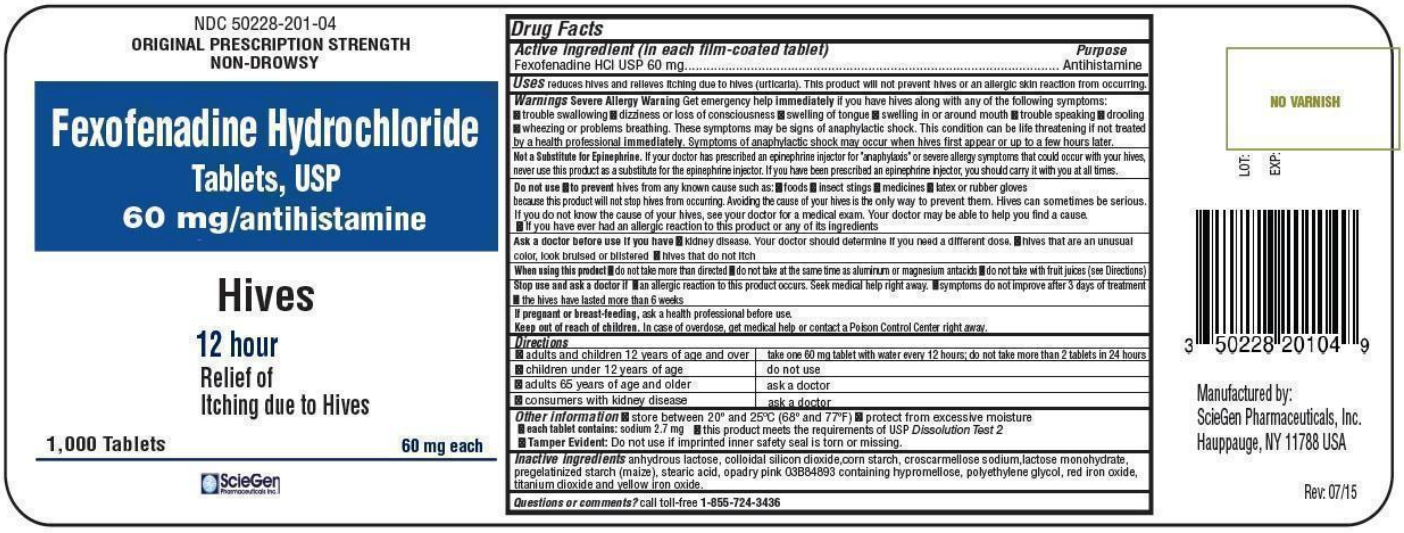


Package/Label Principal Display Panel

Fexofenadine Hydrochloride Tablets USP 60mg



Package/Label Principal Display Panel

Fexofenadine Hydrochloride Tablets USP 180mg

FRONT

NDC 50228-202-03

ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

Fexofenadine Hydrochloride
Tablets, USP
180 mg/antihistamine

Hives

24 hour
Relief of
Itching due to Hives

30 Tablets 180 mg each

ScieGen Pharmaceuticals Inc

Drug Facts

Active ingredient (in each film-coated tablet)	Purpose
Fexofenadine HCl USP 180 mg	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. ▶

PEEL HERE▼

NO VARNISH

LOT: EXP:

3 50228 20203 9

Manufactured by:
ScieGen Pharmaceuticals, Inc.
Hauppauge, NY 11788 USA Rev: 12/14

BACK

Temporary Glue

Drug Facts (continued)

■ 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	
■ 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
■ **each tablet contains:** sodium 8.2 mg ■ this product meets the requirements of USP *Dissolution Test 2*
■ **Tamper Evident:** Do not use if imprinted inner safety seal is torn or missing.

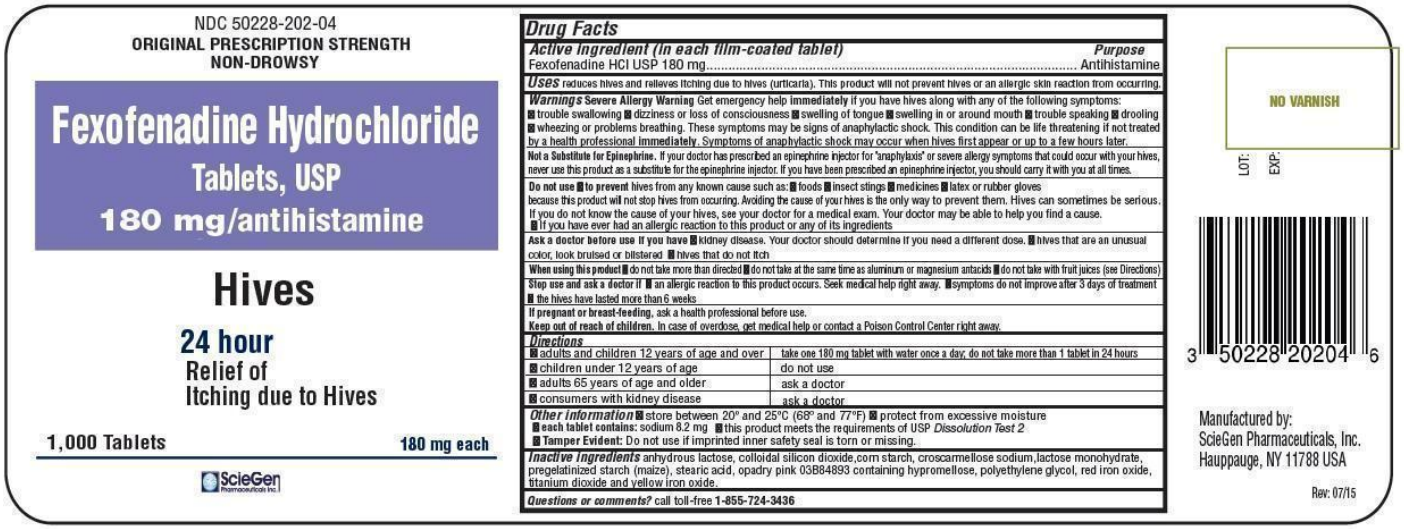
Inactive ingredients anhydrous lactose, colloidal silicon dioxide,corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.

Questions or comments? call toll-free 1-855-724-3436

Permanent Glue

Package/Label Principal Display Panel

Fexofenadine Hydrochloride Tablets USP 180mg



Package/Label Principal Display Panel

Fexofenadine Hydrochloride Tablets USP 60mg

FRONT

NDC 50228-201-01
ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

Fexofenadine Hydrochloride
Tablets, USP
60 mg/antihistamine

Allergy

Indoor and Outdoor Allergies
12 hour Relief of
▪ Sneezing ▪ Runny Nose
▪ Itchy, Watery Eyes ▪ Itchy Nose or Throat

30 Tablets 60 mg each

ScieGen Pharmaceuticals Inc.

Drug Facts

Active ingredient (in each film-coated tablet) ***Purpose***
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.

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. ▶

PEEL HERE▼

NO VARNISH

LOT: EXP:

3 50228 20101 8

Manufactured by:
ScieGen Pharmaceuticals, Inc.
Hauppauge, NY 11788 USA Rev: 12/14

BACK

Temporary Glue

Drug Facts (continued)

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 ■ store between 20° and 25°C (68° and 77°F) ■ protect from excessive moisture
■ **each tablet contains:** sodium 2.7 mg ■ this product meets the requirements of USP *Dissolution Test 2*
■ **Tamper Evident:** Do not use if imprinted inner safety seal is torn or missing.

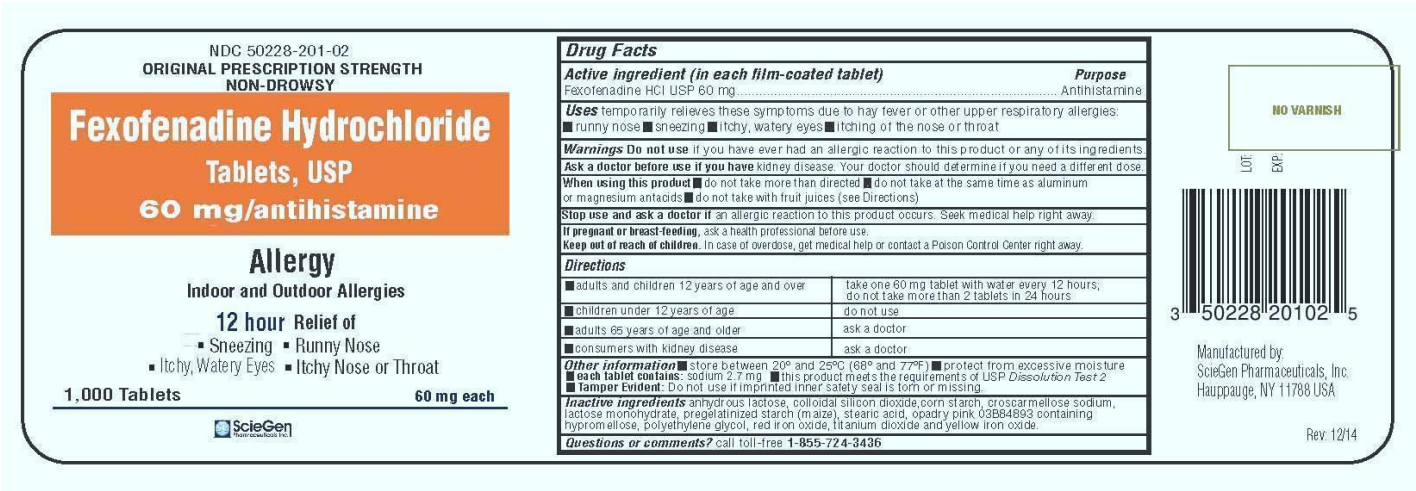
Inactive ingredients anhydrous lactose, colloidal silicon dioxide,corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.

Questions or comments? call toll-free **1-855-724-3436**

Permanent Glue

Package/Label Principal Display Panel

Fexofenadine Hydrochloride Tablets USP 60mg



Package/Label Principal Display Panel

Fexofenadine Hydrochloride Tablets USP 180mg

FRONT

NDC 50228-202-01
ORIGINAL PRESCRIPTION STRENGTH
NON-DROWSY

Fexofenadine Hydrochloride
Tablets, USP
180 mg/antihistamine

Allergy

Indoor and Outdoor Allergies
24 hour Relief of
- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Nose or Throat

30 Tablets **180 mg each**

ScieGen Pharmaceuticals Inc.

Drug Facts

Active ingredient (in each film-coated tablet) ***Purpose***
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.

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. ▶

PEEL HERE▼

NO VARNISH

LOT: EXP:

3 50228 20201 5

Manufactured by:
ScieGen Pharmaceuticals, Inc.
Hauppauge, NY 11788 USA Rev: 12/14

BACK

Temporary Glue

Drug Facts (continued)

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 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
■ **each tablet contains:** sodium 8.2 mg ■ this product meets the requirements of USP *Dissolution Test 2*
■ **Tamper Evident:** Do not use if imprinted inner safety seal is torn or missing.

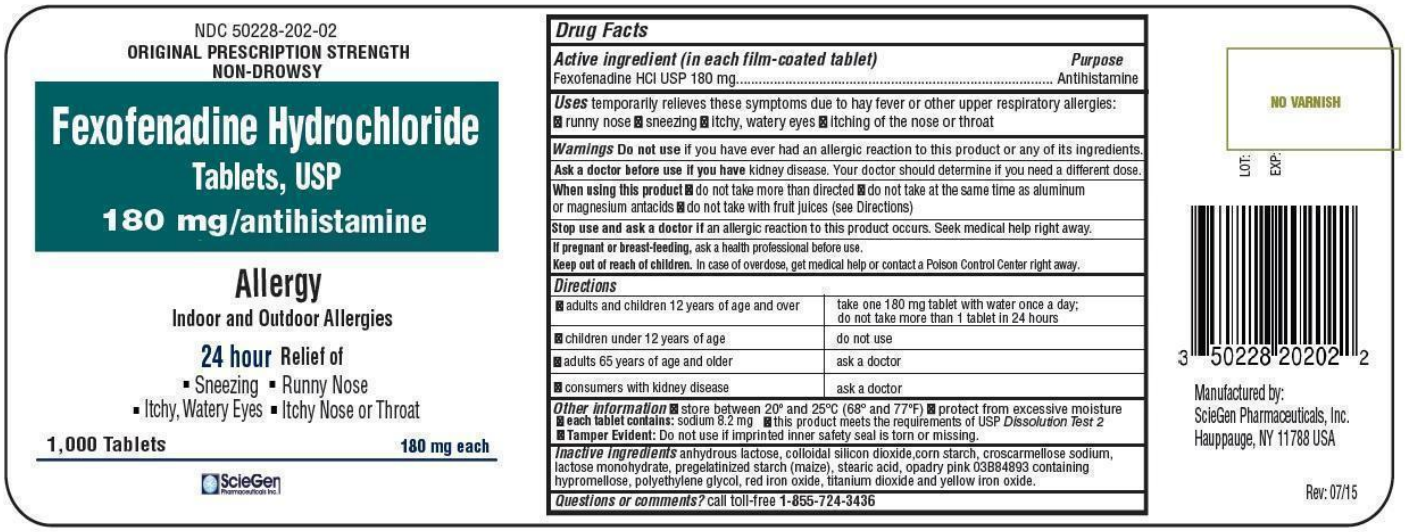
Inactive ingredients anhydrous lactose, colloidal silicon dioxide,corn starch, croscarmellose sodium, lactose monohydrate, pregelatinized starch (maize), stearic acid, opadry pink 03B84893 containing hypromellose, polyethylene glycol, red iron oxide, titanium dioxide and yellow iron oxide.

Questions or comments? call toll-free **1-855-724-3436**

Permanent Glue

Package/Label Principal Display Panel

Fexofenadine Hydrochloride Tablets USP 180mg



FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50228-201
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	OVAL	**Size**	12mm

Flavor		**Imprint Code**	SG;201
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50228-201-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2014	
2	NDC:50228-201-02	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2014	
3	NDC:50228-201-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2014	
4	NDC:50228-201-04	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	12/26/2014	

FEXOFENADINE HCL

fexofenadine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50228-202
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**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	CAPSULE	**Size**	17mm
Flavor		**Imprint Code**	SG;202
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50228-202-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2014	
2	NDC:50228-202-02	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2014	
3	NDC:50228-202-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2014	
4	NDC:50228-202-04	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/26/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204507	12/26/2014	

Labeler - ScieGen Pharmaceuticals, Inc. (079391286)

Registrant - ScieGen Pharmaceuticals, Inc. (079391286)

Establishment

Name	Address	ID/FEI	Business Operations
ScieGen Pharmaceuticals, Inc.		079391286	ANALYSIS(50228-201, 50228-202) , MANUFACTURE(50228-201, 50228-202) , PACK(50228-201, 50228-202) , LABEL(50228-201, 50228-202)

Revised: 1/2020 ScieGen Pharmaceuticals, Inc.