# PICNIC ANTIHISTAMINE- fexofenadine hydrochloride tablet, film coated 30M One, Inc.

-----

### Thirty Madison Inc Antihistamine Drug Facts

### Active ingredient (in each tablet)

Fexofenadine HCl 180 mg

### **Purpose**

**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

- 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 (1-800-222-1222).

#### **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

- do not use if printed foil under cap is broken or missing
- store between 20° -25°C (68° -77°F)
- protect from excessive moisture
- this product meets the requirements of USP Dissolution Test 2

#### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

#### Questions or comments?

1-800-719-9260

### Package/Label Principal Display Panel

**ALLERGY** 

picnic

FEXOFENADINE HYDROCHLORIDE TABLETS 180 mg

**Antihistamine** 

Compare to the active ingredient in Allegra® Allergy / Non-Drowsy / 24 HR / Indoor / Outdoor

Allergy Relief of: Sneezing; Runny Nose; Itchy, Watery Eyes & Itchy Nose or Throat

**Actual Size** 

90 TABLETS



#### **PICNIC ANTIHISTAMINE**

fexofenadine hydrochloride tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80159-112

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		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics						
Color	PINK	Score	no score			
Shape	OVAL	Size	18mm			
Flavor		Imprint Code	L847			
Contains						

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80159-112- 03	1 in 1 CAPSULE	04/25/2022	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:80159-112- 01	1 in 1 CARTON	04/24/2022	
2		30 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	ANDA212971	04/24/2022		

## **Labeler -** 30M One, Inc. (117621005)

Revised: 4/2022 30M One, Inc.