

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209089Orig1s000

209090Orig1s000

LABELING

Xyzal Allergy 24 Hour Tablet Blister Carton

01.06.17

Xyzal_Allergy 10ct_CTN_2016_r5_CLEAN

Drug Facts

Active ingredient (in each tablet) Purpose
Levocetirizine dihydrochloride 5 mg....Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other respiratory allergies:
 ■ runny nose ■ itchy, watery eyes
 ■ sneezing ■ itching of the nose or throat

Warnings
Do not use
 ■ if you have kidney disease
 ■ if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine

Ask a doctor before use if you have
 ■ ever had trouble urinating or emptying your bladder

When using this product
 ■ drowsiness may occur
 ■ avoid alcoholic drinks
 ■ alcohol, sedatives, and tranquilizers may increase drowsiness
 ■ be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
 ■ you have trouble urinating or emptying your bladder
 ■ an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:
 ■ if breast-feeding: not recommended
 ■ if pregnant: 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).

Drug Facts (continued)

Directions
adults 65 years of age and older ■ ask a doctor

adults and children 12-64 years of age
 ■ take 1 tablet (5 mg) once daily in the evening
 ■ do not take more than 1 tablet (5 mg) in 24 hours
 ■ ½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms

children 6-11 years of age
 ■ take ½ tablet (2.5 mg) once daily in the evening
 ■ do not take more than ½ tablet (2.5 mg) in 24 hours

children under 6 years of age ■ do not use

consumers with kidney disease ■ do not use

Other information
 ■ store between 20° and 25°C (68° and 77°F)
 ■ safety sealed: do not use if carton was opened or if individual blister unit is open or torn

Inactive ingredients
colloidal anhydrous silica, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, titanium dioxide

Questions or comments?
call 1-800-630-1610

NDC 41167-3510-0

CLINICALLY PROVEN RELIEF IN 60 MINUTES

CLINICALLY PROVEN RELIEF FROM INDOOR AND OUTDOOR ALLERGIES

CLINICALLY PROVEN RELIEF FOR 24 HOURS

ORIGINAL PRESCRIPTION STRENGTH

XYZAL®

ALLERGY 24HR

levocetirizine dihydrochloride tablet
5 mg / antihistamine

10 TABLETS

24 HOUR RELIEF OF
 ○ SNEEZING
 ○ RUNNY NOSE
 ○ ITCHY NOSE OR THROAT
 ○ ITCHY, WATERY EYES

UPC FP0

LOT: _____

EXP: _____

The trade dress of this Xyzal® package is subject to trademark protection.

Dist. By: Chatterm, Inc.,
a Sanofi Company,
Chattanooga, TN
37409-0219 ©2017

Origin: Switzerland

50122365 

Read directions and warnings before use. Keep this carton. It has important information.

Xyzal Allergy 24 Hour Tablet Blister

1.03.17

Xyzal_Allergy 10ct_PeelPush Blister_2016_r1_CLEAN



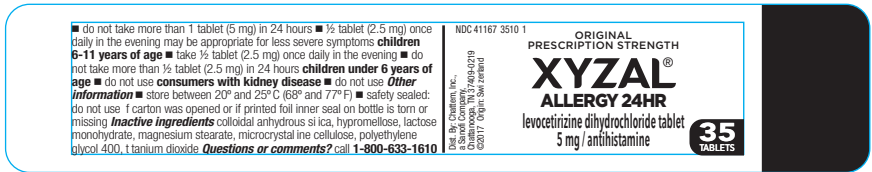
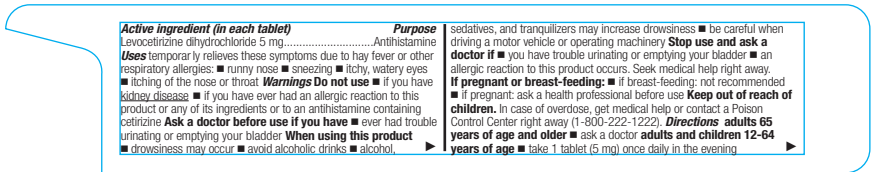
Xyzal Allergy 35ct CTN 2016 r3 CLEAN



Xyzal Allergy 24 Hour Tablet Bottle Label

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Xyzal_Allergy_35ct_Label_2016_r5_CLEAN



Xyzal Allergy 24 Hour Tablet Bottle Bonus Carton

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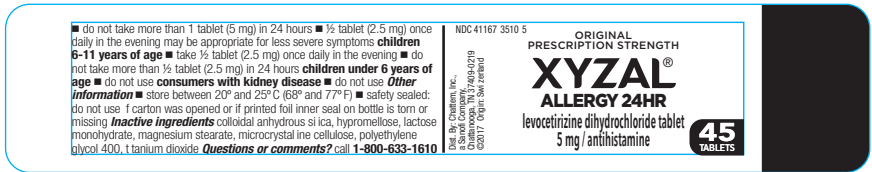
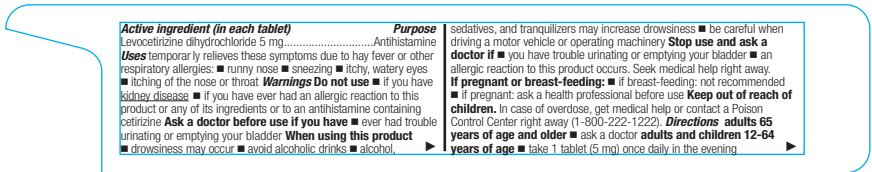
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Xyzal Allergy 24 Hour Tablet Bottle Label

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Xyzal_Allergy_45ct_Label_2016_r4_CLEAN



Xyzal Allergy 24 Hour Tablet Bottle Carton

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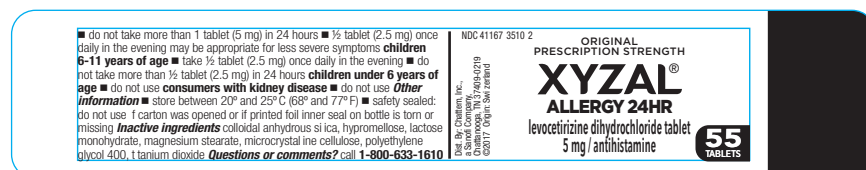
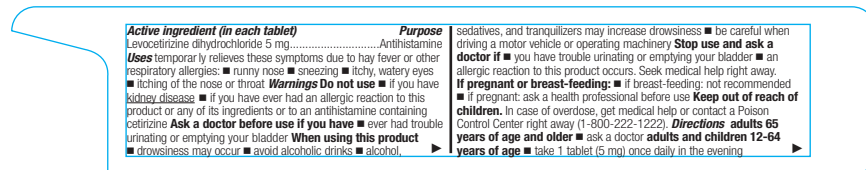
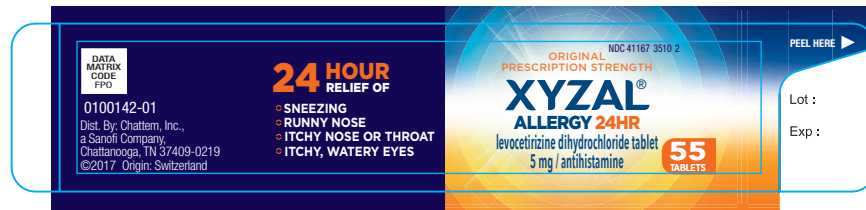
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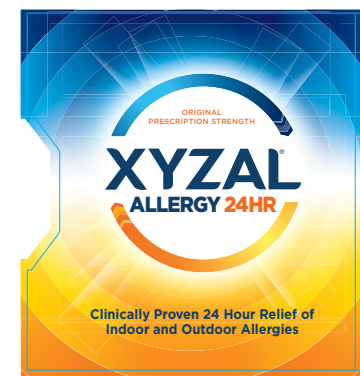
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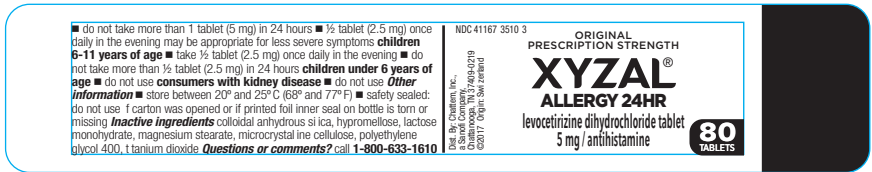
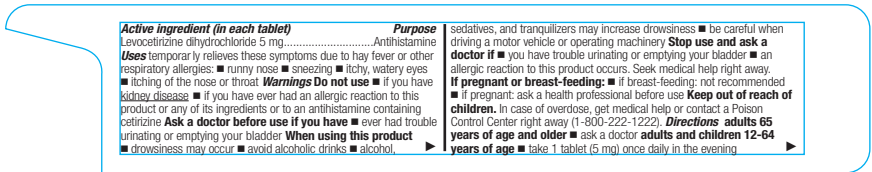
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Xyzal Allergy 80ct CTN 2016_r3_CLEAN



Xyzal Allergy 24 Hour Tablet Bottle Label

01.06.17

Xyzal_Allergy_80oct_Label_2016_r4_CLEAN



Xyzal Allergy 24 Hour Club Card
01.06.17
Xyzal_Allergy_110ct_ClubCard_2016_r3_CLEAN

NDC 41167-3510-4

ORIGINAL
PRESCRIPTION STRENGTH

XYZAL[®]

ALLERGY 24HR

levocetirizine dihydrochloride tablet

5 mg / antihistamine

24 HOUR
RELIEF OF

○ SNEEZING

○ RUNNY NOSE

○ ITCHY NOSE OR THROAT

○ ITCHY, WATERY EYES

110
TABLETS

0051552-01

LOT
EXP

XYZAL[®]

ALLERGY 24HR

CLINICALLY PROVEN RELIEF
IN 60 MINUTES

CLINICALLY PROVEN RELIEF
FOR 24 HOURS

Drug Facts

Active ingredient (in each tablet)
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Purpose
Antihistamine

Uses
temporarily relieves these symptoms due to hay fever or other respiratory allergies:
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Warnings
Do not use
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■ be careful when driving a motor vehicle or operating machinery
Stop use and ask a doctor if
■ you have trouble urinating or emptying your bladder
■ an allergic reaction to this product occurs. Seek medical help right away.
If pregnant or breast-feeding:
■ if breast-feeding: not recommended
■ if pregnant: 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).

Drug Facts (continued)

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adults 65 years of age and older
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adults and children 12-64 years of age
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children under 6 years of age
■ do not use

consumers with kidney disease
■ do not use

Other information
■ store between 20° and 25°C (68° and 77°F)
■ safety sealed: do not use if sealed package was torn or opened, or if printed foil inner seal on bottle is torn or missing
Inactive ingredients
colloidal anhydrous silica, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, titanium dioxide
Questions or comments?
call 1-800-633-1610

Read directions and warnings before use. Keep this carton. It has important information.

UPC
FPO

DATA
MATRIX
FPO

0051552-01

Reference ID: 4048999

Xyzal Allergy 24 Hour Tablet Bottle Induction Seal

1.22.16

Xyzal_Allergy Tablet_Bottle Safety Seal_2016

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Children's Xyzal Allergy 24 Hour Oral Solution Carton

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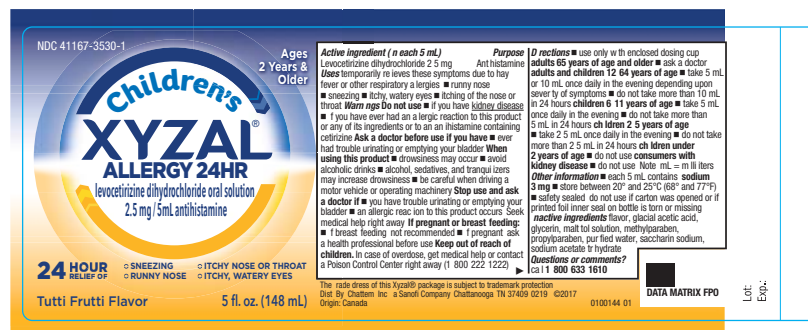
Xyzal_Childrens_Allergy 5oz_CANADA_CTN_2016_r3_CLEAN



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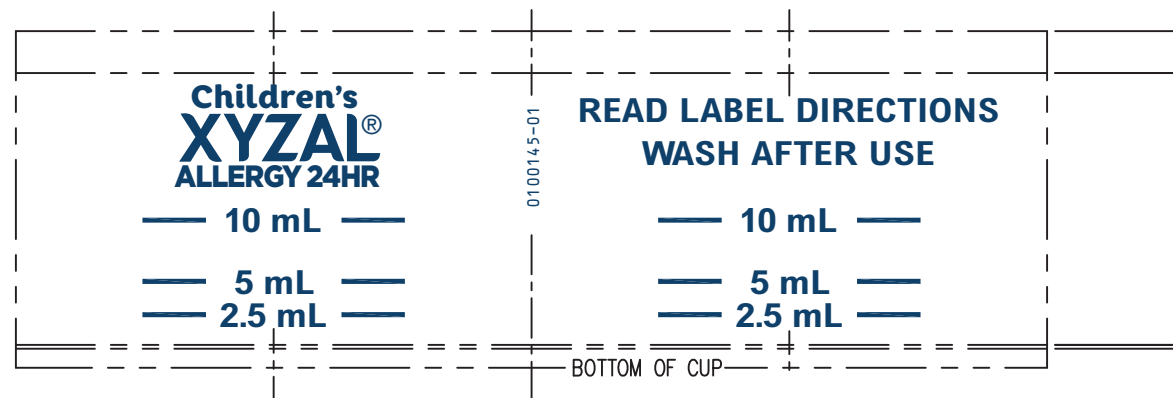
Xyzal Childrens Allergy 5oz CANADA Label 2016 r3 CLEAN



Xyzal Allergy 24 Hour Oral Solution Dosing Cup

1.03.17

Xyzal_Allergy_Dosing Cup_2016_r2_CLEAN



Detailed rendering of dosing cup on next page

Xyzal Allergy 24 Hour Oral Solution Dosing Cup
Digital Rendering
1.03.17



Xyzal Allergy 24 Hour Oral Solution Induction Seal

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Xyzal_Allergy Liquid_Bottle Safety Seal_2016

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
01/31/2017