CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE- cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release
Padagis Israel Pharmaceuticals Ltd

Perrigo Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Drug Facts

Active ingredients (in each extended release tablet)

Cetirizine HCl 5 mg

Pseudoephedrine HCl 120 mg

Purpose

Antihistamine

Nasal decongestant

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
- nasal congestion
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives.

When using this product

- **do not use more than directed**
- 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

- an allergic reaction to this product occurs. Seek medical help right away.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

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)

Directions

- do not break or chew tablet; swallow tablet whole

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 years of age	ask a doctor

consumers with liver or kidney disease	ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)
- **do not use if blister unit is broken or torn**
- see side panel for lot number and expiration date
- meets USP *Dissolution Test 2*

Inactive ingredients

colloidal silicon dioxide, hypromellose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Zyrtec-D® active ingredients

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride

Extended Release Tablets

5 mg/120 mg

Antihistamine / Nasal Decongestant

NASAL CONGESTION + SINUS PRESSURE

• Sneezing

• Itchy, Watery Eyes

• Runny Nose

• Itchy Nose or Throat

Indoor + Outdoor Allergies

12 HOUR RELIEF

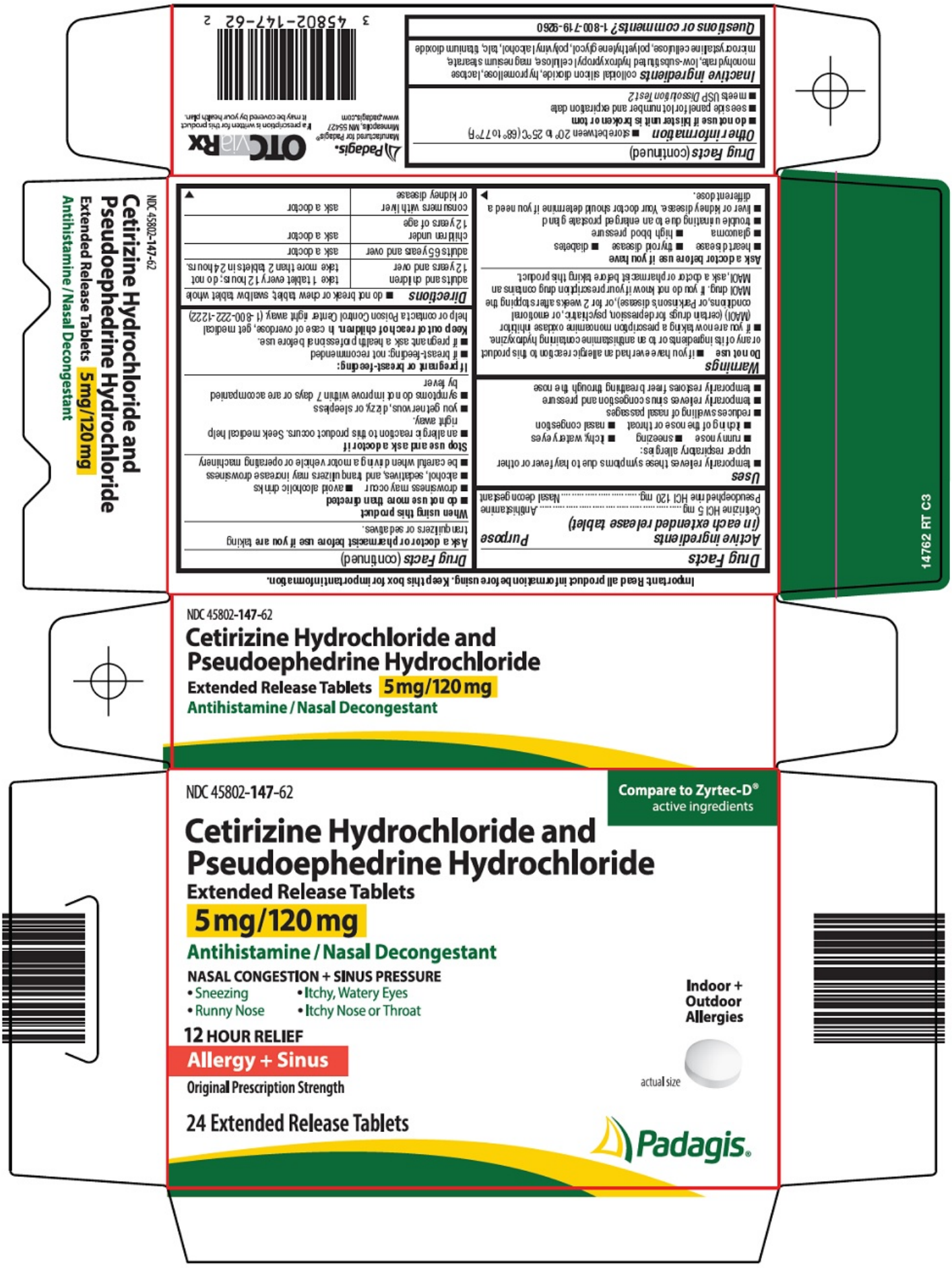
Allergy + Sinus

Original Prescription Strength

actual size

24 Extended Release Tablets

Padagis®



NDC 45802-147-62

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride

Extended Release Tablets 5 mg/120 mg

Antihistamine / Nasal Decongestant

14762 RT C3

Important: Read all product information before using. Keep this box for important information.

Drug Facts

Active ingredients (in each extended release tablet) — **Purpose**

Cetirizine HCl 5 mg ..... Antihistamine

Pseudoephedrine HCl 120 mg ..... Nasal decongestant

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Ask a doctor before use if you have
- heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure
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Drug Facts (continued)

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Questions or comments? 1-800-719-9260

OTC Via Rx

If a prescription is written for this product, it may be covered by your health plan.

Manufactured for Padagis® Minneapolis, MN 55427 www.padagis.com

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NDC 45802-147-62

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Extended Release Tablets 5 mg/120 mg

Antihistamine / Nasal Decongestant

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12 HOUR RELIEF

Allergy + Sinus

Original Prescription Strength

24 Extended Release Tablets

Compare to Zyrtec-D® active ingredients

Indoor + Outdoor Allergies

actual size

Padagis.

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45802-147
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	L147
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45802-147-53	12 in 1 CARTON	03/31/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:45802-147-62	24 in 1 CARTON	03/31/2020	
2		1 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	ANDA210719	03/31/2020	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 2/2025 Padagis Israel Pharmaceuticals Ltd