

Xyzal[®] Allergy 24HR (levocetirizine) products – Rx-to-OTC Approval

- On February 1, 2017, [Sanofi announced](#) the [FDA approval](#) of [Xyzal Allergy 24HR \(levocetirizine\)](#) tablets and Children’s Xyzal Allergy 24HR oral solution, as an over-the-counter (OTC) treatment to temporarily relieve symptoms of runny nose, sneezing, itchy and watery eyes, and itching of the nose or throat due to hay fever or other respiratory allergies.
- Levocetirizine is an antihistamine. Examples of other oral single agent OTC antihistamines used to treat similar symptoms include chlorpheniramine (eg, [Chlor-Trimeton[®] 12 Hour](#)), clemastine (eg, [Dayhist[®] Allergy](#)), diphenhydramine (eg, [Benadryl[®]](#)), triprolidine (eg, [Histex[™]](#)), fexofenadine (eg, [Allegra[®] Allergy](#)), loratadine (eg, [Claritin[®]](#)), and cetirizine (eg, [Zyrtec[®]](#)).
- Warnings of Xyzal Allergy 24HR state the following:
 - Do not use if the patient has kidney disease or if the patient ever had an allergic reaction to this product, any of its ingredients or to cetirizine.
 - Ask a doctor prior to use if the patient has ever had trouble urinating or emptying the bladder.
 - When using this product: drowsiness may occur; avoid alcoholic drinks; alcohol, sedatives and tranquilizers may increase drowsiness; and be careful when driving a motor vehicle or operating machinery.
 - Patients should stop use and ask a doctor if they experience trouble urinating or emptying of the bladder or if an allergic reaction occurs.
 - If an allergic reaction to Xyzal Allergy 24HR occurs, medical attention should be sought right away.
- The recommended doses of Xyzal Allergy 24HR products are as follows:

Product(s)	Patient age	Dose
Xyzal Allergy 24HR tablets/ Children’s Xyzal Allergy 24HR oral solution	Adults and children 12 - 64 years of age	2.5 mg or 5 mg once daily dependent on symptom severity (2.5 mg: 1/2 tablet or 5mL; 5 mg: 1 tablet or 10 mL)
	Children 6 - 11 years of age	2.5 mg once daily (1/2 tablet or 5 mL)
Children’s Xyzal Allergy 24HR oral solution	Children 2 - 5 years of age	1.25 mg once daily (2.5 mL)

- Xyzal Allergy 24HR products are administered in the evening and a single dose should not be taken more than once in a 24 hour period.
- Adults ≥ 65 years of age should consult with a doctor prior to use.
- Xyzal Allergy 24HR tablets should not be used in children < 6 years of age.
- Children’s Xyzal Allergy 24HR oral solution should not be used in children < 2 years of age.
- Prescription [Xyzal[®] \(levocetirizine\)](#) is currently available and indicated for the following:
 - Relief of symptoms associated with seasonal allergic rhinitis in adults and children ≥ 2 years of age
 - Relief of symptoms associated with perennial allergic rhinitis in adults and children ≥ 6 months of age

- Treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children \geq 6 months of age.
- Sanofi plans to launch Xyzal Allergy 24HR 5 mg tablets and Children's Xyzal Allergy 24HR 2.5 mg/5 mL oral solution in the Spring of 2017.



OptumRx[®] specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum[®] company — a leading provider of integrated health services. Learn more at optum.com.

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews[®] is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.