



# Otrimia

Adult - Child  
Nasal Drop Solution

## Composition:

**Otrimia Adult** Nasal Solution contains Xylometazoline Hydrochloride 0.1, Benzalkonium chloride 0.011% as a preservative.  
**Otrimia Child** Nasal Solution contains Xylometazoline Hydrochloride 0.05%, Benzalkonium chloride 0.011% as a preservative.

## Excipient:

Monobasic sodium phosphate, Disodium edetate, Dibasic sodium phosphate, Sodium chloride, Sorbitol 70%, Hypromellose and Water for injection.

## Mechanism of action:

Xylometazoline Hydrochloride is a sympathomimetic agent with marked alpha-adrenergic activity, and is intended for use in the nose. It constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighboring regions of the pharynx. This enables patients suffering from colds to breathe more easily through the nose. The effect of **Otrimia** nasal solution begins within a few minutes and lasts for up to 10 hours. **Otrimia** nasal solution is generally well tolerated and does not impair the function of ciliated epithelium.

## Pharmacokinetics:

Systemic absorption may occur following nasal application of xylometazoline hydrochloride solutions.

## Indications:

**Otrimia** nasal solution is indicated for the symptomatic relief of nasal congestion, perennial and allergic rhinitis (including hay fever), sinusitis

## Contraindications:

**Otrimia** nasal solution is contraindicated in the following cases:

- Known hypersensitivity to Xylometazoline Hydrochloride or to any of the excipients.
- Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater
- Concomitant use of other sympathomimetic decongestants- Patients with Cardiovascular disease including hypertension
- Patients with diabetes mellitus - People with phaeochromocytoma. - Hyperthyroidism - Narrow-angle glaucoma
- Concomitant use of Monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment
- Concomitant use of Beta-blockers - Inflammation of the skin and/or mucosa of the nasal vestibule - Children under the age of 6 years (Child Nasal Drops)

## Warnings and precautions:

- Patients should be advised not to take decongestants for more than seven consecutive days.
- Like other products belonging to the same class of active substances, Xylometazoline should be used Only with caution in patients showing a strong reaction to sympathomimetic agents evidenced by signs of insomnia, dizziness etc.
- Caution is recommended in patients with hypertension, cardiovascular disease, hyperthyroidism, narrow angle glaucoma or diabetes mellitus.

## Warnings and precautions Label:

- Do not exceed the stated dose
- The product should not be used continuously for more than seven consecutive days. If symptoms persist, consult your doctor
- If there is Pregnancy, taking other medicines or under a doctor's care, consult your doctor before using Xylometazoline.
- Adult Nasal drops and Nasal Spray are not being used for infants or children under 12 years.
- Each Xylometazoline pack should be used by one person only to prevent any cross infection
- For reasons of hygiene do not use this bottle for more than 28 days after first opening it- Keep product out of the reach of children

## Additional warnings and precautions:

- Do not use products if patient is sensitive to any of the ingredient of the product.
- Do not take with any other cough and cold medicine - Do not use if patient has had recent neurosurgery.
- Consult doctor before using Xylometazoline if patient has heart or circulatory disease.
- Some patients who have sensitive nasal passages may feel some local discomfort when applying the product.
- Other side effects such as palpitations, nausea and headache are very rare.
- Small children may show restlessness or sleep disturbance when Xylometazoline is used. If this occurs Product should be stopped

## Pregnancy and lactation:

In view of Xylometazoline Hydrochloride potential systemic vasoconstrictor effect, it is advisable to take the precaution of not using **Otrimia** nasal solution during pregnancy. No evidence of any adverse effect on the breast fed infant. However, it is not known if Xylometazoline Hydrochloride is excreted in breast milk, therefor caution should be exercised and **Otrimia** nasal solution should be used only on the advice of a doctor whilst breast feeding.

## Undesirable effects:

- The following side effects have occasionally been encountered: Burning sensation in the nose and throat, Local irritation, nausea, headache and dryness of the nasal mucosa.
- Systemic cardiovascular effects have occurred, and this should be kept in mind when giving xylometazoline to people with cardiovascular disease particularly with prolonged and/or excessive use. .In isolated cases, systemic allergic reactions and transient visual disturbances. - Rebound congestion (rhinitis medicamentosa)-especially with prolonged and/or heavy use
- Tolerance with diminished effect- especially with prolonged and/or heavy use.
- CNS effects (as with oral agents)particular with prolonged and/or excessive use.

## Drug Interactions:

As for all sympathomimetic, the systemic effects of xylometazoline by concomitant Use of monoamine oxidase inhibitors, tricyclic or tetracyclic antidepressants, cannot be excluded,Especially in case of overdose

## Dosage and administration:

### **Otrimia Child- Nasal Drop Solution:**

- Contra-indicated in children under 6 years of age.
- Children between 6 and 12 years: 1 or 2 drops, in each nostril one or twice during day
- Can not be used for more than 5 days without the advice of a doctor.
- Not more than 2 doses should be given in any 24 hours. - Do not exceed the stated dose

### **Otrimia Adult- Nasal Drop Solution:**

- Adults and elderly: 2 or 3 drops in each nostril 2-3 times daily. - The drops are suitable for children over 12 years of age.

### **Nasal Spray Solution:**

- Adults, children over 12 years old and elderly: One application in each nostrils 2-3 times daily. Not suitable for children under 12 years.

## Overdose:

In rare instances of accidental poisoning in children, the clinical picture has been marked chiefly by signs such as acceleration and irregularity of the pulse, elevated blood pressure and sometimes consciousness clouding. There is no specific treatment. Appropriate supportive measures should be initiated.

## Storage conditions:

Store protected from heat at temperature below 25°C, out of reach of children. - Discard the content after 28 days from opening.

## Packaging:

**Otrimia** nasal solution is filled in polyethylene bottle 10mL with dropper, tightly sealed with a polyethylene closer, within a carton box.

Produced by MIAMED Pharmaceutical Industries –Damascus countryside –Syria

This is a medicament
- A medicament is a product but unlike any other products.
- A medicament is a product which affect your health, and its consumption contrary to instructions is dangerous for you.
- follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
Keep medicaments out of reach of children

Council of Arab Health Ministers

Arab pharmacist Association



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