GSK Consumer
Healthcare S.A.
CH-1260, Nyon, Switzerland Global Regulatory Affairs

Global Labelling & Compliance

Otrivin 0.1%
Moisturising Formula (F.5)

Metered-Dose Spray 0.1% (F.5)

Xylometazoline hydrochloride 0.1%

Core Summary of Product Characteristics (SmPC)

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1. NAME OF THE MEDICINAL PRODUCT

Otrivin 0.1%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mg/ml of xylometazoline hydrochloride.

3. PHARMACEUTICAL FORMS

Nasal Spray Solution (metered-dose spray) 0.1% (1 mg/ml)

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Rhinitis of various origin.
To aid drainage of secretions in affections of the paranasal sinuses.
As an adjuvant in otitis media, to decongest the nasopharyngeal mucosa. To facilitate rhinoscopy.

4.2. Posology and method of administration

For adults and children over 12 years of age.

1 application into each nostril. 3 times daily. Repeat if necessary. Do not use more than 3 times a day.

Before use, thoroughly clean the nasal passages. Remove the protective cap. Before the first use of the spray, it is necessary to press the sprayer several times until uniform spraying appears. For subsequent use, the spray is ready for use. If after repeated pressing of the sprayer, the spraying does not come out completely, for example, after temporarily stopping the use of the spray, press the sprayer again 4 times. It is necessary to place the tip in the nasal passage and sharply press the atomizer 1 time, and at the same time take a shallow inhale for optimal distribution of the drug. After use it is necessary to put on the protective cap again.

4.3. Contraindications

Hypersensitivity to any ingredient, closed angle glaucoma, atrophic rhinitis, dry rhinitis, trans-sphenoidal hypophysectomy (or transnasal or transoral surgical interventions with exposure of the dura mater).

4.4. Special warnings and special precautions for use

Talk with your doctor before using xylometazoline if you have a heart condition (such as long QT syndrome). Patients with long QT syndrome who are receiving xylometazoline may be at increased risk of developing serious ventricular arrhythmias.
Otrivin should be used with caution in patients with:

- arterial hypertension, cardiovascular diseases
- hyperthyroidism, diabetes mellitus, pheochromocytoma
- prostatic hypertrophy
- who are taking, or have taken monoamine oxidase inhibitors in the last 14 days
- with increased sensitivity to sympathomimetics, which is manifested by symptoms such as insomnia, dizziness, etc.

Like other topical vasoconstrictors, Otrivin should not be used continuously for more than 1 week, since it is possible to develop rhinitis medicamentosa with swelling of the nasal mucosa, the symptoms of which are similar to a runny nose.

Do not exceed the recommended dose, especially in children and in the elderly.
Otrivin nasal metered-dose spray 0.1% should not be used in children under 12 years of age.
Benzalkonium chloride, which is part of the medicine, can cause irritation and swelling of the nasal mucosa, especially with prolonged use.

4.5. Interactions with other medicinal products and other forms of interaction

Monoamine oxidase inhibitors. Xylometazoline can enhance the action of monoamine oxidase inhibitors and cause hypertensive crisis. Xylometazoline is not recommended in patients who are taking or have taken monoamine oxidase inhibitors within the past 14 days.
Tri- or tetracyclic antidepressants. The simultaneous use of tri- or tetracyclic antidepressants with sympathomimetic agents is not recommended, since it can cause an increase in the sympathomimetic action of xylometazoline.

4.6. Pregnancy and lactation

Pregnancy
In view of its vasoconstrictor effect, as precaution, do not use Otrivin during pregnancy.
Lactation
It is not known whether xylometazoline passes into breast milk. The use of the drug Otrivin during breastfeeding is possible only as prescribed by a doctor.

Fertility

There are no relevant data on the effect of Otrivin on fertility. Controlled animal studies are not available. Since the systemic exposure of xylometazoline is very low, the likelihood of an effect on fertility is extremely small.

4.7. Effects on ability to drive and use machines

With prolonged use and high dosages of xylometazoline, possible systemic effects with cardiovascular effects cannot be ruled out.

4.8. Undesirable effects

The adverse reactions are listed below according to system class and frequency. The frequencies are defined as follows: Very common (≥1/10), common (<1/10, ≥1/100), uncommon (<1/100, ≥1/1,000), rare (<1/1,000, ≥1/10,000), very rare (<1/10,000).

Within each group, adverse events are presented in decreasing order of severity.
Immune system disorders: very rare - hypersensitivity reactions (rash, itching, angioedema).
Nervous system disorders: common- headache.
Eye disorders: very rare - temporary visual disorder.
Cardiovascular disorders: very rare- irregular or increased heart rate, hypertension, arrhythmia.
Respiratory disorders: common- dryness, discomfort, burning of the nasal mucosa, drug rhinitis.
Gastrointestinal disorders: common- nausea.
General disorders: common- burning sensation at the place of application.
In case of occurrence of the listed adverse reactions or reactions not mentioned in this leaflet, you should consult a doctor.

4.9. Overdose

Excessive topical use of xylometazoline or accidental ingestion can cause sympatholytic effects, including central nervous system depression (e.g., drowsiness, coma), hypertension or hypotension, tachycardia, and bradycardia. Gastrointestinal symptoms may also occur, such as nausea and vomiting. Other symptoms are pallor, excessive hidrosis, hypothermia, myosis, respiratory depression, ataxia, and anxiety.
Severe symptoms after accidental overdose were not observed.

In one newborn (age 2 weeks), the use of 1 drop of a 0.1% solution into each nasal passage led to a coma.
In small children, the use of the drug up to 0.5 mg / kg body weight did not cause clinically relevant symptoms. Due to the lack of data on the use of more than 0.5 mg / kg of body weight, severe symptoms cannot be excluded. In such cases, medical supervision after consultation with an experienced clinician or toxicological information center and taking a single dose of activated charcoal are indicated. There is no specific antidote.
Symptomatic treatment; with bradycardia use atropine.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group

R01A A07: decongestants for topical use, sympathomimetics.

Mechanism of action and pharmacodynamic effects

Xylometazoline is a sympathomimetic agent acting on α-adrenergic receptors in the nasal mucosa.
Administered in the nose, it constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and pharyngonasal cavity. Reliefs nasal breathing.
Contains sorbitol and methylhydroxypropyl cellulose, which can reduce the symptoms of dryness of the nasal mucosa.
The effect begins within a few minutes and lasts for up to 12 hours.
Otrivin does not violate the function of the ciliated epithelium.

5.2. Pharmacokinetic properties

Plasma concentrations of xylometazoline after local application of the product are near to the limit of detection.

5.3. Preclinical safety data

Non-clinical safety data for xylometazoline hydrochloride have not revealed findings which are of relevance to the recommended dosage and use of these products.
Carcinogenesis and mutagenesis
There are no carcinogenicity data available for xylometazoline hydrochloride, however, available *in-vitro* and *in-vivo* genotoxicity data for this active ingredient do not indicate a genotoxic potential.
Reproductive Toxicology
No teratogenic effects were shown in a study where xylometazoline was given subcutaneously in mice and rats.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzalkonium chloride,
Disodium edetate,
Sodium dihydrogen phosphate dihydrate,
Disodium phosphate dodecahydrate,
Sodium chloride,
Sorbitol, liquid (noncrystallising),
Hypromellose,
Purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years. 1 month after the first opening of the package. Do not use after the date indicated on the package.

6.4. Special precautions for storage

Store not above 30 ˚ C. Keep out of the sight and reach of children.

6.5. Nature and contents of container

High density polyethylene bottle mounted with a metered-dose pump (material in contact with product: polyethylene) and a polypropylene nozzle with cap. Content: 10 ml.

7. MARKETING AUTHORISATION HOLDER

GSK Consumer Healthcare S.A.,
Route de l`Etraz, 1260 Nyon, Switzerland.

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION IN ARMENIA / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15-06-2004
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10. DATE OF REVISION OF THE TEXT
08.08.19