SUMMARY OF PRODUCT CHARACTERSTICS

1. NAME OF THE MEDICINAL PRODUCT

Otrivin – Xylometazoline Hydrochloride 0.05% and 0.1%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Nasal drops 0.05% contain 0.5 mg/ml xylometazoline hydrochloride; 1 drop contains 0.0125 mg xylometazoline hydrochloride.

Nasal drops 0.1% contain 1 mg/ml xylometazoline hydrochloride; 1 drop contains 0.025 mg xylometazoline hydrochloride.

Metered-dose spray 0.05% contains 0.5 mg/ml xylometazoline hydrochloride; 1 spray (= 0.07 ml) contains 0.035 mg xylometazoline hydrochloride.

Metered-dose spray 0.1% contains 1 mg/ml xylometazoline hydrochloride; 1 spray (= 0.14 ml) contains 0.14 mg xylometazoline hydrochloride.

3. PHARMACEUTICAL FORM

Nasal drops

Clear colourless to slightly yellowish solution, practically odorless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief of nasal congestion due to colds, hay fever or other allergic rhinitis,
sinusitis.

For easing the flow of mucus in inflammations of the nasal sinuses.

For otitis media as an adjunct for decongestion in the nasopharyngeal area.

For easing of rhinoscopy.

4.2 Posology and method of administration

Otrivin Nasal Drops 0.05%/Otrivin Metered-Dose Spray 0.05%

Children 1–5 years old use under adult supervision.

Normally, 1–2 drops of the 0.05% solution 1–2x daily, or 1 spray with the 0.05% metered-dose spray in each nostril are sufficient; you must not exceed 3 applications per day.

Children aged 6-11 years: use under adult supervision.

Use 2-4 drops drops into each nostril, 1 to 2 sprays into each nostril, 2 to 3 times daily as needed.

Do not exceed 3 applications daily into each nostril.

Children aged below 1 year: the product should not be used.

Otrivin Metered-Dose Spray 0.1%

Only suitable for adults and adolescents aged 12 years and above.

1 spray in each nostril. Repeat as needed, however, do not exceed 3 applications per day.

Otrivin nasal drops 0.1%/Otrivin Nebuliser 0.1% are only suitable for adults and adolescents from 12 years of age.

2–4 drops of the 0.1% solution or 1 spray (nebuliser 0.1%) in each nostril. Repeat as needed, however, the dose must not exceed 3 applications a day.

The last application of the day should preferably be shortly before going to bed.

Otrivin should not be used for longer than 1 week as longer-term use can lead to Rhinitis medicamentosa.

How to use the drops:

Clean (blow) the nose thoroughly before use.

Tilt the head back slightly. Insert the drops into each nostril and briefly keep the head tilted back so that the drops can spread out. Clean and dry the dropper before screwing it back onto the bottle.

How to use the nebuliser:

Clean (blow) the nose thoroughly before use.

To ensure a fine mist, hold the nebuliser vertically with its opening pointing up. Ensure that the mist does not come into contact with the eyes. Insert the spray nozzle into the nostril and squeeze the spray container. Remove the spray nozzle before releasing pressure. Optimal distribution of the mist can be achieved by breathing in lightly through the nose while spraying. Clean and dry the spray nozzle before replacing the protective cap.

How to use the metered-dose spray:

Clean (blow) the nose thoroughly before use. remove the protective cap. Activate the pump 4 times before the first use. The metered-dose spray is ready to use for all other applications. If the mist is not fully emitted after pumping, e.g. after a break from use, activate the pump again 4 times. Insert the spray opening into the nostril and press down strongly on the nozzle, once. Optimal distribution of the mist can be achieved by breathing in lightly through the nose while spraying. Replace the protective cap after use.

4.3 Contraindications

Otrivin must not be used in patients with history and progression of trans-sphenoid hypophysectomy (or after trans-nasal or trans-oral surgeries which expose the dura mater), or for dry nasal mucosa (Rhinitis sicca), atrophic rhinitis, closed-angle glaucoma or in cases of known hypersensitivity to xylometazoline or any other excipient.

4.4 Special warnings and precautions for use

Otrivin should be used with caution in patients

• with high blood pressure, cardiovascular disorders, Patients with a long QT syndrome have an increased risk of severe ventricular arrhythmia when undergoing treatment with xylometazoline

• with hyperthyreosis, diabetes mellitus, phaeochromocytoma,

• with prostatic hypertrophy,

• who are being treated with MAO inhibitors or who have received these within the last 14 days (see "Interactions"),

• with intensified reactions to sympathomimetic substances with signs of insomnia, light headedness, etc.

As with other topical vasoconstrictors, ongoing treatment with Otrivin lasting longer than 1 week is not indicated as Rhinitis medicamentosa with nasal mucosal swelling can occur; this has very similar symptoms to a head cold.

This product should be discontinued immediately, and medical advice sought if signs/symptoms of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) develop. Symptoms reported included sudden onset of severe headache, nausea, vomiting, and visual disturbances.

The recommended dose should not be exceeded, especially in children and elderly patients.

Otrivin 0.05% (nasal drops and metered-dose spray) should not be used by children aged under 1 year. For children aged from 1 to 2 years, use only according to the doctor's prescription. For children aged from 2 to 11 years, use only under adult supervision.

Otrivin Head Cold Metered-Dose Spray 0.1% should not be used by children under 12 years of age.

4.5 Interaction with other medicinal products and other forms of interaction

MAO inhibitors: xylometazoline can intensify the effect of MAO inhibitors and cause a hypertensive crisis. Xylometazoline is not recommended for patients who are taking MAO inhibitors, or who have taken one within the last 14 days (see "Warnings and precautions").

Tri- or tetra-cyclic antidepressants: the concurrent administration of tricyclic or tetracyclic antidepressants with sympathomimetics can lead to intensification of the sympathomimetic effect of xylometazoline and is therefore not recommended.

4.6. Fertility, Pregnancy and Lactation

Pregnancy: As a precaution, Otrivin should not be used during pregnancy due to its vasoconstrictive properties.

Lactation: it is not known whether xylometazoline passes into the breast milk.

Otrivin should only be used on medical advice during lactation.

Fertility: there is no relevant data regarding the effect of Otrivin on fertility and no controlled studies in animals are available. As the systemic exposure of xylometazoline is very low, effects on fertility are unlikely

4.7 Effects on ability to drive and use machines

For longer-term application or higher doses of xylometazoline drugs, possible systemic actions with cardiovascular effects cannot be excluded.

4.8 Undesirable effects

The undesirable effects are listed below according to system class and frequency. The frequencies are defined as follows: Very common (≥1/10), common (≥1/100 to <1/10) uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000). The undesirable effects are listed in decreasing order of severity within each frequency group.

Immune system:

Very rare: hypersensitivity reactions (angio-oedema, rash, pruritus).

Nervous system:

Common: headaches.

Eyes:

Very rare: temporary visual disturbances.

Heart:

Very rare: irregular and increased heart rate, hypertension, arrhythmias.

Respiratory tracts:

Common: nose dryness, nasal discomfort, burning sensation, Rhinitis medicamentosa.

Gastrointestinal disorders:

Common: nausea.

General:

Common: a burning sensation at the application site.

4.9 Overdose

Excessive use of topical xylometazoline or accidental ingestion can cause sympatholytic effects, including CNS depression (such as drowsiness, coma), hypertension by or hypotension, as well as tachycardia and bradycardia. Gastrointestinal symptoms such as nausea and vomiting can also occur. Further symptoms include paleness, excessive sweating, hypothermia, miosis, respiratory depression, ataxia and restlessness.

Severe symptoms after accidental exposure have not been observed; however, in a newborn (2 weeks old) the use of 1 drop of 0.1% solution in each nostril led to a coma.

In infants, the ingestion of up to 0.5 mg/kg body weight did not lead to clinically relevant symptoms. Owing to a lack of data, severe symptoms following the ingestion of more than 0.5 mg/kg body weight cannot be excluded. In such cases, medical monitoring and administration of a single dose of activated charcoal is indicated after consultation with an experienced clinician or a toxicological information centre. There is no specific antidote. The therapy is symptomatic; bradycardia can be treated with atropine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Xylometazoline is a sympathomimetic and acts on the alpha-adrenergic receptors in the nasal mucosa.

After application in the nose, the blood vessels are constricted which decreases the swelling in the nasal mucosa and the neighbouring areas of the pharynx. This eases nasal breathing.

Furthermore, Otrivin contains ingredients (sorbitol solution and methylhydroxypropyl cellulose) intended to prevent the drying of the nasal mucosa.

The effect begins within minutes and lasts for up to 12 hours. Otrivin does not affect the function of the ciliated epithelium.

5.2 Pharmacokinetic properties

After nasal application, the plasma concentrations of xylometazoline in humans are generally low and close to the limit of detection.

5.3 Preclinical safety data

Xylometazoline has no mutagenic effect. No teratogenic effects were observed following subcutaneous application of xylometazoline in mice and rats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate dihydrate, disodium phosphate dodecahydrate, disodium edetate, benzalkonium chloride (as solution) as a preservative, sorbitol, hypromellose, sodium chloride.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Keep out of the reach and sight of children.
Do not use this medicine after the expiry date ("EXP") stated on the pack.
Do not store above 30ºC.

6.5 Nature and contents of container

Nasal drops (0.05%): 10 ml.
Nasal drops (0.1%): 10 ml.
Nebuliser (0.1%): 10 ml.
Metered dose nasal spray (0.05%): 10 ml.
Metered dose nasal spray (0.1%): 10 ml.

Not all of these forms are available in all countries.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

World Wide Commercial Ventures Limited,
RC325074, Plot A1 Block 9 Adejumo Estate, Ilupeju Industrial Estate, Lagos, Nigeria.

DRUG PRODUCT MANUFACTURER

GSK Consumer Healthcare SARL
Route de l'Etraz
1260, Nyon
Switzerland

NAFDAC REGISTRATION NUMBER

Nasal drops (0.05%): 10 ml: 04-5350
Nasal drops (0.1%): 10 ml: 04-0026
Metered dose nasal spray (0.1%): 10 ml: B4-0350

DATE OF REVISION OF THE TEXT

Dec 2024