COMPOSITION:
OTRIVIN MENTHOL NASAL METERED-DOSE SPRAY: 1 ml contains 1 mg of xylometazoline hydrochloride.
Preservative: 0,01 % m/v benzalkonium chloride.
Excipients: disodium edetate, disodium phosphate dodecahydrate, eucalyptol (Cineole), menthol (Levomenthol), polyoxyl 40 hydrogenated castor oil (Cremophor RH 40), purified water, sodium chloride, sodium dihydrogen phosphate dihydrate, sorbitol 70 % (non-crystallising).

CATEGORY AND CLASS:
A16.1 Nasal Decongestants.

PHARMACOLOGICAL ACTION:
OTRIVIN MENTHOL contains xylometazoline, which belongs to the group of the alkyl imidazolines and acts on the α-adrenergic receptors. OTRIVIN MENTHOL has vasoconstrictor action, producing decongestion of the nasal and pharyngeal mucosa when administered locally.

INDICATIONS:
Decongestion of naso-pharyngeal mucosa in colds, sinusitis, rhinitis, hay-fever, otitis media and to facilitate rhinoscopy.

CONTRAINDICATIONS:
OTRIVIN MENTHOL is contraindicated in cases of hypersensitivity to xylometazoline or to any of the ingredients of OTRIVIN MENTHOL. OTRIVIN MENTHOL is contraindicated in the following conditions:
- Hyperthyroidism,
- patients with or predisposed to narrow angle glaucoma,
- diabetes mellitus,
- ischaemic heart disease, other heart disease including angina or hypertension,
- rhinitis sicca or atrophic rhinitis,
- patients being treated with monoamine oxidase (MAO) - inhibitors or 14 days after stopping treatment.

OTRIVIN MENTHOL should not be employed in status post transsphenoidal hypophysectomy (or after transnasal or transoral surgical interventions in which the dura mater has been exposed).

WARNINGS AND SPECIAL PRECAUTIONS:
OTRIVIN MENTHOL should be used with caution in patients showing a strong reaction to sympathomimetic agents, as evidenced by signs of insomnia, dizziness, tremor, cardiac dysrhythmias or elevated blood pressure.
OTRIVIN MENTHOL should be used with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, diabetes mellitus, epistaxis, phaechromocytoma, prostatic hypertrophy, monoamine oxidase inhibitors (MAOI) treatment or who have received them in the last two weeks (see INTERACTIONS).
Do not exceed the recommended dose, especially in children and in the elderly.
OTRIVIN MENTHOL should not be employed continuously for periods exceeding ten days: prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

INTERACTIONS:
The concomitant use of OTRIVIN MENTHOL with monoamine oxidase (MAO) inhibitors or tricyclic or tetracyclic antidepressants may cause an increase in blood pressure due to cardiovascular effects of these substances (see WARNINGS AND SPECIAL PRECAUTIONS).

HUMAN REPRODUCTION:
The use of OTRIVIN MENTHOL during pregnancy is not advisable due to its potential systemic absorption. OTRIVIN MENTHOL should be used with caution during lactation and only under medical advice.

DOSAGE AND DIRECTIONS FOR USE:
OTRIVIN MENTHOL Metered-dose spray is for nasal administration only, in adults and children over 12 years of age: 1 application of the metered-dose spray into each nostril; a total of 3 applications a day is usually sufficient. OTRIVIN MENTHOL should be used after blowing the nose.

Use of OTRIVIN MENTHOL Nasal Metered-Dose Spray:
Remove the protective cap. Before the first application prime the pump by actuating **4 times**. Once primed, the pump will normally remain charged throughout regular daily treatment periods. If the spray is not ejected during the full actuation stroke, or if the product has not been used for longer than 7 days, the pump will need to be reprimed with **4 actuations**. Be very careful not to spray in the eyes or mouth.

Insert the nozzle into the nostril and press once firmly on the spray head and breathe in at the same time. Then withdraw the nozzle before releasing pressure. Repeat the operation in the other nostril. Replace the protective cap.

The dosing spray ensures the OTRIVIN MENTHOL solution is well distributed over the surface of the nasal mucosa. The standardized valve with which it is fitted permits accuracy of dosage and precludes the possibility of unintentional overdosage.

SIDE EFFECTS:
Side effects are reported according to the MedDRA system organ class and frequency.
Frequencies are classified as follows:

Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1000 and < 1/100), Rare (≥ 1/10 000 and < 1/1000), Very rare (< 1/10 000). Not known (cannot be estimated from the available data) and include isolated reports.

Immune system disorders
Very rare: hypersensitivity reaction (angioedema, skin rash, pruritis)

Nervous system disorders
Common: headache
Unknown: insomnia

Eye disorders
Very rare: transient visual disturbances

Cardiac disorders
Very rare: heart rate irregular, heart rate increase (palpitations)
Unknown: dizziness

Respiratory, thoracic and mediastinal disorders
Common: nasal discomfort, dryness of the nasal mucosa, a burning sensation in the nose and throat
Very rare: apnoea in young infants and newborns
Unknown: anosmia, epistaxis, rebound congestion after discontinuation

Gastrointestinal disorders
Common: nausea

General disorders and administration site condition
Common: application site burning, local irritation

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Signs: Excessive administration of OTRIVIN MENTHOL or accidental ingestion may cause severe dizziness, perspiration, severely lowered body temperature, headache, bradycardia, hypertension, respiratory depression, coma and convulsions. Hypertension may be followed by hypotension. Small children are more sensitive to toxicity than adults. In instances of accidental poisoning in children, the clinical picture may be marked chiefly by signs such as accelerated and irregularity of the pulse, elevated blood pressure and sometimes clouding of consciousness, sweating, drowsiness, coma, convulsions, circulatory collapse.
Treatment: symptomatic treatment under medical supervision is indicated.

IDENTIFICATION:
Nasal Metered-Dose Spray: opalescent to clear, colourless to white solution with an odour of menthol and eucalyptol.

PRESENTATION:
OTRIVIN MENTHOL NASAL METERED-DOSE SPRAY: High density polyethylene bottle mounted with a metered-dose pump and a polypropylene nozzle with a protective cap. Content: 10 ml.

STORAGE INSTRUCTIONS:
OTRIVIN MENTHOL NASAL METERED- DOSE SPRAY: Store at or below 25 °C, protected from light and do not freeze.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
OTRIVIN MENTHOL Nasal Metered-Dose Spray: 31/16.1/0319

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
GlaxoSmithKline Consumer Healthcare South Africa (Pty) Ltd
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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
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Date of most recently revised professional information as approved by the Council: 15 January 2019.

Namibia: NS1 Reg. No. 10/16.1/0511