COMPOSITION:
OTRIVIN ADULT NASAL DROPS and OTRIVIN ADULT NASAL METERED-DOSE SPRAY: 1 ml contains 1 mg of xylometazoline hydrochloride. Preservative: 0,011 % m/v benzalkonium chloride.
OTRIVIN PAED NASAL DROPS and OTRIVIN PAED NASAL METERED-DOSE SPRAY: 1 ml contains 0,5 mg of xylometazoline hydrochloride. Preservative: 0,011 % m/v benzalkonium chloride.

Excipients: disodium edetate, disodium phosphate dodecahydrate, methylhydroxypropyl-cellulose, purified water, sodium chloride, sodium dihydrogen phosphate dihydrate, sorbitol 70 % (non-crystallising).

CATEGORY AND CLASS:
A16.1 Nasal Decongestants.

PHARMACOLOGICAL ACTION:
OTRIVIN contains xylometazoline, which belongs to the group of the arylalkyl imidazolines.
OTRIVIN has a vasoconstrictor action, producing decongestion of the nasal and pharyngeal mucosa when administered locally.
The effect of OTRIVIN sets in within a few minutes and persists for several hours.

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

CONTRAINDICATIONS:
OTRIVIN is contraindicated in cases of hypersensitivity to xylometazoline or to any of the ingredients of OTRIVIN.
OTRIVIN is contraindicated in the following conditions:
- Hyperthyroidism,
- narrow angle glaucoma,
- ischaemic heart disease,
- rhinitis sicca or atrophic rhinitis,
- patients being treated with monoamine oxidase (MAO) - inhibitors or 10 days after stopping treatment.

OTRIVIN should not be employed in status post transsphenoidal hypophysectomy (or after transnasal or transoral surgical interventions in which the dura mater has been exposed).
OTRIVIN PAED NASAL DROPS and OTRIVIN PAED NASAL METERED-DOSE SPRAY are contraindicated in children aged less than 2 years old.
OTRIVIN PAED should be used in children aged 2 to 11 years old only under adult supervision.
OTRIVIN ADULT NASAL DROPS and OTRIVIN ADULT NASAL METERED-DOSE SPRAY are contraindicated in children aged less than 12 years.

WARNINGS AND SPECIAL PRECAUTIONS:
OTRIVIN should be used with caution in patients showing a strong reaction to sympathomimetic agents, as evidenced by signs of insomnia, dizziness as manifested by signs of insomnia, dizziness, tremor, cardiac dysrhythmias or elevated blood pressure.
OTRIVIN 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 should not be used for more than ten consecutive days: prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

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

DOSAGE AND DIRECTIONS FOR USE:
OTRIVIN ADULT NASAL DROPS and OTRIVIN ADULT NASAL METERED-DOSE SPRAY (1 mg/ml) are for nasal administration only, in adults and children over 12 years of age: 2 to 3 drops of the 1 mg/ml solution into each nostril per application, or one puff from the metered-dose spray, into each nostril per application; a total of 3 applications a day is usually sufficient.
OTRIVIN PAED NASAL DROPS and OTRIVIN PAED NASAL METERED-DOSE SPRAY (0,5 mg/ml) are for nasal administration only, for children aged 2 up to 12 years of age: 1 to 2 drops of the 0, 5 mg/ml solution or one puff of the metered-dose spray into each nostril, once or twice daily, are generally sufficient; a total of 2 applications a day should not be exceeded.

OTRIVIN should be used after blowing the nose.

Use of OTRIVIN PAED AND ADULT NASAL METERED-DOSE SPRAYS:
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 for the OTRIVIN PAED NASAL METERED-DOSE SPRAY will need to be reprimed with **2 actuations** and the pump for the OTRIVIN ADULT NASAL METERED-DOSE SPRAY will need to be re-primed with **4 actuations.** 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. Clean and replace the protective cap.

NOTE: In children aged 2 up to 12 years of age, only OTRIVIN PAED NASAL DROPS and OTRIVIN PAED NASAL METERED-DOSE SPRAY of 0, 5 mg/ml should be employed.

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
Less frequently: Skin rash or transient visual disturbances
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 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 acceleration 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:
Drops and Metered-Dose Spray: Clear, colourless solution.

PRESENTATION:
OTRIVIN PAED NASAL DROPS (0, 5 mg/ml solution): High Density Polyethylene dropper bottles containing 10 ml.
OTRIVIN PAED NASAL METERED-DOSE SPRAY (0, 5 mg/ml solution): High Density Polyethylene bottle mounted with a metered-dose pump and a polypropylene nozzle with a protective cap. Content:10 ml.
OTRIVIN ADULT NASAL DROPS (1 mg/ml solution): High Density Polyethylene dropper bottles containing 10 ml.
OTRIVIN ADULT NASAL METERED-DOSE SPRAY (1 mg/ml solution): High Density Polyethylene bottle mounted with a metered-dose pump and a polypropylene nozzle with a protective cap. Content:10 ml.

STORAGE INSTRUCTIONS:
OTRIVIN ADULT NASAL DROPS, PAED NASAL DROPS, PAED NASAL METERED-DOSE SPRAY and ADULT NASAL METERED-DOSE SPRAY: Store at or below 25 °C.

Do not use more than 30 days after opening.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBERS:
OTRIVIN ADULT NASAL DROPS and OTRIVIN ADULT NASAL METERED-DOSE SPRAY 1 mg/ml: H/16.1/1382
OTRIVIN PAED NASAL DROPS and OTRIVIN PAED NASAL METERED-DOSE SPRAY 0, 5 mg/ml: H/16.1/1381

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
GlaxoSmithKline Consumer Healthcare South Africa (Pty) Ltd

39 Hawkins Avenue
Epping Industria 1
7640

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:
Date on the registration certificate of the medicine: Otrivin Adult: 24 June 1992; Otrivin Paed: 24 June 1994.
Date of most recently revised professional information as approved by the Council: 15 March 2019.

Namibia: Otrivin Paed (Nasal Drops & Nasal MDS) NS1 Reg. No.: 10/16.1/0509 Otrivin Adult (Nasal Drops & Nasal MDS) NS1 Reg. No.: 10/16.1/0510
Botswana: Otrivin Paed Nasal Drops S3 Reg. No.: B9302680 Otrivin Adult Nasal Drops S3 Reg.No.: B9302695 Otrivin Adult Nasal MDS S3 Reg.No.: B9302690
Malawi: Otrivin Paed Nasal Drops Reg.No.: PMPB/PL/260/4 Otrivin Adult Nasal Drops Reg.No.: PMPB/PL/260/5 Otrivin Adult Nasal MDS Reg.No.: PMPB/PL/260/10
Zambia: Otrivin Paed Nasal Drops Reg.No.:242/013 P Otrivin Adult Nasal Drops Reg.No.: 242/014 P Otrivin Adult Nasal MDS Reg.No.: 242/006 P
Zimbabwe: Otrivin Paed Nasal Drops Reg.No.: 90/20.2.4/2368 Otrivin Adult Nasal Drops Reg.No.: 90/20.2.4/2367 Otrivin Adult Nasal MDS Reg.No.: 90/20.2.4/2369