PROFESSIONAL INFORMATION

SCHEDULING STATUS **S1**

PROPRIETARY NAME AND DOSAGE FORMS

OTRIVIN ADULT DROPS

OTRIVIN ADULT NASAL METERED-DOSE SPRAY

OTRIVIN PAED. DROPS

OTRIVIN PAED. NASAL METERED-DOSE SPRAY

COMPOSITION

OTRIVIN ADULT 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. 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 edentate, 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 DROPS and OTRIVIN PAED NASAL METERED 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 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.

ABILITY TO DRIVE AND OPERATE MACHINERY

OTRIVIN has no or negligible influence on the ability to drive and use machines.

DOSAGE AND DIRECTIONS FOR USE

OTRIVIN ADULT DROP and OTRIVIN ADULT 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. DROPS and OTRIVIN PAED. 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 METERED-DOSE SPRAY

Remove the protective cap. Before the first application, perform several pumping motions until an even spray appears in the air.

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.

NOTE: In children aged 2 up to 12 years of age, only OTRIVIN PAED. DROPS and OTRIVIN PAED.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 new borns

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. DROPS (0, 5 mg/ml solution):

Polyethylene dropper bottles containing 10 ml.

OTRIVIN PAED. METERED-DOSE SPRAY (0, 5 mg/ml solution):

Polyethylene metered-dose spray bottle containing 10 ml.

OTRIVIN ADULT DROPS (1 mg/ml solution):

Polyethylene dropper bottles containing 10 ml.

OTRIVIN ADULT METERED-DOSE SPRAY (1 mg/ml solution):

Polyethylene metered-dose spray bottle containing 10 ml.

STORAGE INSTRUCTIONS

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

OTRIVIN ADULT METERED- DOSE SPRAY: Store at or below 25 °C.

Keep out of the reach of children.

REGISTRATION NUMBERS

OTRIVIN ADULT DROPS and OTRIVIN ADULT METERED-DOSE SPRAY 1 mg/ml:

H/16.1/1382

OTRIVIN PAED.DROPS and OTRIVIN PAED. 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) Limited

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: 08 October 2018

Namibia: Otrivin Paed (Nasal Drops and MDS) Reg. No.: 10/16.1/0509 NS1 Otrivin Adult (Nasal Drops and MDS) Reg. No.: 10/16.1/0510 NS1
Botswana: Otrivin Paed Nasal Drops Reg. No.: B9302680 S3 Otrivin Adult Nasal Drops Reg.No.: B9302695 S3 Otrivin Adult MDS Reg.No.: B9302690 S3
Malawi: Otrivin Paed Nasal Drops Reg.No.: PMPB/PL/260/4 Otrivin Adult Nasal Drops Reg.No.: PMPB/PL/260/5 Otrivin Adult 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 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 MDS Reg.No.: 90/16.1/1919