

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using OTRIVIN MENTHOL NASAL METERED-DOSE SPRAY.

OTRIVIN MENTHOL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use OTRIVIN MENTHOL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share OTRIVIN MENTHOL with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

SCHEDULING STATUS

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

OTRIVIN MENTHOL METERED-DOSE SPRAY (1 ml contains 1 mg of xylometazoline hydrochloride).

1. WHAT OTRIVIN MENTHOL CONTAINS

The active substance in OTRIVIN MENTHOL is xylometazoline hydrochloride

Preservative: 0,011 % *m/v* benzalkonium chloride.

The inactive ingredients are: disodium edetate, disodium phosphate dodecahydrate, eucalyptol (Cineole), menthol (Levomenthol), polyoxyl 40 hydrogenated castor oil (Cremophor RH40), purified water, sodium chloride, sodium dihydrogen phosphate dehydrate and sorbitol 70 % (non-crystallising)

2. WHAT OTRIVIN MENTHOL IS USED FOR

OTRIVIN MENTHOL is a nasal decongestant that quickly clears blocked noses. It also contains soothing ingredients that help prevent dryness and irritation of the nasal passages.

OTRIVIN MENTHOL are used for the relief of blocked nose caused by colds, hay fever or other allergic rhinitis, sinusitis.

The effect of **OTRIVIN MENTHOL** starts within minutes and persists for several hours. It is well tolerated, even by patients with a sensitive nasal mucosa.

OTRIVIN MENTHOL may also be used in ear infections to help to decongest the nasopharyngeal mucosa. It may also be prescribed by your doctor in the event of examination of the nose.

3. BEFORE YOU USE OTRIVIN MENTHOL

Do not use OTRIVIN MENTHOL:

- in children less than 12 years of age.
- if you are allergic to xylometazoline or to any of the other ingredients of OTRIVIN MENTHOL.
- If you suffer from a condition called hyperthyroidism (a condition in which the thyroid gland makes too much thyroid hormone). The condition is often referred to as an "overactive thyroid."
- if you suffer from a heart disease characterized by ischaemia (reduced blood supply) to the heart muscle, usually due to coronary artery disease (atherosclerosis of the coronary arteries)
- if you are being treated with medicine known as monoamine oxidase (MAO)- inhibitors (e.g. moclobemide, selegiline) or 10 days after stopping treatment.
- if you have undergone recent trans-nasal surgery (brain surgery where the operation was carried out through the nose or mouth)

- if you have narrow angle glaucoma (increased pressure in eyes).
- if you have chronic nasal inflammation with very dry nasal passages (rhinitis sicca or atrophic rhinitis)

Tell your doctor or pharmacist if any of the above apply to you because OTRIVIN MENTHOL is not suitable for you in these circumstances.

Do not use after the expiry date printed on the pack.

Take special care with OTRIVIN MENTHOL:

Talk to your doctor or pharmacist before use if any of the below apply:

- if you have high blood pressure, heart disease, overactive thyroid, narrow angle glaucoma or diabetes
- difficulty in urinating and/or enlarged prostate gland
- a tendency to have nose bleeds
- if you have a benign tumour of the adrenal gland that produces high amounts of adrenaline and noradrenaline (phaeochromocytoma) or a particular sensitivity to adrenaline and noradrenaline as you may experience dizziness, tremor, rapid heart rate, raised blood pressure and sleeplessness
- if you are taking an antidepressant medicine

If any of the above apply, do not use OTRIVIN MENTHOL before talking to your doctor or pharmacist.

OTRIVIN MENTHOL is not intended for use in the eyes or mouth.

OTRIVIN MENTHOL may give rise to sleep disturbances, dizziness, and tremor in very sensitive patients. Consult your doctor if such signs prove troublesome.

Like other nasal decongestants, **OTRIVIN MENTHOL** should not be used for more than 10 consecutive days. If symptoms persist, consult your doctor. Prolonged or excessive use may cause stuffiness in the nose to recur or worsen.

Do not exceed the recommended dose, especially in children and the elderly.

Pregnancy and breast-feeding:

Do not use **OTRIVIN MENTHOL** during pregnancy. If you are breast-feeding, ask your doctor.

Taking other medicines with OTRIVIN MENTHOL:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of OTRIVIN MENTHOL with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other health care professional for advice.

It is particularly important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Monoamine oxidase inhibitors (MAOI) antidepressants, e.g. moclobemide, selegiline
- Tricyclic (e.g. amitriptyline, clomipramine) or tetracyclic (e.g. mianserin, mirtazapine) antidepressants,

Tell your pharmacist if you are taking any other medicines or herbal remedies including those you have bought yourself.

4. HOW TO USE OTRIVIN MENTHOL

Always use OTRIVIN MENTHOL exactly as your doctor has instructed you. You should check

with your doctor or pharmacist if you are unsure about the dosage. If you have the impression that the effect of OTRIVIN MENTHOL is too strong or too weak, talk to your doctor or pharmacist.

OTRIVIN MENTHOL NASAL METERED-DOSE SPRAY (1 mg/ml) is for nasal administration only, in adults and children over 12 years of age:

one or two applications from the metered-dose spray, into each nostril per application; a total of 3 to 4 applications a day is usually sufficient.

Instructions for use/handling

Metered-Dose Spray

1. Do not cut the nozzle. The metered-dose is ready to prime before use.



2. Clear your nose.
3. Remove the protective cap.
4. 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.
5. Hold bottle upright with thumb under base and nozzle between two fingers.



6. Lean forward slightly and insert the nozzle into a nostril.
7. Depress pump and sniff at the same time, so as to ensure optimal distribution of the spray.



8. Repeat for the other nostril.
9. Clean and dry the nozzle before replacing back the cap right after use.
10. To avoid possible spread of infection, the spray should only be used by one person.

If you take more OTRIVIN MENTHOL than you should:

In case of accidental ingestion, tell your doctor immediately.

If you forget to take OTRIVIN MENTHOL:

If you miss a dose and you remember within one hour or so of the missed dose, use it right away. However, if you do not remember until later, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

5. POSSIBLE SIDE EFFECTS

OTRIVIN MENTHOL can have side effects, although not everybody gets them. Not all side effects reported for this medicine are included in this leaflet. **Should your general health worsen while**

taking this medicine, discontinue use and please consult your doctor, pharmacist or other health care professional for advice.

STOP using OTRIVIN MENTHOL and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- Difficulty breathing, speaking or swallowing
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with a red rash or raised bumps

Common side effects (may affect up to 1 in 10 people):

- Dryness or irritation of the nasal mucosa, nausea, headache, local burning sensation

Very rare side effects (may affect less than 1 in every 10 000 people):

- Allergic reactions (skin rash, itching), blurred vision, irregular or fast heartbeat.

Frequency of occurrence unknown:

- nose bleeding, taste disturbances, rebound congestion after discontinuation, sleeplessness, visual disturbances.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF OTRIVIN MENTHOL

- OTRIVIN MENTHOL NASAL METERED-DOSE SPRAY:
- Store at or below 25 °C.
- Keep out of the reach and sight of children.
- Do not use after the expiry date which is stated on the container. The expiry date refers to

the last day of that month.

- Medicines should not be disposed of via wastewater or household waste. If you no longer need your OTRIVIN MENTHOL, take the unused medicine to your pharmacist for safe disposal.

7. PRESENTATION OF OTRIVIN MENTHOL

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

High Density Polyethylene metered-dose spray bottle containing 10 ml.

8. IDENTIFICATION OF OTRIVIN MENTHOL

Opalescent to clear, colourless to white solution with an odour of menthol and eucalyptol.

9. REGISTRATION NUMBER

OTRIVIN MENTHOL NASAL METERED-DOSE SPRAY

31/16.1/0319

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Haleon South Africa (Pty) Ltd

11 Hawkins Avenue

Epping Industria 1

7450

Tel: (011) 745 6000

11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

15 January 2019

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