SCHEDULING STATUS

S2

PROPRIETARY NAME and dosage form

OTRIVIN PLUS Nasal Spray (solution).

Please read all of this leaflet carefully because it contains important information for you

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

- Keep this leaflet. You may need to read it again.
- Do not share OTRIVIN PLUS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

1. What OTRIVIN PLUS is and what it is used for

OTRIVIN PLUS is nasal spray, solution.

It is used for the short-term symptomatic treatment of nasal congestion and rhinorrhea associated with common colds in adults.

2. What you need to know before you use OTRIVIN PLUS

Do not use OTRIVIN PLUS if you:

- are hypersensitive (allergic) to xylometazoline hydrochloride and ipratropium bromide or any of the other ingredients of OTRIVIN PLUS (listed in section 6).
- have had hypersensitivity reaction to atropine or similar substances, e.g. hyoscyamine and scopolamine.
- have glaucoma.
- have rhinitis sicca.
- recently had a surgical operation where dura mater may have been penetrated, e.g. transsphenoidal hypophysectomy or other transnasal operation.
- are a child under the age of 18 years.

Warnings and precautions

Consult your doctor, pharmacist or healthcare provider before using OTRIVIN PLUS if you have the following conditions:

- hypertension

- heart disease

- thyroid problems

- diabetes mellitus

- prostate and bladder problems

- eye problems

- nose bleeds

- phaeochromocytoma (a rare tumor of the adrenal gland)

- cystic fibrosis

- paralytic ileus (blockage of the intestine)

Dose not use OTRIVIN PLUS for more than 7 days

Avoid spraying OTRIVIN PLUS in or around the eye.

Other medicines and OTRIVIN PLUS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.

Pregnancy and breastfeeding:

The safety of OTRIVIN PLUS during pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Mothers using OTRIVIN PLUS are advised to not breastfeed their babies.

Driving and using machines:

Visual disturbances (including blurred vision and mydriasis), dizziness and fatigue have been reported with OTRIVIN PLUS. Patients should be advised that if affected they should not drive, operate machinery or take part in activities where these symptoms may put themselves or others at risk.

3. HOW TO TAKE OTRIVIN PLUS

Do not share medicines prescribed for you with any other person. Always take OTRIVIN PLUS exactly as your doctor or pharmacist 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 PLUS is too strong or too weak, talk to your doctor or pharmacist.

Before the first application, prime the pump by actuating 4 times. Once primed the pump will normally remain charged throughout regular daily treatment periods. Should the spray not be ejected during the full actuation stroke, or if the product has not been used for longer than 6 days, the pump will need to be reprimed with 4 actuations as initially performed.

Adults:

1 puff in each nostril up to 3 times daily. At least 6 hours should elapse between two doses. Do not exceed 3 applications daily into each nostril.

The treatment duration should not exceed 7 days (see “warnings and special precautions”).

It is recommended to stop treatment, when the symptoms have diminished, even before the maximum duration of treatment of 7 days, in order to minimize the risk of adverse reactions (see section ’side effects’).

Paediatric population:

OTRIVIN PLUS is not recommended for use in children and adolescents below 18 years of age due to lack of sufficient efficacy and safety data.

Elderly:

There is only limited experience of use in patients above 70 years of age.

If you take more OTRIVIN PLUS than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use OTRIVIN PLUS:

If you miss a dose, administer one as soon as you remember. If it is nearly time for your next dose, administer the next dose at the usual time. Do not administer a double dose to make up for the one you missed.

4. Possible side effects

OTRIVIN PLUS can have side effects. Not all side effects reported for OTRIVIN PLUS are included in this leaflet. Should your general health worsen while using OTRIVIN PLUS, please consult your doctor, pharmacist or other health care professional for advice.

Some side effects could likely be serious. If you notice any of these, stop using OTRIVIN PLUS and tell a doctor or pharmacist immediately:

Frequent side effects:

- Epistaxis (nose bleeds)
- Nasal dryness
- Change in taste sensation
- Headache
- Nasal discomfort
- Nasal congestion
- Dry throat
- throat irritation
- nasal pain
- Dry mouth

Less frequent side effects:

- Insomnia
- Parosmia
- Dizziness
- Tremor
- Eye irritation, dry eye
- Palpitations
- Tachycardia
- Nasal ulcer
- Sneezing
- Oropharyngeal pain, cough
- Dysphonia
- Dyspepsia, nausea
- Discomfort
- Fatigue

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.org.za/Publications/index/8. By reporting side effects, you can help provide more information on the safety of OTRIVIN PLUS.

5. How to store OTRIVIN PLUS

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Protect from light and moisture. Do not refrigerate.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- There are no special storage instructions for OTRIVIN PLUS.

6. Contents of the pack and other information

What OTRIVIN PLUS contains

1 ml contains 0.5 mg xylometazoline hydrochloride and 0.6 mg ipratropium bromide.

The other ingredients are:

Disodium edetate, Glycerol 85 %, Hydrochloric acid (for pH – adjustment), Sodium hydroxide (for pH – adjustment), Purified water.

What OTRIVIN PLUS looks like and contents of the pack

10 ml multidose (approx. 70 puffs) HDPE bottle mounted with metered-dose spray pump (materials in contact with the solution: LDPE, HDPE, PE / butyl, stainless steel) and PP nozzle with protective cap.

Holder of Certificate of Registration

Haleon South Africa (Pty) Ltd

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Registration number

46/16.1/0819

7. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

The date of registration of the medicine: 23 February 2021.

Date of the most recently revised patient information leaflet: 23 February 2021