Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Otrivine Child Nasal Drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Xylometazoline Hydrochloride 0.05 %w/v.

Excipients: Benzalkonium chloride 0.01% w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal drops, solution
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a nasal decongestant for relief of the symptoms of acute rhinitis in allergic or upper respiratory tract infections, including the common cold or influenza.

4.2 Posology and method of administration

Otrivine Child Nasal Drops are contra-indicated in children under 6 years of age (see section 4.3).

Children aged 6- 12 years:

1 or 2 drops into each nostril once or twice daily.

Not more than 2 doses should be given in any 24 hours. Maximum duration of use is 5 days.

Route of administration: Nasal use.

4.3 Contraindications

1. Use in patients with a known hypersensitivity to xylometazoline.
2. Use in patients who are receiving monoamine oxidase inhibitors or within fourteen days of stopping such treatment.
3. Use in acute coronary disease, cardiac asthma, hyperthyroidism or closed angle glaucoma.
4. Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.
5. Use in children below 6 years of age.

4.4 Special warnings and precautions for use

1. Use with great care in patients suffering from hypertension and cardiovascular disease.

2. This product should be given with care to patients with prostatic enlargement, as it may increase difficulty in micturition.

3. Use with caution in diabetic patients as this product may cause an increase in blood sugar level.

4. Prolonged use may cause rebound congestion and drug induced rhinitis.

5. Do not exceed the recommended dosage.

6. Decongestants should not be used for more than 5 consecutive days. If symptoms persist consult your doctor.

7. If your child is receiving medicines or is under a doctor’s care consult him before giving Otrivine Child Nasal Drops.

8. Each Otrivine pack should be used by one person only to prevent any cross infection.

9. Some patients who have sensitive nasal passages may feel some local discomfort when applying nasal drops. Other side effects are very rare.

10. Occasionally small children may show restlessness or sleep disturbances when Otrivine is used. If this occurs Otrivine should be stopped.

11. Keep all medicines out of reach of children.

12. Expectant mothers should consult their doctor before using Otrivine for themselves.

13. It is recommended that if a child is under 12 years, a pharmacist or doctor should be consulted before the child is given Otrivine.

14. It is recommended that Otrivine should not be taken with any other cough and cold medicine.

4.5 Interaction with other medicinal products and other forms of interaction

This product may alter the effects of some anti-hypertensives, such as beta-blockers and of some anti-depressants such as tricyclic and tetracyclic anti-depressants.

4.6 Fertility, pregnancy and lactation

This product should not be used in pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The following side effects have occasionally been encountered: A burning sensation in the nose and throat, local irritation, nausea, headache, and dryness of the nasal mucosa.

4.9 Overdose

No cases of overdosage in adults have yet been reported. In rare instances of accidental poisoning in children, the clinical picture has been marked chiefly by signs such as acceleration and irregularity of the pulse, elevated blood pressure, drowsiness, respiratory depression or irregularity. There is no specific treatment and appropriate supportive treatment should be initiated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A sympathomimetic agent with marked alpha-adrenergic activity. It is a vasoconstrictor with a rapid and prolonged action used for the relief of nasal congestion.

5.2 Pharmacokinetic properties

Systemic absorption may occur following nasal application of xylometazoline hydrochloride solutions. It is not used systemically.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium phosphate dodecahydrate (sodium phosphate)
Disodium edetate
Sodium dihydrogen phosphate dihydrate (sodium acid phosphate)
Sodium chloride
Sorbitol liquid (non-crystallising), E420
Hypromellose
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years
Opened: 28 days

6.4 Special precautions for storage

Don’t store above 25°C. Keep the bottle in the outer carton.

6.5 Nature and contents of container

Bottle:	High density polyethylene.
Cap:	Polypropylene.
Pipette rod:	Low density polyethylene.
Pipette bulb:	Halogenated butyl elastomer.
Carton:	Cardboard.

The pipette forms and integral part of the cap.

Pack size: 10 ml.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

1. Clear the nose.
2. Tilt the head back as far as is comfortable or lying on a bed, hang the head over the side.
3. Apply the drops into each nostril and keep the head tilted back for a short time to allow the drops to spread throughout the nose.
4. Replace cap right after use.

7 MARKETING AUTHORISATION HOLDER

Novartis Consumer Health UK Limited
Wimblehurst Road
Horsham
West Sussex, RH12 5AB
England

8 MARKETING AUTHORISATION NUMBER

PA 30/26/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 24 May 2009

10 DATE OF REVISION OF THE TEXT

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