SUMMARY OF PRODUCT CHARACTERISTIC (SPC)

1. NAME OF THE MEDICINAL PRODUCT

OXYSPRAY (Oxymetazoline Hydrochloride)0.05%w/v Nasal Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Oxymetazoline Hydrochloride USP	0.500mg
Benzalkonium Chloride (50%) Solution NF	0.330mg
Purified Water USP	q.s to 1ML

For the full list excipient, see section 6.1

3. PHARMACEUTICAL FORM

Nasal spray

Clear colorless solution filled in white HDPE bottle sealed with metered dose pump, fitted with actuator and dust cap.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS:

Symptomatic treatment of nasal congestion.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION:

Posology

Adults and children over 12 years: 1 – 2 sprays up each nostril maximum 2 – 3 times daily.

Not recommended for use in children under 12 years.

The preparation should not be used for more than 5 – 7 days in a row.

Method of administration: nasal use.

4.3 CONTRAINDICATIONS:

Oxymetazoline Hydrochloride Nasal Spray should not be used:

- in case of hypersensitivity to the active substance or to any of the excipients listed in section List of Excipients.
- by patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs in the previous two weeks.
- in patients with narrow-angle glaucoma. Oxymetazoline Hydrochloride Nasal Spray should not be used by patients after trans-sphenoidal hypophysectomy.
- by children under 12 years of age.
- where there is inflammation of the skin and mucosa of the nasal vestibule and encrustation (rhinitis sicca).
- by patients with acute coronary disease or cardiac asthma

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

- Caution should be exercised in case of hypertension, cardiac diseases including angina, hyperthyroidism, diabetes mellitus and prostatic hypertrophy.
- Do not exceed the recommended dose.
- If symptoms worsen or do not improve after 3 days, physician should re-evaluate clinical situation.
- Oxymetazoline Hydrochloride Nasal Spray should be used for a maximum of 7 consecutive days to avoid rebound-effect and drug induced rhinitis.
- Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. If such a reaction (persistent nasal congestion) is suspected, a product for nasal administration which contains no preservative should be used if possible. If such products for nasal administration are not available without preservative, the use of another dosage form should be considered.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

This product should not be used in combination with MAOIs, or for up to 14 days after taking MAOIs as there is a risk of interactions leading to hypertension.

This product is known to interact with tricyclic antidepressants with a possible increased risk of hypertension and arrhythmias.

The effects of beta-blockers or other antihypertensive drugs e.g., methyldopa, Bethanidine, Debrisoquine and Guanethidine may be antagonised.

Possible additive cardiovascular toxicity may occur when sympathomimetics are given with anti-parkinsonian drugs such as bromocriptine.

4.6 PREGNANCY AND LACTATION

Pregnancy

For oxymetazoline no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Breast-feeding

It is unknown whether oxymetazoline hydrochloride is excreted into breast milk. The recommended dose should not be exceeded because overdosing can decrease placental blood flow and reduce milk production.

Caution should be exercised during pregnancy and lactation as oxymetazoline may be systemically absorbed.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Oxymetazoline Hydrochloride Nasal Spray has no influence on the ability to drive and use machines.

4.8 UNDESIRABLE EFFECTS

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	**Adverse Drug Reaction**
Respiratory, thoracic and mediastinal disorders	
Uncommon (1/100 - 1/1000):	sneezing, dryness and irritation in nose, mouth and throat
Nervous system disorders	
Rare (<1/1000):	anxiety, sedative effect, irritability, sleep disorders in children
Cardiac and Vascular disorders	
Rare (<1/1000):	tachycardia, palpitations, increased blood pressure
General disorders and administration site conditions	
Rare (<1/1000):	reactive hyperaemia, headache, nausea, exanthema and visual disturbances.

Use for longer than recommended may lead to reduced effect and/or rebound congestion.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. To report adverse events, email us at drugsafety@zyduslife.com or visit www.zyduslife.com.

4.9 OVERDOSE

Symptoms of overdose:

Symptoms of moderate or severe overdose can be mydriasis, nausea, cyanosis, fever, spasms, tachycardia, cardiac arrhythmia, cardiac arrest, hypertension, oedema of the lungs, dyspnoea, psychic disturbance. The inhibition of functions of the central nervous system such as somnolence, lowering of the body temperature, bradycardia, shocklike hypotension, apnoea and loss of consciousness is also possible.

Treatment of overdose:

Symptomatic treatment of overdose is required. A nonselective alpha-lytic such as phentolamine may be administered to depress the increased blood pressure, Intubation and artificial respiration may be necessary in serious cases.

In the case of moderate or severe inadvertent oral consumption, the administration of activated carbon (absorbent) and sodium sulphate (laxative) or perhaps gastro-lavage in the case of large amounts should be undertaken. Further treatment is supportive and symptomatic.

Vasopressor drugs are contraindicated.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Pharmacodynamic properties:

Pharmacotherapeutic group: Sympathomimetics, plain

ATC code: R01AA05

Mechanism of action

Oxymetazoline is a direct-acting sympathomimetic amine. It acts on alpha- adrenergic receptors in the vessels of the nasal mucosa producing vasoconstriction and decongestion. Onset of action is within minutes and lasts up to 12 hours.

5.2 Pharmacokinetic properties:

Absorption

With local use on the nasal mucosa, there is no clinically relevant absorption of oxymetazoline hydrochloride.

5.3 Preclinical safety data:

Preclinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity or toxicity to reproduction. Oxymetazoline Hydrochloride Nasal Spray Nasal Spray has not been tested for genotoxicity or carcinogenicity.

Preclinical data suggest that benzalkonium chloride can produce a concentration- and time-dependant toxic effect on cilia, including irreversible immobility, and can induce histopathological changes in the nasal mucosa.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients:

Benzalkonium chloride
Edetate disodium dihydrate
Glycerine
Propylene glycol
Sodium phosphate dibasic, dihydrate
Sodium phosphate monobasic, dihydrate
Sorbitol
Water for Injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage
Store upto 30ºC. Protect from freezing.

6.5 Nature and contents of container
10ml clear colorless solution filled in 15ml white HDPE bottle, fitted with seal on metered dose pump with actuator and dust cap. One bottle is packed into an outer carton.

6.6 Special precautions for disposal and other handling
No applicable.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)
08172/NMR/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Date of first authorisation : 17/10/2022

10. DATE OF REVISION OF THE TEXT
November 2023

11. REFERENCE