(Summary of product characteristics)

1. Name of the medicinal product
XYLOFACT - Xylometazoline Nasal Drops BP 0.05 % w/v

2. Qualitative and quantitative composition
Each ml contains:-

Xylometazoline Hydrochloride BP……0.5 mg
Banzalkonium chloride Solution BP…0.02% w/w
(as preservative)
For full list of excipients, see section 6.1

Distribution Category: - POM (Prescription only medicine)

3. Pharmaceutical form
Nasal Drops

Description: - Colorless to almost colorless, clear solution filled in 20 ml with plastic LDPE Squeeze bottle.

4. Clinical particulars
4.1 Therapeutic indications
For the symptomatic relief of nasal congestion, perennial and allergic rhinitis (including hay fever), sinusitis.

4.2 Posology and method of administration
Posology

Paediatric population

Xylofact Congestion Relief 0.05 % Nasal Drops should not be used in children aged less than 12 years old.

Method of administration

Strength	Age	Posology
0.05 % w/v	Adults and adolescents over 12 years of age	1 drops into each nostril, 1 to 3 times daily as needed. Do not exceed 3 applications daily into each nostril.

The metered-dose drops permits accuracy of dosage and ensures that the solution is well distributed over the surface of the nasal mucosa. It precludes the possibility of unintentional overdose.

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 drops not be ejected during the full actuation stroke, the pump will need to be reprimed with the same number of actuations as initially performed.

Be careful not to drops in the eyes.

1. Blow the nose gently.

2. Remove protective cap.

3. Do not cut the nozzle. The metered dose drops is ready to prime before use.

4. Hold the bottle upright with thumb under base and nozzle between two fingers.

5. Lean forward slightly and insert the nozzle into a nostril.

6. Drops and breathe in gently through the nose at the same time.

7. Repeat in the other nostril

8. Clean and dry the nozzle before replacing back the cap right after use.

To avoid possible spread of infection, the drops should only be used by one person.

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Like other vasoconstrictors,

Xylofact Congestion Relief 0.05 % Nasal Drops should not be used in patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.

Narrow-angle glaucoma, rhinitis sicca or atrophic rhinitis as well as children under 12 years.

4.4 Special warnings and precautions for use
Xylofact Congestion Relief 0.05 % Nasal Drops, like other sympathomimetic agents, should be used with caution in patients showing a strong reaction to adrenergic substances, as manifested by signs of insomnia, dizziness, tremor, cardiac arrhythmias or elevated blood pressure.

Xylofact Congestion Relief 0.05 % Nasal Drops should not be used for more than seven consecutive days.

Caution is recommended in patients with hypertension, cardiovascular disease, hyperthyroidism, narrow angle glaucoma or diabetes mellitus.

Label warnings and precautions

• Do not exceed the stated dose

• Do not use continuously for more than seven consecutive days. If symptoms persist consult your doctor

• If you are pregnant or taking other medicines or are under a doctor's care consult your doctor before using Xylofact

• Not to be used for infants or children under 12 years

• Each Xylofact pack should be used by one person only to prevent any cross infection

• Keep medicines out of the sight and reach of children

Additional leaflet warnings and precautions

• Do not use if you are sensitive to any of the ingredients of Xylofact

• Do not use if you have had recent neurosurgery

• Consult your doctor before using Xylofact if you have heart or circulatory disease

• Some patients who have sensitive nasal passages may feel some local discomfort when applying nasal drops.

• Other side effects such as palpitations, nausea and headache are very rare

Information concerning excipients

This medicine contains polyoxyl hydrogenated castor oil (2.750 mg/ml) which may cause skin reactions.

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

4.5 Interaction with other medicinal products and other forms of interaction

Like for all sympathomimetics, a reinforcement of the systemic effects of xylometazoline by concomitant use of monoamine oxidase inhibitors, tricyclic or tetracyclic antidepressants, cannot be excluded, especially in case of overdose.

4.6 Fertility, pregnancy and lactation

Pregnancy

No foetal toxicity or fertility studies have been carried out in animals. In view of its potential systemic vasoconstrictor effect, it is advisable to take the precaution of not using Xylofact Congestion Relief 0.05 % Nasal Drops during pregnancy.

Breastfeeding

No evidence of any adverse effect on the breast-fed infant. However, it is not known if xylometazoline is excreted in breast milk, therefore caution should be exercised and Xylofact should be used only on the advice of a doctor whilst breastfeeding.

Label warning: If you are pregnant or taking any other medicines or are under a doctor's care, consult your doctor before using Xylofact.

4.7 Effects on ability to drive and use machines

Xylofact Congestion Relief 0.05 % Nasal Drops has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Systemic cardiovascular effects have occurred, and this should be kept in mind when giving this product to people with cardiovascular disease.

Adverse reactions are listed below, by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) or very rare (<1/10,000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Adverse reactions

Immune system disorders		
	Very rare:	Hypersensitivity reaction (angioedema, rash, pruritus)
Nervous system disorders		
	Common:	Headache
Eye disorders		
	Very rare:	Transient visual impairment
Cardiac Disorders		
	Very rare:	Heart rate irregular and heart rate increased
Respiratory, thoracic and mediastinal disorders		
	Common:	Nasal dryness or discomfort, burning sensation
Gastrointestinal disorders		
	Common:	Nausea
General disorders and administration site conditions		
	Common	Application site burning

4.9 Overdose
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 and sometimes clouding of consciousness.

There is no specific treatment. Appropriate supportive measures should be initiated and symptomatic treatment under medical supervision is indicated.

5. Pharmacological properties
ATC Code: R01A A07

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: decongestants for topical use, sympathomimetics, plain.

Mechanism of action and pharmacodynamic effects

Xylometazoline is a sympathomimetic agent acting on alpha-adrenergic receptors in the nasal mucosa. Administered in the nose, it constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighbouring regions of the pharynx. This decongests nasal passages and enables patients suffering from blocked nose to breathe more easily through the nose. The effect of Xylofact begins within a few minutes and lasts for up to 10 hours.

In a double-blind, saline solution controlled study in patients with common cold, the decongestant effect of Xylofact 0.05 % nasal solution was significantly superior ($p<0.0001$) to saline solution based on rhinomanometry measurement. Relief of blocked nose developed twice as fast in the Xylofact group compared to saline solution as of 5 minutes post treatment ($p= 0.047$).

Xylofact is well tolerated, even by patients with a sensitive mucosa, and does not impair the mucociliary function.

5.2 Pharmacokinetic properties
Plasma concentrations of xylometazoline in man after local nasal application of the product are very low and close to the limit of detection.

5.3 Preclinical safety data
Xylometazoline has no mutagenic effect. No teratogenic effects were shown in a study where xylometazoline was given subcutaneously in mice and rats.

6. Pharmaceutical particulars
6.1 List of excipients

1. Disodium EDTA
2. Sodium Chloride
3. Sodium dihydrogen phosphate dihydrate
4. Sodium Phosphate
5. Distilled Water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life

36 months

Shelf life after opening the bottle: - 60 Days

6.4 Special precautions for storage
Store at a temp. Below 30^0C. Protect from light.

6.5 Nature and contents of container
20 ml white plastic LDPE Squeeze Bottle

6.6 Special precautions for disposal and other handling
No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder
Biodeal Pharmaceuticals Pvt. Ltd.
Village Sainimajra, Nalagarh Ropar Road,
Distt. Solan, H.P-174101, India.

8. Marketing authorisation number(s)

TAN 22 HM 0374

9. Date of first authorisation/renewal of the authorization

21/09/2022

10. Date of revision of the text
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