Summary of product characteristics for pharmaceutical products

1.Name of the medicinal product
BIXTONIM XYLO 0.5/ml nasal spray, solution

2.Qualitative and quantitative composition
One millilitre of nasal spray, solution, contains 0.5mg xylometazoline hydrochloride.
Excipients with known effect: 0.2 mg benzalkonium chloride.
For the full list of excipients, see section 6.1.

3.Pharmaceutical form
Nasal spray, solution
Clear, colourless and odourless solution, free from visible particles.

4.Clinical particulars
4.1 Therapeutic indications
Bixtonim XYLO is indicated in children under 10 years old for:
- treatment of nasal congestion due to coryza, vasomotor and allergic rhinitis;
- facilitating the evacuation of secretions in affections of paranasal sinuses;
- as adjuvant treatment in otitis media, for the decongestion of nasopharyngeal mucosa;
- facilitating rhinoscopy.

4.2 Posology and method of administration
Adults and children over 10 years
For adults and children over 10 years old,another concentration of Xylometazoline hydrochloride is recommended,such as Bixtonim XYLO Img/ml

Children under 10 years of age
For children between 2 to 10 years of age,
1-2 sprays each nostril,according to need,but not more than 3 times per day

Elderly
Same doses as for adults.

Duration of administration
Bixtonim XYLO should not be used for longer than 5 days unless prescribed by the doctor.

Method of administration
For administration, the protective cap is removed. Before the first administration, it is sprayed into the air by pressing the spray pump 2-3 times, in order to ensure the correct release of the doses. Thus, the pump is prepared for administration.
Before using the nasal spray, the nose is blown gently. It is recommended for the last dose to be administered before bedtime.
For the use, after removing the protective cap, the spray nozzle is introduced into the nostril and the pump is pressed once, and gently inhale through the nose.

During administration, the bottle is kept in a vertical position, with the pump upwards. The product is not used in a horizontal position or downwards.
After use, it is covered with a protective cap.

For hygiene reasons and to avoid infections, each spray bottle should only be used by the same person.

4.3 Contraindications
Hypersensitivity to the xylometazoline or to any of the excipients listed in section 6.1.
Rhinitis sicca (inflammation of the nasal mucosa not accompanied by secretion).
Glaucoma, particularly narrow-angle glaucoma.
In patients with transsphenoidal hypophysectomy or following surgical interventions exposing dura mater.
In patients with antecedents of cerebral stroke or with risk factors that can favour the occurrence of cerebral stroke through the alpha-sympathomimetic activity (treatment with vasoconstrictors, convulsions antecedents, urine retention in patients with prostatic hyperplasia, association with direct-acting sympathomimetics.
Children under 10 years of age.

4.4 Special warnings and precautions for use
As in the case of other sympathomimetic drugs, xylometazoline should be used with caution in patients with a strong reaction to the administration of adrenergic substances, manifested by insomnia, dizziness, tremor, cardiac arrhythmias or high blood pressure.

Patients requiring prolonged treatment with xylometazoline can use this drug for a longer period of time only under careful clinical monitoring, as there is a risk of nasal mucosa atrophy.

In case of repeated and/or prolonged administration of xylometazoline, there is a risk of tachyphylaxis and iatrogenic rhinitis occurrence.
In case of repeated and/or prolonged administration of xylometazoline, there is a risk of systemic absorption of xylometazoline in quantities that could determine systemic adverse reactions.

Xylometazoline should be administered with caution and only if the therapeutic benefit exceeds the potential risks in case of patients treated with monoamine oxidase inhibitors (MAO inhibitors) or other medicinal products with a potentially hypertensive effect, severe cardiovascular disorders (e.g severe coronary disorders, hypertension). Patients with prolonged QT syndrome treated with xylometazoline may present an increased risk of severe ventricular arrhythmia.

Also, xylometazoline should be administered with caution and only if the therapeutic benefit exceeds the potential risks in patients with pheochromocytoma or with metabolic disorders (e.g. hyperthyroidism, diabetes mellitus)

Sympathomimetic decongestants may produce reactive hyperaemia of the nasal mucosa, especially following prolonged treatment or if it is administered in high doses. In case of repeated treatment or in case of prolonged use of this medicine, a congestive rebound syndrome and the narrowing of airways can occur. It can possibly be manifested by chronic congestion of nasal mucosa (could be followed by ozaena). In moderate cases, the administration of the medicine in one nostril should be stopped, being administered only into the other nostril until the reduction of symptoms intensity, in order to partly maintain the permeability of nasal respiratory ways.

Bixtonim XYLO contains benzalkonium chloride.
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

Simultaneous administration of xylometazoline with monoamine oxidase inhibitors (MAO inhibitors) or with tricyclic antidepressants may determine the increase in blood pressure (due to the cardiovascular effects induced by xylometazoline).

The simultaneous use of other nasal preparations containing sympathomimetics is not recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy
Data from the administration of xylometazoline to pregnant women are non-existent or limited.
Xylometazoline administration is not recommended during pregnancy and in women of childbearing potential and not using contraception.

Lactation
It is not known whether xylometazoline is excreted in human milk. Breast-feeding should be discontinued during treatment with xylometazoline.

4.7 Effects on ability to drive and use machines

Xylometazoline has a little or moderate influence on the ability to drive or use machines, and there is a risk of adverse reactions at the central nervous system and cardiovascular system level when the treatment is prolonged or in case of high doses of xylometazoline.

4.8 Undesirable effects

Adverse reactions are classified on apparatus, organs and systems and are presented based on frequency, using the following convention: 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); very rare (<1/10,000), not known (cannot be estimated from the available data). Within each frequency group, adverse reactions are presented in order of decreasing seriousness.

Cardiac disorders
Very rare: intrasinus topical administration may determine systemic effects of sympathomimetic type such as palpitations, tachycardia or high blood pressure.

Nervous system disorders
Very rare: headache.

Psychiatric disorders
Very rare: insomnia.

General disorders and at administration site level
Very rare: asthenia.

Ocular disorders
Very rare: visual disturbances.

Respiratory, thoracic and mediastinal disorders
Uncommon: epistaxis
Rare: in patients with hypersensitivity, xylometazoline may produce a local, moderate and transitory irritation (burning or dryness sensation of the nasal mucosa).
Very rare: congestive rebound syndrome (reactive hyperaemia) after the interruption of medicine administration. Prolonged treatment, frequent and/or in high doses of xylometazoline may determine irritation (burning or dryness sensation of the nasal mucosa), as well reactive congestion with rhinitis drug-induced. This effect may appear within only 5 days of treatment, and if the administration is continued, chronic damage of the nasal mucosa can occur with crust formation.

Gastrointestinal disorders
Not known frequency: nausea.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this section.

4.9 Overdose

Signs and symptoms of intoxication
Overdosage can determine the following clinical manifestations: mydriasis, nausea, vomiting, cyanosis, fever, convulsions, tachycardia, arrhythmias, collapse, cardiac arrest, high blood pressure, pulmonary oedema, dyspnoea, psychiatric disorders. It can also produce the inhibition of the central nervous system: somnolence, decrease of body temperature, bradycardia, blood pressure collapse until shock, apnoea and coma.

Treatment of intoxication
Oxygen administration is recommended. Phentolamine is administered to decrease blood pressure. Vasopressors are contraindicated. If necessary, antipyretic anticonvulsants are administered.

5.PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: decongestants and other nasal preparations for topical use, sympathomimetics, plain, **ATC code**: R01AA07.

Xylometazoline is a sympathomimetic agent (imidazole derivative) acting on α-adrenergic receptors at the level of the nasal mucosa. After nasal administration, xylometazoline determines the constriction of blood vessels, resulting in nasopharyngeal mucosa decongestion.
The onset of action usually occurs within 5-10 minutes from the administration.
Pharmacodynamic studies have shown that xylometazoline also reduces the frequency of cilia movement in mucociliary cell. This action is reversible.

5.2 Pharmacokinetic properties

After nasal administration, the absorbed amount of substance can occasionally be sufficient to induce systemic effects, e.g. on the central nervous system and on the cardiovascular system.
Metabolites and the excretion routes were not identified.

5.3 Preclinical safety data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzalkonium chloride
Potassium dihydrogen phosphate
Disodium phosphate dodecahydrate
Sorbitol
Disodium edetate
Sodium chloride
Purified water

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3 years.

Use within maximum 28 days after the first opening of the bottle.

6.4 Special precautions for storage
Store below 30°C, in the original packaging.

6.5 Nature and contents of container
One amber glass bottle with a spray pump, containing 10 ml nasal spray, solution.

6.6 Special precautions for disposal and other handling
There are no special requirements.

7.Marketing Authorization Holder
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8. Marketing Authorization Number
CTD12067

9.Date of first authorization/Renewal of the authorization
13/02/2025

10.Date of revision of the text
16/05/2023