SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

BRUZOLIN NASAL DROPS (Xylometazoline Nasal Drops BP 0.05% w/v)

2. Qualitative and quantitative composition

Composition:

Xylometazoline Hydrochloride BP ……0.05% w/v

Benzalkonium Chloride Solution BP …….0.01% w/v

Purified water BP ……...q.s

3. Pharmaceutical form

Nasal Drops

Clear colorless solution filled in white LDPE Bottle.

4. Clinical particulars

4.1 Therapeutic indications

For the relief of nasal congestion associated with the common cold, perennial and allergic rhinitis (including hay fever), sinusitis.

4.2 Posology and method of administration

Adults and elderly: Not applicable.

Bruzolin Nasal Drops are contra-indicated in children under 6 years of age.

Children between 6 and 12 years under adult supervision (all indications): 1 or 2 drops, in each nostril up to 2 times a day.

Not to be used for more than 5 days without the advice of a doctor. (see warnings and precautions)

Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

Not more than 2 doses should be given in any 24 hours.

Route of administration: Nasal use Do not exceed the stated dose

Keep out of the reach and sight of children.

4.3 Contraindications

Known hypersensitivity to Bruzolin or any of the excipients

Concomitant use of other sympathomimetic decongestants

Cardiovascular disease including hypertension

Diabetes mellitus

Phaeochromocytoma

Prostatic hypertrophy

Hyperthyroidism

Closed angle glaucoma

Monoamine oxidase inhibitors (MAOIs, or within 14 days of stopping treatment, see section 4.5)

Beta-blockers – (see section 4.5)

Inflammation of the skin and/or mucosa of the nasal vestibule

Trans-sphenoidal hypophysectomy or nasal surgery exposing the dura mater

Not to be used in children under the age of 6 years

Rhinitis sicca or atrophic rhinitis

4.4 Special warnings and precautions for use

Patients are advised not to take decongestants for more than five consecutive days. Prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa.

Bruzolin, like other preparations belonging to the same class of active substances, should be used only with caution in patients showing a strong reaction to sympathomimetic agents as evidenced by signs of insomnia, dizziness, tremor, cardiac arrhythmias or elevated blood pressure.

Use with caution in occlusive vascular disease

If any of the following occur, Bruzolin should be stopped

• Hallucinations

• Restlessness

• Sleep disturbances

Keep away from eyes.

Keep medicines out of the sight and reach of children.

Bruzolin 0.05% is contraindicated in children aged less than 6 years old

Information concerning excipients

Bruzolin contains benzalkonium chloride. This may cause irritation of the nasal mucosa.

4.5 Interaction with other medicinal products and other forms of interaction

The concomitant use of xylometazoline with **monoamine oxidase (MAO) inhibitors**, **reversible inhibitors of monoamine oxidase (RIMAs)** or **tri- and tetra-cyclic antidepressants**, may cause an increase in blood pressure due to the cardiovascular effects of these substances (*see Contraindications*).

Moclobemide: risk of hypertensive crisis.

Antihypertensives (including adrenergic neurone blockers & beta-blockers): Bruzolin may block the hypotensive effects.

Cardiac glycosides: increased risk of dysrhythmias

Ergot alkaloids (ergotamine & methylsergide): increased risk of ergotism

Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension

Oxytocin – risk of hypertension

4.6 Fertility, Pregnancy and lactation

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 Bruzolin during pregnancy.

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 Bruzolin should be used only on the advice of a doctor whilst breastfeeding.

4.7 Effects on ability to drive and use machines.

Bruzolin has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The adverse effects listed below are classified by system organ class and frequency according to 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) or very rare (<1/10,000).

MeDRA SOC	**Adverse reaction**	**Frequency**
Immune System Disorders	Hypersensitivity reaction (angioedema, rash, pruritus)	Very rare
Nervous System Disorders	Headache	Common
	Irritability, Anxiety, Restlessness, Excitability, Insomnia, Hallucinations and Paranoid Delusions - particularly with prolonged and/or excessive use	Unknown
Eye Disorders	Transient visual impairment	Very rare
Cardiac Disorders	Heart rate irregular, Heart rate increased - particularly with prolonged and/or excessive use	Very rare
	Other cardiac dysrhythmias and hypertension- particularly with prolonged and/or excessive use	Unknown
Respiratory, thoracic and mediastinal disorders	Nasal Dryness Nasal Discomfort Epistaxis	Common Common Uncommon
Gastrointestinal disorders	Nausea	Common
General disorders and administration site	Application site burning	Common
	Tolerance with diminished effect – especially with prolonged and/or heavy use	Unknown
	Rebound congestion (rhinitis medicamentosa) – especially with prolonged and/or heavy use	Unknown
	Irritation & dryness	Unknown

4.9 Overdose

Symptoms and Signs

Excessive administration of topical xylometazoline hydrochloride or accidental ingestion may cause severe dizziness, perspiration, severely lowered body temperature, headache, bradycardia, hypertension, respiratory depression, coma and convulsions. Hypertension may be followed by hypotension. Small children are more sensitive to toxicity than adults.

Treatment

Appropriate supportive measures should be initiated in all individuals suspected of an overdose, and urgent symptomatic treatment under medical supervision is indicated when warranted. This would include observation of the individual for several hours.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Bruzolin Nasal Drops is a sympathomimetic agent with marked alpha-adrenergic activity, and is intended for use in the nose. It constricts the nasal blood vessels, thereby decongesting the mucosa of the nose and neighbouring regions of the pharynx. This enables patients suffering from colds to breathe more easily through the nose. The effect of Bruzolin Nasal Drops begins within a few minutes and lasts for up to 10 hours. Bruzolin Nasal Drops is generally well tolerated and does not impair the function of ciliated epithelium.

In a double-blind, saline solution (Otrisal) controlled study in patients with common cold, the decongestant effect of Bruzolin was significantly superior ($p<0.0001$) to Otrisal saline solution based on rhinomanometry measurement at 1 hour after administration of the study drugs.

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:

There are no findings in the preclinical testing which are of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium chloride

Disodium edetate

Sodium chloride

Sodium citrate

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Keep out of reach of children.

6.5 Nature and contents of container

1 X 15ml LDPE Bottle packed in a carton along with package insert.

6.6 Special precautions for disposal and other handling

This medicinal product does not require any special storage conditions.

7. Marketing authorisation holder

Brawn Laboratories Limited.

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8. Marketing authorisation number(s)

06522/08105/REN/2021

9. Date of first authorisation/renewal of the authorisation

Sep 8, 2021

10. Date of revision of the text

18.07.2023