

Septanazol®: The nasal spray solution contains xylometazoline hydrochloride and dexpanthenol. Indicated for adults and children over the age of 6 for reducing swelling of the nasal mucosa in rhinitis and as supportive treatment for healing the mucous membrane lesions, for the relief in vasomotor rhinitis and for the treatment of nasal respiratory obstruction after nasal surgery.

Adults and children over 6 years of age: The usual dose of Septanazol® for adults and children aged 6 years or over is one spray into each nostril up to 3 times a day. Regarding the duration of treatment in children, a doctor should always be consulted.

Precautions: This medicinal product may be used only after a careful assessment of the risks and benefits in cases of: patients being treated with the monoamine oxidase inhibitors (MAOIS) and other drugs which potentially increase blood pressure, increased intraocular pressure, especially narrow-angle glaucoma, serious heart and circulatory diseases (e.g., coronary heart disease, hypertension), phaeochromocytoma, metabolic disorders (e.g., hyperthyroidism), porphyria and prostate hyperplasia. Use during chronic rhinitis may only be carried out under medical supervision owing to the danger of the atrophy of the nasal mucosa. The prolonged use and overdose of decongestant sympathomimetics in particular may lead to reactive hyperaemia of the nasal mucosa. This rebound effect causes narrowing of the airways, with the consequence that the patient repeatedly uses the medicinal product until its use becomes permanent. The consequences are chronic swelling (rhinitis medicamentosa) or even atrophy of the nasal mucosa. In less severe cases consideration can be given to discontinuing the use of the sympathomimetic in one nostril initially and after the symptoms have abated changing to the other side in order to maintain at least part of the nasal respiration. Direct contact of the medicinal product with the eyes should be avoided. In case of misuse or use of excessive amounts of the spray, the absorption of xylometazoline can cause systemic adverse effects, particularly in children (cardiovascular and neurological adverse effects) (see sections 4.8 and 4.9). Concomitant use of the product with medicinal products for local or systemic treatment of the flu and sympathomimetics contained in cough-and-cold medicines (e.g.: pseudoephedrine, ephedrine, phenylephrine, oxymetazoline, xylometazoline, tramazoline, naphazoline, tuaminoheptane) is not recommended in order to avoid an increased risk of possible cardiovascular and neurological adverse effects (see section 4.5).

Contraindications: Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 of the SPC, dry inflammation of the nasal mucosa, history of transsphenoidal hypophysectomy or other surgical interventions which expose dura mater. Septanazol® for adults is contraindicated in children under 6 years of age.

Fertility, pregnancy and lactation: Septanazol should not be used during pregnancy, as there is not sufficient data available concerning the use of xylometazoline hydrochloride by pregnant women. Septanazol should not be used during the lactation period, since it is not known whether xylometazoline hydrochloride is excreted in the breast milk. There is no data on the influence of Septanazol on fertility.

Adverse reactions: Uncommon: hypersensitivity. Rare: palpitations, tachycardia, hypertension. Very rare: restlessness, insomnia, fatigue, headache, hallucinations, , rebound congestion, nosebleed, convulsions. Not known: burning and dryness of nasal mucosa, sneezing.

Shelf life: 2 years. **Legal category:** Medicinal product not subject to medical prescription. **Marketing authorisation number:** PA1347/058/002. **Marketing authorisation holder:** Krka, d. d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia. http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1347-058-002_19012017142039.pdf **Date of Preparation:** 06/2017. Additional information is available on request from Krka Pharma Dublin Ltd. Unit 4A, Leopardstown Business Centre, Ballyogan Road, Leopardstown, Dublin 18. D18 KX88. **Reference number:** 01-09-2017.