VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Indication: Temporary symptomatic treatment of nasal congestion due to rhinitis or sinusitis.

Rhinitis and sinusitis is common, affecting 10 to 30 % of adults and children in the industrialized countries. It may be less common in some parts of the world, although even developing countries report significant rates.

Nasal congestion due to rhinitis or sinusitis is a very common reaction and is not specific for any population or pattern.

VI.2.2 Summary of treatment benefits

The rapid onset und duration of xylometazoline's decongestive properties was shown throughout all trials detected in literature. A variety of older placebo- and active-controlled studies in rhinitis of different pathogenesis demonstrated evidence of efficacy and good tolerability.

Xylometazoline has been approved in Denmark since 1981 and today it is widely used in almost all countries of the world.

It can be concluded that the efficacy is well established.

VI.2.3 Unknowns relating to treatment benefits

There are no data on the transport of xylometazoline across the placenta or excretion into breast milk. Due to the risk of systemic vasoconstrictive effect, Klarigen/Klarimax/Xylofin should not be used during pregnancy or lactation.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
• Acute glaucoma / Narrow angle glaucoma (Angle-closure glaucoma)	Angle-closure glaucoma is a known contraindication. Xylometazoline can cause/worsen increased pressure in the eyes due to pupil expanding and thereby blocking of the drain from the (narrow) chamber angle of the eye in patients with angle-closure glaucoma.	There is no specific measure to prevent the risk. The risk is mentioned as a contraindication in the summary of Product Characteristics and patient information leaflet. The risk can be reduced by not allowing the product to be used in patients who are at risk of angle-closure glaucoma.

Risk	What is known	Preventability
	Patients with angle-closure glaucoma should therefore not use Klarigen/Klarimax/Xylofin.	
• Operations where the outer brain membrane (the dura mater) has been exposed, either via hypophysis, nasal or oral operation. (Transsphenoidal hypophysectomy or transnasal/transoral operations where the dura mater has been exposed.)	Transsphenoidal hypophysectomy or transnasal/transoral operations where the dura mater has been exposed is a known contraindication. Patients that have undergone transsphenoidal hypophysectomy or transnasal/transoral operations where the dura mater has been exposed should therefore not use Klarigen/Klarimax/Xylofin.	There is no specific measure to prevent the risk. The risk is mentioned as a contraindication in the summary of Product Characteristics and patient information leaflet. The risk can be reduced by not allowing the product to be used in patients who have been operated by Transsphenoidal hypophysectomy or transnasal/transoral operations where the dura mater has been exposed.
• Use in patients with cardiovascular diseases, hypertension, tachycardia, hyperthyroidism or diabetes, and in connection with enlargement of the prostate gland (prostatic hyperthrophy) and tumor of adrenal gland tissue (pheochromocytoma).	Caution should be exercised when using xylometazoline, as with other pharmaceutical substances of the same group, with patients who react strongly to sympathomimetics. In them, use may cause, e.g., sleeplessness, vertigo, tremor, arrhythmia or elevated blood pressure.	There is no specific measure to prevent the risk. The risk is mentioned as a warning in the summary of Product Characteristics and patient information leaflet.
• Concomitantly use of xylometazoline with tri- or tetracyclic antidepressants	Xylometazoline is not recommended to be used together with tri- or tetracyclic antidepressants as the amount of xylometazoline overall in the body may increase, resulting in increased side effects such as high heart rate, irregular pulse and high blood pressure.	There is no specific measure to prevent the risk. The risk is mentioned as an interaction in the summary of Product Characteristics and patient information leaflet.
• Use in children aged under 10 years	Klarigen/Klarimax/Xylofin must not be used in children below the age of 10 years.	There is no specific measure to prevent the risk. The risk is mentioned in the dosage section in the summary of Product Characteristics and patient information leaflet.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
• Concomitantly use of xylometazoline with monoamine oxidase (MAO) inhibitors, or for two weeks following the use of MAO inhibitors	Xylometazoline is not recommended to be used together with monoamine oxidase (MAO) inhibitors, or for two weeks following the use of MAO inhibitors, as the amount of xylometazoline overall in the body may increase, resulting in increased side effects such as high heart rate, irregular pulse and high blood pressure.

Missing information

Risk	What is known
• Reproduction toxicity.	The potential reproduction toxicity of xylometazoline has not been adequately investigated. Rats that were exposed during the entire period of organ formation showed decreased birth weight. In guinea pigs and rabbits damage to the hearing or balance functions of the ear following intravenous administration has been observed.
• Use in pregnancy and lactation.	There are no data available if xylometazoline enters the embryo via the placenta or if xylometazoline enters into breast milk from the mother. Due to the risk of side effects like increased blood pressure, xylometazolineshould not be used during pregnancy or lactation.

VI.2.5 Summary of risk minimisation measures by safety concern

Routine Pharmacovigilance is used for all safety concerns.
There are no specific risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for xylometazoline can be found in Annex 2.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable as this is the initial Risk Management Plan.

Major changes to the Risk Management Plan over time

Version	**Date**	**Safety Concerns**	**Comment**
	At time of authorisation dd/mm/yyyy	Identified Risks Potential Risks Missing information	
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