

VI.2 Elements for a Public Summary

VI.2.1 *Overview of disease epidemiology*

The eye is a common site of irritant responses, reflecting reactions that have a range of clinical manifestations. Management of ocular irritant conjunctivitis is directed at alleviating the signs and symptoms of the condition, such as irritation and redness of the eye area. In general, treatment is based on the symptoms, severity and characteristics of the reaction.

VI.2.2 *Summary of treatment benefits*

Murine is a sterile, clear, colourless liquid eye drop preparation indicated for the treatment of redness and minor irritations of the eye caused by, for example, dusty atmosphere, wind, swimming, smoke, air pollutants and close work such as computer use or reading. Murine contains naphazoline hydrochloride, a sympathomimetic agent, which is a well-established drug substance used for alleviating the signs and symptoms associated with ocular reactions and associated conditions. Murine has a rapid and prolonged action in reducing swelling and congestion when applied to mucous membranes, such as the eye. It is widely used in the form of eye drops as a conjunctival decongestant. The effect of a topical application of naphazoline hydrochloride to the eyes is a constriction of the

vascular system of the conjunctiva, such that the small arterioles are constricted and conjunctival congestion is temporarily relieved.

VI.2.3 Unknowns relating to treatment benefits

There is no recorded experience with the product in children under 12 years, so use in this age group is not recommended. Currently there is no information regarding the use of Murine and the effect upon absorption of other ocular products being used at the same time.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Hypersensitivity to the active substance or to any of the excipients	Allergic reactions to pharmaceutical ingredients are always possible, although very rare for Murine.	Do not use if hypersensitive to any of the ingredients.
Use when there is raised pressure inside the eyeball (glaucoma), damage to the corneas, inflammation of the iris (acute iritis) or any other serious eye disease.	Use of naphazoline in the eye may liberate pigment granules from the iris. Murine is not indicated for the treatment of serious eye disease.	Do not use if you suffer from raised pressure inside your eyeball (glaucoma), damage to your corneas (outer layer of the eyes), inflammation of the iris (the coloured part of the eye), or from any other serious eye disease.
Use if there is an eye condition characterised by continued redness, pain or blurring of vision.	Murine is not indicated for the treatment of serious eye disease.	Do not use if you suffer from an eye condition characterised by continued redness, pain, or blurred vision.
Use prior to peripheral iridectomy in eyes susceptible to angle closure because mydriatic action may precipitate angle block.	Mydriatic action may precipitate angle block	Warning not to use product prior to peripheral iridectomy in eyes susceptible to angle closure
Use with anaesthetics which sensitise the myocardium to sympathomimetics	Some anaesthetics sensitise the myocardium to sympathomimetics. Naphazoline is a sympathomimetic agent with marked alpha-adrenergic activity. It is a vasoconstrictor with a rapid and prolonged action in reducing swelling and congestion when applied to mucous membrane	Warning not to use with anaesthetics which sensitise the myocardium to sympathomimetics. However, the concentration of naphazoline is low in this formulation and there are no reports of systemic adverse reactions.
Contact with soft contact lenses (benzalkonium chloride is known to discolour soft contact lenses).	Known to discolour soft contact lenses. Refer to Benzalkonium chloride potential risk below.	Do not use at the same time as soft contact lenses. Recommend a short interval of 15 minutes be allowed between the use of Murine and replacement of contact lenses.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Contains benzalkonium chloride which may cause eye irritation.	Benzalkonium chloride, for ocular administration, is an excipient with a known effect according to guideline CPMP/463/00 July 2003. May cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour contact lenses.
Overuse - the product is for intermittent or occasional use only	Frequent or prolonged use may produce increased (rebound) redness of the eye.

Missing information

Risk	What is known
Use in children under 12 years	There are few reports looking at the use of topical anaesthesia in children younger than 12 years of age. No clinical toxicity has been observed, but safety has not been proven.
Interaction with concomitant ocular products	Currently there is no information regarding the use of Murine and the absorption of concomitant ocular products. So, patients should be advised to leave a short interval between the administration of Murine and other ocular products. It is generally recommended that this interval should be of about 15 minutes duration.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

List of studies in post authorisation development plan

No studies are proposed in post-authorisation development of the marketing authorisation.

Studies which are a condition of the marketing authorisation

No studies are conditions of the marketing authorisation.

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

Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
1.0	29 November 2013	<p>Important identified risks:</p> <ul style="list-style-type: none">- hypersensitivity to the active substance or to any of the excipients.- use when there is raised pressure inside the eyeball (glaucoma), damage to the corneas, inflammation of the iris (acute iritis) or any other serious eye disease.- use if there is an eye condition characterised by continued redness, pain or blurring of vision.- use prior to peripheral iridectomy in eyes susceptible to angle closure because mydriatic action may precipitate angle block.- use with anaesthetics which sensitise the myocardium to sympathomimetics.- contact with soft contact lenses (benzalkonium chloride is known to discolour soft contact lenses). <p>Important potential risks:</p> <ul style="list-style-type: none">- contains benzalkonium chloride which may cause eye irritation.- overuse - the product is for intermittent or occasional use only. <p>Missing information:</p> <ul style="list-style-type: none">- use in children under 12 years- interaction with concomitant ocular products.	New RMP, first issue.