Part VI: Summary of the risk management plan by product

VI.1 Elements for summary tables in the EPAR

VI.1.1 Summary table of Safety concerns

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

VI.1.2 Table of on-going and planned studies in the Post-authorisation Pharmacovigilance Development Plan

Not applicable.

VI.1.3 Summary of Post authorisation efficacy development plan

Not applicable.

VI.1.4 Summary table of Risk Minimisation Measures

Not applicable.

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Intraocular pressure measurement and inspection of corneal epithelial damage are routine procedures in ophthalmic visits. Many of the patients receiving Oxybuprocaine/Fluorescein Santen, are glaucoma patients or have suffered an eye injury.

Glaucoma is a progressing disease of the optic nerve, which causes damage to the head of the optic nerve and affects the visual field of the patient. In most patients glaucoma progresses slowly. Risk of glaucoma increases significantly with aging and it is considered that the risk for glaucoma doubles every ten years (1). Other risk factors include high intraocular pressure, diabetes, near-sightedness and genetic background. Glaucoma is a heavily underdiagnosed disease – in the developing countries only half of glaucoma patients are aware of the disease.

Eye injuries are more common in males than in females. The most severe eye injuries tend to occur in children and young adult males.

VI.2.2 Summary of treatment benefits

Oxybuprocaine numbs the surface of the eye for a short period of time (about 15 minutes), allowing the doctor to perform the intraocular pressure measurement. Comparative studies have demonstrated at least equal therapeutic efficacy to other commonly used surface anaesthetics such as lidocaine (30, 31).

Fluorescein colors the transparent front part of the eye in a way that allows the doctor to examine any possible damage that might have occurred on the cornea of the eye. Fluorescein is particularly well suited to this task due to its fluorescent properties and its high visibility at low concentrations.

Examination of injury of transparent front part of the eye using fluorescein is a standard practice and it is an essential tool in evaluating the health of the transparent front part of the eye (32, 33, 34).

Combinations of local anaesthetics including oxybuprocaine with fluorescein are routinely used when measuring eye pressure. The use of oxybuprocaine/fluorescein combination is well established in long-term clinical practice and is described in detail in leading ophthalmology textbooks (35, 36).

In conclusion, using Oxybuprocaine/Fluorescein Santen eye drops according to the instructions does not constitute excessive risk to a patient or the community providing that contraindications, precautions and possible interactions are adequately taken into account.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

None.

Important potential risks

None.

Missing information

None.

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.

SmPC and PL for Oxybuprocaine/Fluorescein Santen can be found in the national competent authority's website.

No additional risk minimisation measures are proposed.

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.