VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

The term “dry eye” (sicca syndrome or keratoconjunctivitis sicca) is used to describe a variety of ocular disorders with different causes but similar symptoms: discomfort, a feeling of dryness, burning or stinging, grittiness, foreign body sensation and sensitivity to light. The signs which may vary according to the precise cause of dry eye include conjunctival and lid margin redness, tear film debris, reduced tear secretion as evidenced by Schirmer’s test, tear film instability as evidenced by reduced break-up time and corneal and conjunctival staining with Rose Bengal dye.

The condition of dry eye is caused mainly by under-secretion of tear fluid from the lacrimal gland but could also be due to a defect in the quality of tears e.g. mucin deficiency in disorders affecting the conjunctival goblet cells. The causal disorders of dry eye vary widely. Consequently, they may persist for only a few days or for the remainder of the patient’s life although the common causes of dry eye tend to be long-term. In any case, the appearance of the various dry eye disorders and therefore their treatment are, in general, the same.

In its milder forms, dry eye is common in otherwise healthy individuals as tear secretion decreases with advancing age. It has been estimated that the condition develops in up to 16% of the elderly population without connective tissue disorders. The severe forms of dry eye are less common and are usually associated with auto-immune disorders e.g. as Sjogren’s syndrome in 10% of patients with rheumatoid joint disease.

VI.2.2 Summary of treatment benefits

The treatment of dry eye is to a limited extent dependent on its exact cause. However, regardless of cause, since there is no drug yet available which can satisfactorily improve tear fluid secretion, therapy of the dry eye largely relies on the use of tear substitutes such as ocular wetting or lubricant agents which provide temporary relief from subjective symptoms. The ocular lubricants commonly used are aqueous solutions of polymers (such as polyvinylalcohol 1.4% and hydroxypropylmethylcellulose 0.3% - 1.0%); sodium hyaluronate 0.1% to 0.3%; and carbomers.

Carbomers are commonly used due to their relative lack of toxicity, good muco-adhesive and lubricating properties. The main advantage of carbomer gels over conventional ocular lubricants such as hydroxypropylmethylcellulose and polyvinylalcohol is their increased ocular retention time and, therefore, the need to use it less frequently to obtain relief from discomfort and sensation of dryness.

VI.2.3 Unknowns relating to treatment benefits

Experience with the use of carbomer eye gel is not available in children. Therefore, this medicine should not be used in children.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergy to carbomer or any of the other ingredients in this medicine.	Rash, swelling of the lips, eyes and mouth, shortness of breath, and more rarely wheezing can result from an allergic reaction to either carbomer or one of the other ingredients in this medicine.	Yes, patients with known allergy to carbomer or any of the other ingredients should not use this medicine.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Cetrimide preservative	Carbomer Eye Gel contains the preservative cetrimide which may cause eye irritation and is known to discolour soft contact lenses.
Symptoms may continue or worsen during treatment.	The eye condition may not respond during treatment with this medicine; such cases require specialist supervision.

Important missing information

Risk	What is known
Limited information on use in children	This medicine has not been studied in children. Therefore, it is best avoided in children.

VI.2.5 Summary of additional risk minimisation measures by safety concern

Not Applicable

VI.2.6 Planned post authorisation development plan (if applicable)

Not Applicable

VI.2.7 Summary of changes to the risk management plan over time

Table 10. Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
1	At the time of submission of the Repeat Use procedure 24/06/2013	Identified Risks Potential Risks Missing information	