



## **Hydrocortisone sodium phosphate (Softacor®) for the treatment of mild non-infectious allergic or inflammatory conjunctival diseases**

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 6 August 2018.

*Zorginstituut Nederland* has carried out an assessment of the medicinal product hydrocortisone sodium phosphate (Softacor®), whereby the following conclusion was reached.

In a letter dated 15 May 2018 (CIBG-18-06295), the Minister of Health, Welfare and Sport (VWS) asked *Zorginstituut Nederland* to assess whether the medicinal product Softacor® can be included in the Medicine Reimbursement System (GVS). The Ministry requested a marginal assessment.

Softacor® is an ocular corticosteroid registered for the treatment of mild non-infectious allergic or inflammatory conjunctival diseases. Softacor® is available as 3.35 mg/ml eye drops, as a solution in a single-dose package. One drop contains about 0.12 mg hydrocortisone sodium phosphate. The recommended dose is 2 drops 2 to 4 X a day in the affected eye. Hydrocortisone sodium phosphate (Softacor®) does not contain any preservatives.

### **Conclusion in relation to the marginal assessment**

Based on the criteria for interchangeability, the conclusion can be drawn that hydrocortisone sodium phosphate (Softacor®) is interchangeable with other drugs in GVS cluster 0S01BABG. This cluster includes: prednisolone (Minims prednisolone di-sodium phosphate) and dexamethasone (Monofree dexamethasone). These two are also ocular corticosteroids, specifically eye-drops without preservatives for the treatment of, among other things, allergic conjunctivitis.

This fulfils the criterion for marginal assessment that the cluster must include at least two products; the said products are structural analogues.

### **Standard dose**

No DDD has been established for hydrocortisone sodium phosphate. When the World Health Organisation (WHO) calculates a DDD for single-use packages of eye drops, they regard the volume of the package as a single dose. A single-dose package of hydrocortisone sodium phosphate contains 0.4 ml (which is enough to treat both eyes). On average 3 X 0.4 ml is needed each day, i.e. 3 packages a day. The standard dose of hydrocortisone sodium phosphate can therefore be fixed at 1.2 ml per day, i.e. 3 packages a day.

### **Advice**

Based on the above marginal assessment, we advised the Minister to place Softacor® on List 1A of the GVS in cluster 0S01BABG. The standard dose for Softacor® can be fixed at 3 packages.

For further information, please contact: JBoer@zinl.nl; warcg@zinl.nl

*The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived based on the Dutch version of Zorginstituut Nederland's advice.*

*Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.*