Zorginstituut Nederland

Cysteamine with delayed release (Procysbi®)

Summary of recommendations by *Zorginstituut Nederland* dated 23 March 2017

Zorginstituut Nederland carried out an assessment of the medicine cysteamine with delayed release (Procysbi®) whereby they reached the following conclusion.
Based on the criteria of the Medicines Reimbursement System (GVS), cysteamine with delayed release is interchangeable with a product that is included in the GVS.

In a letter dated 14 November 2016 (CIBG-16-03219) the Minister of Health, Welfare and Sport asked asked Zorginstituut Nederland to carry out an assessment of whether cysteamine with delayed release (Procysbi®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). With the advice of the Scientific Advisory Board (WAR), the Zorginstituut has now completed its assessment.

The manufacturer has asked for inclusion on List 1B of the Health Insurance Decree.

Registered indication

Cysteamine with delayed release is available as hard enteric-coated capsules. Each capsule contains 25 mg or 75 mg of cysteamine (as mercaptamine bitartrate). It is indicated for the treatment of proven nephropathic cystinosis. Cysteamine reduces cystine accumulation in some cells (e.g. leukocytes, muscular and liver cells) of nephropathic cystinosis patients and, when treatment is started early, it delays the development of renal failure.

The initial dose is 1/6 to 1/4 of the targeted maintenance dose of 1.3 gram/m^2/day, in two divided doses given every 12 hours. The dose should be raised if there is adequate tolerance and the cystine level remains > 1 nmol hemicystine/mg protein. The maximum recommended dose of cysteamine is 1.95 gram/m^2/day.

Conclusion on interchangeability

Based on considerations in the GVS report and the enclosed pharmacotherapeutic report, it appears that there are no proven clinically relevant differences between cysteamine with delayed release and cysteamine with immediate release. Based on the other criteria too, this can be regarded as a case of interchangeability.
Based on the criteria for interchangeability, the conclusion is that cysteamine with delayed release (Procysbi®) can be regarded as interchangeable with cysteamine with immediate release. Cysteamine with immediate release (Cystagon®) is already included in the GVS on List 1B.

Zorginstituut Nederland's advice

Cysteamine with delayed release (Procysbi®) can be placed on List 1A in a new cluster together with cysteamine with immediate release (Cystagon®). The standard dose of cysteamine with delayed release (Procysbi®) and with immediate release (Cystagon®) is 2 gram per day.

For further information, please contact: PPasman@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 on the basis of 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.