Zorginstituut Nederland

Ivermectin (Soolantra®)

Summary of recommendations by Zorginstituut Nederland dated 22 February 2016

Zorginstituut Nederland has assessed the medicine ivermectin (Soolantra®). They reached the following conclusion.
Based on the criteria of the Medicines Reimbursement System (GVS), eculizumab can be included in the GVS on List 1A in cluster 0D06BXADC V. The applicable standard dose is 1 gram.

Background

In a letter dated 10 August 2015 (CIBG-15-0736), the Minister of Health, Public Welfare and Sport asked Zorginstituut Nederland to carry out a substantive assessment on whether ivermectin (Soolantra®) is mutually replaceable with a drug that is included in the GVS system.
Zorginstituut Nederland, advised by the Scientific Advisory Board (WAR), has now completed this assessment.

Ivermectin is available in the form of a cream (10 mg/g). The registered indication is: "for the topical treatment of inflammatory lesions as a consequence of rosacea (papulopustular) in adult patients." The cream (10 mg/g) is used once daily during 4 months. If there is no improvement after 3 months, treatment should cease. The course of treatment can be repeated.

Ivermectin cream has a clinically relevant effect on patients with moderate to severe papulopustulous rosacea. This effect is comparable with the effects obtained with metronidazole cream and azelaic acid gel. This has been demonstrated with subjective, though validated outcome measures that indicated a positive effect on both the severity of the disease and quality of life. Adverse events due to ivermectin cream are typically local skin reactions, generally mild or moderate in severity, and comparable to those of local metronidazole and local azelaic acid.

Assessment of mutual replaceability

Based on current criteria, ivermectin (Soolantra®) is mutually replaceable with metronidazole cream. Ivermectin can therefore be placed on List 1A of the GVS, in cluster 0D06BXADC V, with generic metronidazole (10 mg/g metronidazole cream), Rozex®(7.5 mg/g metronidazole gel) and Rosiced® (7.5 mg metronidazole cream).
According to agreements for the local application of dermatological drugs, the standard dose of ivermectin can be fixed at 1 gram.

Zorginstituut Nederland's advice

Zorginstituut Nederland advises the Minister of Public Health, Welfare and Sport to include ivermectin (Soolantra®) in the GVS on list 1A, in cluster 0D06BXAD V. The applicable standard dose is 1 gram.

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

The original text of this 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.