HAUTE AUTORITÉ DE SANTÉ

DERMATOLOGY
New medicinal product
January 2015

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

TOPISCAB 5% (permethrin), antiparasitic

Minor improvement in the management of human scabies

Main points

- TOPISCAB cream has Marketing Authorisation in the topical treatment of human scabies.
- Its efficacy has been demonstrated compared with orally administered ivermectin. It is based on compliance with two skin applications 1 week apart.
- This medicine can be used in children from 2 months of age and in pregnant women, populations not covered by the other currently available scabicides, in a context of an extended stock shortage of ASCABIOL. It offers a minor improvement in the treatment of human scabies.

Therapeutic use

- The local treatments of human scabies currently available in France are benzyl benzoate (combined with sulfiram in ASCABIOL, currently out of stock) and esdepallethrine (combined with piperonyl butoxide in SPREGAL). Oral ivermectin (STROMECTOL) is an alternative to local treatments.
- There is not sufficient evidence to preferentially recommend oral or topical treatment or a combination of both. However, there are arguments in favour of systemic treatment with ivermectin: ease of administration, good safety, no major contraindications. In the case of local treatment, in the absence of ASCABIOL, not currently available, permethrin has proven its efficacy.
- Despite a low level of evidence, a second treatment one week later appears necessary for three reasons:
  - different products used topically or systemically are very probably ineffective against eggs and may be ineffective on immature larval forms;
  - the clinical success rate in the case of single treatment is insufficient;
  - permethrin, the standard anti-scabies agent in English speaking countries, is used according to this method, a first treatment being repeated a week later.
- Disinfection of linen and bedding and simultaneous treatment of subjects in contact are essential. A simple cleaning of the premises and furniture must always be performed. Environmental treatment by spraying an acaricide does not seem necessary for most common scabies. It is essential in the case of crusted scabies. It may be considered based on the context: significant number of cases, socio-economic context, repeated episodes.

Role of medicinal product in the therapeutic strategy

TOPISCAB is a first line treatment alongside other local (ASCABIOL, SPREGAL, ANTISCABIOSUM) and oral (STROMECTOL) scabicides in scabies. This proprietary medicinal product can be used in children less than 15 kg (from 2 months of age) and in pregnant women, populations that cannot be treated by other scabicides.

Clinical data

- Assessment of the efficacy and safety of permethrin 5% cream in the treatment of scabies is based on bibliographic data.

- Two old randomised, double-blind studies included in a meta-analysis of the Cochrane Collaboration (2010), and three more recent randomised studies compared one application of permethrin 5% cream with oral ivermectin 200 µg/kg in one administration or in two administrations 15 days apart, The patients included in these studies were adults and children (minimum age 2 years) with scabies diagnosed by a parasitological or clinical examination.
  These studies have shown the superiority of permethrin compared with oral ivermectin in one administration in terms of percentage of patients with a complete clinical response assessed after one week of follow-up. However, after 2 or 4 weeks of follow-up, both treatments achieved percentages of complete clinical response of 85 to 100%, based on the studies, with no significant difference between the treatments.
- A study comparing permethrin to benzyl benzoate was included in the meta-analysis of the Cochrane Collaboration. No difference was observed between the two treatments in terms of complete clinical response assessed after 2 weeks of follow-up. No clinical study was available for the combination of benzyl benzoate + sulfiram (ASCABIOL), which is the standard treatment in France.
- The most common adverse effects with permethrin are paraesthesia, burning sensations on the skin, itching, erythematous rash and dry skin.

Benefit of the medicinal product

- The actual benefit* of TOPISCAB is substantial.
- TOPISCAB provides minor clinical added value** (CAV IV) in the management of scabies.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

HAUTE AUTORITÉ DE SANTÉ
This document was created on the basis of the Transparency Committee Opinion of 21 January 2015 (CT-13688) and is available at **www.has-sante.fr**

[i] * The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no improvement".