HAUTE AUTORITÉ DE SANTÉ

DERMATOLOGY
Focus
February 2015

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

DEXERYL (glycerin, petrolatum, liquid paraffin), emollient

Low actual benefit in the treatment of atopic dermatitis and ichthyosis

Main points

- DEXERYL has Marketing Authorisation in adjuvant treatment for dry skin conditions of certain dermatoses such as atopic dermatitis, ichthyotic states, psoriasis, and adjuvant treatment for superficial burns of small areas.
- Emollients, such as DEXERYL, are used in first-line treatment, alone or in combination with topical or systemic treatments in order to restore the cutaneous barrier and limit the passage of irritants and allergens.
- Given the new clinical data, its actual benefit remains low in the treatment of atopic dermatitis. There have been no new data in the indication of ichthyosis since 2008.
- Its actual benefit remains insufficient in the indications of superficial burns and psoriasis.

Therapeutic use

- Atopic dermatitis:

The treatment of atopic dermatitis is symptomatic. The objectives are to treat flare-ups and prevent relapses through long-term treatment.
Reduction of inflammation and pruritus is the essential measure to relieve the patient.
In most cases, topical steroids effectively treat dermatitis flare-ups. Low-potency topical steroids are ineffective. Those of moderate or high potency are prescribed as a short course for highly inflammatory lesions and as a longer course on lichenified lesions. Very high-potency topical steroids are reserved for short-term treatment for highly inflammatory lesions.
Tacrolimus (PROTOPIC) is indicated in the treatment of moderate to severe atopic dermatitis in adults and children (2 years of age and older) in the case of inadequate response or intolerance to conventional treatments, such as topical steroids.
Hygiene measures are used to prevent superinfections (warm bath, soap-free bars or gels).
The treatment of atopic dermatitis also includes adjuvant and preventive measures for recurrences, such as hygiene, and the removal of irritants and allergens.
Allergy testing can sometimes be helpful in the case of failure of a properly conducted treatment, or abnormal predominant localisations, such as the wrists (metals), hands (occupational allergens), or face (airborne allergens). Apart from these situations, allergy testing is of no use.

- Ichthyosis:

There is no cure for ichthyosis. Prevention of complications is one of the essential aspects of treatment and involves the struggle against permanent desquamation.
General treatments: oral retinoids are sometimes used to improve the skin condition in some children with ichthyosis. The lowest possible doses should be given because of the many side effects for long-term treatments.
Topical treatments: their goal is to achieve desquamation of the hyperkeratosis. Emollient and moisturising creams are applied daily.

Role of the medicinal product in the therapeutic strategy

Emollients, such as DEXERYL, are used in first-line treatment, alone or in combination with topical or systemic treatments in order to restore the barrier function of the skin and limit the passage of irritants and allergens. The use of emollients should all the more important when the cutaneous xerosis is more pronounced.

Clinical data

- A study evaluated the efficacy of DEXERYL versus placebo cream in 238 children aged 2 to 6 years with atopic dermatitis. The results show a difference favouring DEXERYL compared with placebo in the xerosis score (primary efficacy endpoint) of a small effect size: -0.30 xerosis score on a scale of 0 to 4. The assessment of the xerosis on the secondary endpoints also favours DEXERYL compared with placebo.
- Another study evaluated the efficacy of DEXERYL and that of ATOPICLAIR versus no emollient treatment in 335 children aged 2 to 6 years with atopic dermatitis. The results show a difference favouring DEXERYL (35.1%) and ATOPICLAIR (52.6%) compared with no treatment (67.6%) in terms of the percentage of appearance of a new inflammatory outbreak of atopic dermatitis in the 3 months following the treatment of a previous outbreak with a topical corticosteroid. It is unfortunate that no comparison of DEXERYL versus ATOPICLAIR was planned for in the data collected.
- No new data in the treatment of ichthyosis is available.

Benefit of the medicinal product

- The actual benefit* of DEXERYL is low in atopic dermatitis and ichthyosis.
- As a reminder, the committee considered the actual benefit to be insufficient in the indications "superficial burns" and "psoriasis".
- Recommends the continuation of inclusion on the list of reimbursable products for supply by pharmacists in atopic dermatitis and ichthyosis.

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This document was created on the basis of the Transparency Committee Opinion of 18 February 2015 (CT-13664) and is available at **www.has-sante.fr**

* 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.