BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

SORIATANE (acitretin), retinoid

Improve compliance with the measures for prescribing and dispensing in women of childbearing potential to prevent pregnancy under treatment and for 2 years after discontinuation.

Main points

- SORIATANE has Marketing Authorisation in the treatment of psoriasis, severe keratinisation disorders and severe forms of lichen planus.
- Pregnancies have occurred under treatment due to lack of compliance with the prescribing and dispensing conditions.
- The role of SORIATANE in the therapeutic strategy has not changed, but the teratogenic risk and the restrictions imposed on women of childbearing potential, up to 2 years after the last dose, must be considered in the choice of this medicinal product.

Therapeutic use

- **Psoriasis**
  Systemic treatments are intended for severe forms of psoriasis. These include phototherapy, acitretin (retinoid) sometimes used in combination with phototherapy, methotrexate, cyclosporine and biologics (etanercept, infliximab, adalimumab, ustekinumab).
  Methotrexate, despite its adverse effects, is the standard treatment for widespread or severe forms of psoriasis. Acitretin alone is less effective in the standard forms of psoriasis, but the efficacy of the combination with phototherapy is greater. This combination is especially used in widespread forms of psoriasis. Acitretin also has a special role in severe psoriasis associated with immunosuppression or a tumour.
  The current treatment strategy is rotation among the various alternatives; the choice of treatment is guided by the characteristics of the patient and the disease (concomitant disease, extent of the lesions, treatment history) and the medicinal product (adverse effects, cumulative dose).

- **Severe keratinisation disorders**
  Treatment is symptomatic and relies on emollients which must be used daily. Severe keratinisation disorders, including inherited ichthyoses, are generally resistant to emollients and local treatment used alone; systemic treatment with retinoids (acitretin) may be added. In adult scalp and palmoplantar hyperkeratosis, salicylic acid-based keratolytic agents can also be used.

- **Lichen planus**
  The treatment objective for cutaneous forms is to shorten healing time and reduce itching. No treatment has evidenced substantial efficacy. First-line treatment most often combines local corticosteroid therapy (topical corticosteroids classified as potent or very potent) with an emollient treatment.
  The second-line treatment or treatment for the most severe forms is systemic corticosteroid therapy. Acitretin is generally prescribed in the event of failure of corticosteroid therapy due to the side effects associated with acitretin. Phototherapy may also be used as a second-line treatment, as can the PUVA+retinoid combination in severe lichen planus.
Clinical data

- A prescription study conducted by the ANSM [French National Agency for Medicines and Health Products Safety] and the CNAMTS [National Salaried Workers Health Insurance Fund] showed that between 2007 and 2011, the rules for prescribing SORIATANE to avoid its teratogenic effects were hardly ever followed. In particular, the initial pregnancy test for women of childbearing potential was done in only 11% of cases and 357 pregnancies that were exposed to SORIATANE, and therefore exposed to a risk of teratogenicity were identified.

- There are no new efficacy or safety data.

Prescribing and dispensing conditions

Initial 1-year prescription reserved for specialists and services in dermatology and renewable by any physician for a 1-year maximum.

For women of childbearing potential: Prescription limited to 4 weeks.

Medicinal product requiring special monitoring during treatment for women of childbearing potential in order to limit the pregnancy risk:
- prescription requires the patient to consent to treatment and contraceptive use beforehand and to submit a completed patient diary.
- prescription is limited to 1 month of treatment and continuation requires a new prescription. It requires a negative pregnancy test, which must be performed every month within the 3 days prior to prescription; the date and the result of the pregnancy test must be recorded in the patient diary.
- it must be dispensed within 7 days at most from prescription.
- it may only be dispensed after checking all the mandatory information in the patient diary.
- the date of dispensing must be stated in the patient diary.
- A pregnancy test must be done 2 months after the end of treatment and then regularly, on dates set with the physician, for 2 years following administration of the last dose.

Benefit of the medicinal product

- The actual benefit* of SORIATANE remains substantial.

- recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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1 ** 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.

2 ** 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 clinical added value”.

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