Only for the use of Medical Professionals

Soritec®

Acitretin

Description

Soritec® is a preparation of Acitretin, a synthetic aromatic derivative of retinoic acid. This has a favourable therapeutic ratio, with a greater and more specific inhibitory effect on psoriasis and disorders of epithelial keratinisation. The usual therapeutic response to Acitretin consists of desquamation followed by more normal re-epithelialisation. Acitretin reaches peak plasma concentration 1 - 4 hours after ingestion of the drug. Bioavailability of orally administered Acitretin is enhanced by food. Bioavailability of a single dose is approximately 60%, but inter-patient variability is considerable (36 - 95%). Acitretin is highly lipophilic and penetrates readily into body tissues. Protein binding of Acitretin exceeds 99%. Elimination half-life of approximately 50 hours for Acitretin and 60 hours for its main metabolite in plasma.

Indication and usage

Soritec® is indicated for
Severe forms of psoriasis including:
- Erythrodermic psoriasis
- Local or generalized pustular psoriasis

Severe disorders of keratinization such as:
- Congenital ichthyosis
- Pityriasis rubra pilaris
- Darier's disease
- Other disorders of keratinization which may be resistant to other therapies.

Dosage and administration

It is recommended that Soritec® be given only by, or under supervision of, a dermatological specialist. Soritec® capsules are for oral administration. The capsules should be taken once daily with meals or with milk.

There is a wide variation in the absorption and rate of metabolism of Soritec®. This necessitates individual adjustment of dosage. For this reason the following dosage recommendations can serve only as a guide.

Adult

Initial daily dose should be 25mg or 30mg for 2 to 4 weeks. After this initial treatment period the involved areas of the skin should show a marked response and/or side-effects should be apparent. Following assessment of the initial treatment period, titration of the dose upwards or downwards may be necessary to achieve the desired therapeutic response with the minimum of side-effects. In general, a daily dosage of 25 – 50mg taken for a further 6 – 8 weeks achieves optimal therapeutic results. However, it may be necessary in some cases to a maximum of 75 mg/day. Therapy can be discontinued in patients with psoriasis whose lesions have improved sufficiently.

In patients with Darier's disease a starting dose of 10mg may be appropriate. The dose should be increased cautiously as isomorphic reactions may occur.

Patients with severe congenital ichthyosis and severe Darier's disease may require therapy beyond 3 months. The lowest effective dosage, not exceeding 50mg/day, should be given.

Continuous use beyond 6 months is contra-indicated as only limited clinical data are available on patients treated beyond this length of time.

Children
Soritec® is contra-indicated in children unless the benefits significantly outweigh the risks, in view of possible severe side-effects associated with long-term treatment. The dosage should be established according to bodyweight. The daily dosage is about 0.5mg/kg. Higher doses (up to 1mg/kg daily) may be necessary in some cases for limited periods, but only up to a maximum of 35mg/day. The maintenance dose should be kept as low as possible in view of possible long-term side-effects.

Elderly
Dosage recommendations are the same as for other adults.

Combination therapy
Other dermatological therapy, particularly with keratolytics, should normally be stopped before administration of Soritec®. However, the use of topical corticosteroids or bland emollient ointment may be continued if indicated. Use in pregnancy and lactation

Use in pregnancy and lactation
Acitretin is contra-indicated during pregnancy and in women who are breast feeding as it is a known human teratogen. It is also contra-indicated in women of childbearing potential unless specific criteria are met.

Side effects
Most of the clinical side-effects of Acitretin are dose-related and are usually well-tolerated at the recommended dosages. However, the toxic dose of Acitretin is close to the therapeutic dose and most patients experience some side-effects during the initial period whilst dosage is being adjusted. They are usually reversible with reduction of dosage or discontinuation of therapy.

Precautions
Acitretin should only be prescribed by physicians who are experienced in the use of systemic retinoids and understand the risk of teratogenicity associated with Acitretin therapy. The risk of giving birth to a deformed child is exceptionally high if Acitretin is taken before or during pregnancy, no matter for how long or at what dosage. Foetal exposure to Acitretin always involves a risk of congenital malformation. Donation of blood by a patient being treated with Acitretin is prohibited during and for two year after completion of treatment.

Contraindications
Acitretin is contra-indicated in cases of hypersensitivity to it or excipients or to other retinoids. Its use is contra-indicated in pregnant women and women who might become pregnant during or within 2 years of the cessation of treatment. It is also contra-indicated in patients with hepatic or renal impairment and in patients with chronic abnormally elevated blood lipid values.

Drug interactions
Concurrent intake of Acitretin with ethanol led to the formation of Etretinate. However, Etretinate formation without concurrent alcohol intake cannot be excluded. Therefore, since the elimination half-life of Etretinate is 120 days the post-therapy contraception period in women of childbearing potential must be 2 years. An increased risk of hepatitis has been reported following the concomitant use of Methotrexate and Etretinate. Consequently, the concomitant use of Methotrexate and Acitretin should be avoided. The effect of Acitretin on the protein binding of anticoagulants e.g. warfarin revealed no interaction.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light.

Presentation
Soritec® 10 mg capsule: Each capsule contains Acitretin BP 10 mg.
Soritec® 25 mg capsule: Each capsule contains Acitretin BP 25 mg.

Packaging
Soritec® 10 mg capsule: Carton of 30 capsules in blister pack.
Soritec® 25 mg capsule: Carton of 10 capsules in blister pack.

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