Soritin®

Acitretin BP

Description: Soritin® is the preparation of acitretin which is an oral retinoid effective in the treatment of psoriasis.

Mode of Action: Acitretin is a retinoid. Retinoids have a structure similar to vitamin A and are involved in the normal growth of skin cells. Acitretin works by inhibiting the excessive cell growth and keratinisation (process by which skin cells become thickened due to the deposition of a protein within them) seen in psoriasis. It therefore reduces the thickening of the skin, plaque formation and scaling.

Composition
Soritin® 10 capsule: Each capsule contains Acitretin BP 10 mg.
Soritin® 25 capsule: Each capsule contains Acitretin BP 25 mg.

Indications: Acitretin is indicated for the treatment of severe psoriasis in adults. Because of significant adverse effects associated with its use, this should be prescribed only by those knowledgeable in the systemic use of retinoids.

Dosage & 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 Acitretin. 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 25 mg or 30 mg 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 25–50 mg 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 10 mg 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 50 mg/day, should be given.
Continuous use beyond 6 months is contraindicated as only limited clinical data are available on patients treated beyond this length of time.
Children: Acitretin is contraindicated in children unless the benefits significantly outweigh the risks, in view of possible severe side-effects associated with long-term treatment. The dose should be established according to bodyweight. The daily dosage is about 0.5 mg/kg. Higher dosage (up to 1 mg/kg daily) may be necessary in some cases for limited periods, but only up to a maximum of 35 mg/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.

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

Side Effects: Most of the clinical side-effects of Acitretin are dose-related and are usually well-tolerated at the recommended dosages.

Pregnancy & Lactation: Acitretin is contraindicated during pregnancy and in women who are breast feeding as it is a known human teratogen. It is also contraindicated in women of childbearing potential unless specific criteria are met.

Precautions: Acitretin should only be prescribed by physicians who are experienced in the use of systemic retinoid 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. Fetal 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.

Interaction: Concurrent intake of Acitretin with ethanol led to the formation of Etretinate. 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.

Overdose: 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.

Storage: Keep out of reach of children. Store in a dry place, below 25° C temperature and protected from light.

Packaging
Soritin® 10 capsule: Each carton contains 10x1 capsules.
Soritin® 25 capsule: Each carton contains 10x1 capsules.

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