

Skinoren 20% Cream[®] (azelaic acid)

PRESCRIBING INFORMATION

(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 1g of Skinoren Cream contains 200mg azelaic acid (20% w/w) **Indication(s):** Topical treatment of acne vulgaris. **Posology & method of administration:** Skinoren Cream should be applied to the affected areas of skin twice daily (mornings and evenings), and rubbed in gently. **Adults:** As a guide 2.5 cm (approx. 0.5 g) of cream is sufficient for the entire facial area. **Children & adolescents:** Adolescents (12-18 years of age); dose adjustment is not required. Children (below 12 years of age); safety and efficacy of Skinoren cream not established. If other areas of acne, in addition to the face require treatment, for example the chest and back, the amount of cream should be adjusted accordingly. Patients with sensitive skin should use Skinoren only once a day (in the evening) for the first week and then proceed to twice daily applications. Before application, the skin should be thoroughly cleaned with plain water and dried. A mild skin-cleansing agent may be used. The duration of use can vary from patient to patient and also depends on the severity of the acne. In general, a distinct improvement becomes apparent after about 4 weeks. To obtain the best results, Skinoren Cream should be used continuously over a period of several months. It is important to continue to use regularly over the entire period of treatment. However, in the event of intolerable skin irritation, the amount of cream per application should be reduced or the frequency of use of Skinoren Cream should be reduced to once a day until the irritation ceases. If required, treatment might have to be temporarily interrupted for a few days. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings & precautions:** For external use only. Care must be taken when using Skinoren Cream to avoid contact with the eyes, mouth and other mucous membranes. In the event of accidental contact, the eyes, mouth and/or affected mucous

membranes should be washed with large amounts of water. If eye irritation persists, patients should consult a physician. The hands should be washed after each application. Worsening of asthma in patients treated with azelaic acid has been reported rarely during post-marketing surveillance. Skinoren contains a small amount of benzoic acid, which is mildly irritating to the skin, eyes and mucous membranes. Skinoren also contains propylene glycol, which may cause skin irritation. **Pregnancy & lactation:** There are no adequate and well-controlled studies of topically administered azelaic acid in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Infants must not come into contact with treated skin/breast. It is not known if azelaic acid is passed into breast milk in vivo. Caution should be exercised when prescribing azelaic acid to pregnant or nursing women. **Undesirable effects:** *Very common:* application site burning, application site pruritus, application site erythema. *Common:* application site exfoliation, application site pain, application site dryness, application site discolouration, application site irritation. *Serious:* drug hypersensitivity, worsening of asthma. Prescribers should consult the SmPC in relation to other side effects. **Special Precautions for Storage:** Do not store above 30°C. **Legal Category:** POM. **Package Quantities & Basic NHS Costs:** 30 g tubes £ 3.74. **MA Number(s):** PL 00010/0649. **Further information available from:** Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA United Kingdom. Telephone: 01635 563000. **Date of preparation:** June 2014

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Bayer plc. Tel.: 01635 563500, Fax.: 01635 563703, Email: phdsguk@bayer.co.uk