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AZADERM CREAM

QUALITATIVE AND QUANTITATIVE COMPOSITION

Azaderm cream 1 g contains 200 mg (20%) azelaic acid.

CLINICAL PARTICULARS

• **Therapeutic indications** Topical treatment of acne vulgaris.

• **Posology and method of administration** Azaderm cream should be applied to the affected areas twice daily (morning and evening), and rubbed in well. Regular use is important. Patients with sensitive skin should be advised to use Azaderm only once a day (in the evening) for the first week of treatment and then proceed to twice daily applications. Before Azaderm is applied, the skin should be thoroughly washed with water alone or, if necessary, with a mild cleansing agent. The amount of Azaderm to be applied will depend on the size of the affected area. Apply a thin film of Azaderm to the affected areas. The duration of use of Azaderm will vary from person to person 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, Azaderm should be applied over a period of several months but not for more than 6 months.

• **Contraindications** Hypersensitivity to any ingredient of the cream, in particular propylene glycol.

• **Special warnings and precautions for use** For external use only.

Avoid contact with the eyes. If Azaderm comes into contact with the eyes they should immediately be thoroughly rinsed with copious amounts of water. Azaderm contains a small amount of benzoic acid, which is mildly irritating to the skin, eyes and mucous membrane. Azaderm also contains propylene glycol, which may cause skin irritation.

• **Pregnancy and lactation** There is no evidence of the safety of azelaic acid during human pregnancy or lactation. It is therefore advisable to avoid using Azaderm during pregnancy or lactation unless essential and no suitable alternative treatment is available. Animal studies have produced no evidence that would suggest any risk to a fetus from use by a pregnant woman.

• **Effects on ability to drive and use machines** None.

• **Undesirable effects** Local skin irritation (e.g. erythema, scaling, itching or burning) occurs in occasional cases, usually at the start of treatment. However, in the majority of cases the irritation is mild and regresses as treatment continues. If marked skin irritation persists, the amount of cream per application should be reduced, the frequency of application should be reduced, or the treatment temporarily interrupted until the symptoms regress. Photosensitivity reactions have been reported very rarely during the use of Azaderm. Also, in very rare cases, allergic skin reactions (e.g. rash) may occur.

PHARMACOLOGICAL PROPERTIES

• **Pharmacodynamic properties** Azelaic acid inhibits the growth of the propionibacteria involved in the development of acne and their production of acne-promoting fatty acids. Azelaic acid also reduces the multiplication of keratinocytes and their keratinization, and therefore restricts the formation of comedones.

• **Pharmacokinetic properties** After dermal administration of the cream, azelaic acid penetrates all layers of the human skin. The penetration is more rapid into damaged skin than intact skin. A total of 3.6% of the administered dose was absorbed percutaneously after a single administration of 5 g cream to the face, upper back and chest, which are typical regions for acne lesions. Applying 5g of cream twice daily results in a systemic burden ranging from 1 to 1.5mg per kg body weight. 43% of azelaic acid is bound to plasma proteins. Due to the low percutaneous absorption, the amount of azelaic acid reaching the infant via the mother's milk should be negligible i.e. less than 200 µg per day which corresponds to 0.01% of the two 5g doses. A part of the azelaic acid which is absorbed through the skin is eliminated in its original form with urine. The other part is metabolized through ß-oxidation into short-chained dicarboxylic acids (C7, C5 carboxylic acids) which were found in urine as well.

• **Preclinical safety data** In vitro and in vivo studies with the active substance produced no evidence for genotoxic effects on germinal and somatic cells. No signs that azelaic acid has sensitising properties were found in the maximization test in the guinea-pig.

PHARMACEUTICAL PARTICULARS

• **List of excipients:** Benzoic acid , propylene glycol, polysorbate 80, isopropyl myristate, stearic acid, polyoxyl 20 cetyl ether (Ceteth-20), cetostearyl, alcohol, white bees wax, purified water.

• **Shelf life** 3 years.

• **Special precautions for storage** Keep at temperature not exceeding 30°C.

• **Nature and contents of container** The packaging is a tube containing 30 g Azaderm cream.

• **Special precautions for disposal and other handling**

Store the medicine properly and keep it out of the reach of children.

Manufactured by:
Medical Union Pharmaceuticals
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