

Azelaic acid INN 20% w/w

DESCRIPTION

Azelec (Azelaic acid) has been shown to possess antimicrobial activity against Propionibacterium acnes and Staphylococcus epidermidis. The antimicrobial action may be attributable to inhibition of microbial cellular protein synthesis. A normalization of keratinization leading to an anticomedonal effect of Azelec (Azelaic acid) may also contribute to its clinical activity.

COMPOSITION

Each gram of Azelec cream contains 0.2 g (20%) of Azelaic acid INN.

INDICATION

Azelec cream is indicated for the topical treatment of mild-to-moderate inflammatory acne vulgaris.

DOSAGE & ADMINISTRATION

After the skin is thoroughly washed and patted dry, a thin film of Azelec should be gently but thoroughly massaged into the affected areas twice daily, in the morning and evening. The hands should be washed following application.

Safety and effectiveness in pediatric patients under 12 years of age have not been established.

OR AS DIRECTED BY THE PHYSICIAN

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.

CONTRAINDICATION

Azelaic acid is contraindicated in individuals who have shown hypersensitivity to any of its components.

PRECAUTION

For external use only. If Azelaic acid comes into contact with the eyes they should immediately be thoroughly rinsed with copius amounts of water. The patients should consult a physician if eye irritation persists.

PREGNANCY AND LACTATION FDA Pregnancy Category B. This drug should be used during pregnancy only if clearly needed. Caution should be exercised when Azelaic acid is administered to a nursing mother

SUPPLY

Azelec 10 g : Each tube contains 10 g cream.

Keep all medicines out of reach of children. Store in a cool and dry place, protected from light.

* Further information is available on request.

Manufactured by:



The ACME Laboratories Ltd.

Dhamrai, Dhaka, Bangladesh

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