16-11-2021
1st Copy

210mm

Alkeris® Cream
(Aceclofenac)

QUALITATIVE AND QUANTITATIVE COMPOSITION
Alkeris® 1.5% w/w Cream
Each 100g contains:
Aceclofenac Ph. Eur. 1.5g

PHARMACEUTICAL FORM
Cream

CLINICAL PARTICULARS
THERAPEUTIC INDICATIONS:
Treatment of painful and inflammatory manifestations associated with traumatic pathology and musculoskeletal disorders such as:
- Tendinitis/ tenosynovitis.
- Sprains/ strains.
- Dislocation.
- Periarthritis.
- Lumbago.
- Torticollis.

POSOLOGY AND METHOD OF ADMINISTRATION:
Posology: The number of applications, frequency and duration of the treatment will be established by the doctor. As a general guideline, it will be applied on the affected area, depending on its extension, between 1.5 and 2 grams three times a day. (Approximately between 5cm and 7cm).
Method of administration: This drug is intended for external use only, and should not be used in occlusive dressings.

OR
As directed by the physician

CONTRAINDICATIONS:
- Hypersensitivity to the active substance.
- Although possible cross-hypersensitivity to diclofenac has not been established, administration is not recommended in patients with demonstrated hypersensitivity to diclofenac. It will not be administered in those patients who have shown hypersensitivity to other NSAIDs.
- Like other non-steroidal anti-inflammatory agents, it is contraindicated in patients in whom acetylsalicylic acid and other prostaglandin synthetase inhibitors trigger attacks of asthma, urticaria, or acute rhinitis.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
- If the use of this medicine produces symptoms of local irritation, the administration will be suspended and the appropriate therapy will be established. It should not be applied to the eyes or mucous membranes, or to open skin lesions or in any other circumstance in which another skin process occurs at the same point of application.
- There are no clinical data on the use of aceclofenac in children.
- To prevent photosensitivity reactions, avoid intense sun exposure without protection of the treated area.
- *Hypersensitivity and skin reactions:* Like other NSAIDs, allergic reactions, including anaphylactic and anaphylactoid reactions, can occur without prior exposure to the drug. Serious skin reactions, some fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, are known to be reported very rarely in association with the use of NSAIDs. It seems that patients are at higher risk of these reactions at the beginning of treatment; the appearance of these adverse reactions occurs in most cases during the first month of treatment. Aceclofenac should be discontinued immediately at the first symptoms of skin erythema, mucosal lesions, or other signs of hypersensitivity.
- Exceptionally, chickenpox can lead to serious skin complications and soft tissue infections. To date, the contribution of NSAIDs to the aggravation of these infections cannot be ruled out. For this reason, it is recommended to avoid the use of aceclofenac in case of chickenpox.

Excipient warnings: This medicine can cause local skin reactions (such as contact dermatitis) because it contains cetostearyl alcohol.
Aceclofenac can cause allergic reactions (possibly delayed) because it contains propyl parahydroxybenzoate (E-216) and methyl parahydroxobenzoate (E-218).

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION: Although data on interactions of this drug with others are not yet known, it is advisable to take precautions if the patient is being treated with other medications, especially if they contain lithium, digoxin, oral anticoagulants, diuretics and analgesics.

FERTILITY, PREGNANCY AND LACTATION: Although no teratogenic effects were known to occur in experimental studies, the safety of aceclofenac in pregnant and lactating women has not been established, therefore its administration is not recommended in these situations.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Not applicable.

UNDESIRABLE EFFECTS:
- This drug has shown good local tolerance. The most frequently reported adverse reactions are mild to moderate local irritation accompanied by redness and itching of mild intensity that disappear with discontinuation of treatment.
- Exceptionally, serious skin complications and soft tissue infections have been reported during chickenpox in association with treatment with non-steroidal anti-inflammatory drugs.
- In a rare way photosensitivity reactions are known to occur when the treated area has been exposed to strong solar radiation without adequate protection.

Skin and subcutaneous tissue disorders: Uncommon: Photosensitivity, erythema, pruritus. *Very rare:* Bullous reactions (including Stevens-Johnson syndrome and toxic epidermal necrolysis).

OVERDOSE:
A typical picture of aceclofenac overdose is not known. In case of massive accidental absorption or ingestion, it will be treated from the symptomatic point of view.

PHARMACOLOGICAL PROPERTIES
PHARMACODYNAMIC PROPERTIES: Pharmacotherapeutic group: Non-steroidal anti-inflammatory drugs for topical use, **ATC code:** M02AA
Aceclofenac is a new non-steroidal anti-inflammatory that also has analgesic and antipyretic properties.
Mechanism of action: The study of its mechanisms of action, both in animals and in humans, shows that aceclofenac inhibits the formation of prostaglandins and leukotrienes through a reversible inhibition of cyclooxygenase. Aceclofenac has demonstrated its anti-inflammatory and analgesic activity topically in the treatment of musculoskeletal trauma, being as effective as other reference drugs.

PHARMACOKINETIC PROPERTIES:
The pharmacokinetics of aceclofenac administered topically has been studied formulated in cream mode and using various experimental models in both animals and humans. Aceclofenac is absorbed in the area of application in all the species studied, reaching a rapid saturation. It remains in the absorption zone, which results in its anti-inflammatory efficacy, passing to the systemic circulation in a continuous way but in sufficiently low concentrations to ensure the absence of side effects, especially gastrointestinal.
Aceclofenac is distributed throughout the body, is metabolized in the liver and is slowly excreted partly unchanged in urine and feces.

SHELF LIFE
See expiry on the pack.

AVAILABILITY
Alkeris® 1.5% w/w cream in a pack of 20g

INSTRUCTIONS
Dosage: As advised by the physician.
To be sold on the prescription of a registered medical practitioner only.
For external use only.
Keep out of the reach of children.
Avoid exposure to heat, light and freezing.
Store between 15 to 30°C.
Improper storage may deteriorate the medicine.

الکیریز کریم
(ایسکلوفینک)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔
صرف بیرونی استعمال کے لئے ہے۔
بچوں کی پہنچ سے دور رکھیں۔
دوا کو گرمی، روشنی اور منجمد ہونے سے محفوظ ۱۵ سے ۳۰ ڈگری
سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی۔

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
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