

# Alkeris® 100mg Tablets / SR 200mg Tablets (Aceclofenac)

## DESCRIPTION:

Alkeris® (Aceclofenac) is a non-steroidal agent with excellent anti-inflammatory and analgesic properties

## COMPOSITION:

**Alkeris® 100mg Film Coated Tablets**  
Each film coated tablet contains:  
Aceclofenac Ph. Eur. .... 100mg

**Alkeris® SR 200mg Tablets**  
Each sustained release tablet contains:  
Aceclofenac Ph. Eur. .... 200mg

## CHEMISTRY:

Aceclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Aceclofenac is chemically designated as 2-[(2,6-dichlorophenyl) amino] phenylacetoxycetic acid

## MECHANISM OF ACTION:

Aceclofenac works by blocking the action of cyclo-oxygenase which is involved in the production of various chemicals in the body, some of which are known as prostaglandins

## PHARMACOKINETICS:

### Absorption

After oral administration, aceclofenac is rapidly absorbed and the bioavailability is almost 100%. Peak plasma concentrations are reached approximately 1.25 to 3 hours following ingestion. T<sub>max</sub> is delayed with concomitant food intake whereas the degree of absorption is not influenced

### Distribution

Aceclofenac is highly protein bound (>99.7%). Aceclofenac penetrates in to the synovial fluid, where the concentrations reach approximately 60% of those in plasma. The volume of distribution is approximately 30L

### Elimination

The mean plasma elimination half life is 4-4.3 hours. Clearance is estimated to 5 liters per hour. Approximately two-thirds of the administered dose is excreted via the urine, mainly as conjugated hydroxymetabolites. Only 1% of an oral single dose is excreted unchanged. Aceclofenac is probably metabolized via CYP2C9 to the main metabolite 4-hydroxydiclofenac. Diclofenac and 4-hydroxydiclofenac have been detected amongst many metabolites

## PHARMACODYNAMICS:

Aceclofenac is a novel NSAID known to exhibit multifactor mechanism of action. Aceclofenac was developed in order to provide a highly effective pain relieving therapy with a reduced side effect profile, especially GI events that are frequently experienced with NSAID therapy

## INDICATIONS:

Aceclofenac is indicated in management of acute and chronic painful and inflammatory conditions such as rheumatoid arthritis, arthrosis, ankylosing spondylitis, cervicalgia, lumbago, tendonitis, sprain and scapulo-humeral periarthritis

Aceclofenac is also indicated in the treatment of painful conditions of various etiologies such as odontalgia, lumbosciatica, myalgia, post-episiotomy pain, post-labor pain, primary dysmenorrhoea, and extra-articular rheumatism

## DOSAGE AND ADMINISTRATION:

### Adults

**Alkeris® 100mg Film Coated Tablets**

The recommended daily dose is 1 tablet every 12 hours

**Alkeris® SR 200mg Tablets**

The recommended daily dose is 1 tablet a day should be taken with a little water

OR

As directed by the physician

## Children

Alkeris® (Aceclofenac) is not recommended in children

## Dosage in Hepatic Impairment

The dose should be reduced to 100mg daily in patients with hepatic impairment

## CONTRAINDICATIONS:

Aceclofenac should not be administered to patients with gastrointestinal bleeding or with active or suspected ulcer

Aceclofenac should not be administered to patients with hypersensitivity to acetylsalicylic acid or to other non-steroidal anti-inflammatory drugs

## PRECAUTIONS:

Aceclofenac should be administered with caution to patients with gastrointestinal disorders and with a history of peptic ulcer

Aceclofenac should be administered with caution to patients with impaired hepatic, renal or heart function

## WARNINGS:

NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease. A large number of studies support this finding, with varying estimates of how much the risk is increased, depending on the drugs and the doses studied

## Pregnancy and lactation

Sufficient data are not yet available up to date, therefore it is not recommended for use in pregnancy and lactation

## Effects on ability to drive

Caution should be taken in driving or handling dangerous machinery while receiving non-steroidal anti-inflammatory drugs

## Use in elderly

As with other non-steroidal anti-inflammatory drugs, caution should be exercised in the treatment of elderly patients, who are more likely to be suffering from impaired renal, cardiovascular or hepatic function, or interactions with other drugs

## Use in children

Aceclofenac tablets should not be used in children

## Use in renal insufficiency

There is no evidence that the dosage of aceclofenac needs to be modified in patients with mild renal impairment. Nevertheless, as with other non-steroidal anti-inflammatory drugs, caution should be exercised

## Use in hepatic insufficiency

In patients with hepatic impairment, the dose of aceclofenac should be reduced

## DRUG INTERACTIONS:

Due to the possible occurrence of interactions, the doctor should be informed if the patient is undergoing treatment with other drugs

## UNDESIRABLE EFFECTS:

The majority of side effects observed, have been mild and reversible and include gastrointestinal disorders (Flatulence, abdominal pain, nausea and diarrhoea) and occasional occurrence of dizziness

Dermatological complaints, including pruritus and rashes, as well as abnormal hepatic enzyme levels and raised serum creatinine levels, have occasionally been reported

## OVERDOSAGE:

Like other propionic acid derivatives, aceclofenac has a low toxicity in overdosage. Management of acute poisoning with non-steroidal anti-inflammatory drugs essentially consists of supportive and symptomatic measures

## SHELF LIFE:

See expiry on the pack

## AVAILABILITY:

Alkeris® 100mg film coated tablets in a pack of 30's

Alkeris® SR 200mg tablets in a pack of 30's

## INSTRUCTIONS:

Keep out of reach of children. Avoid exposure to heat, light and humidity  
Store between 15 to 30°C. Improper storage may deteriorate the medicine



Manufactured by:  
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**الکیریز** ۱۰۰ ملی گرام ٹیبلٹ / ایس آر ۲۰۰ ملی گرام ٹیبلٹ  
(ایسکلوفینک)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں  
بچوں کی پہنچ سے دور رکھیں

دوا کو گرمی، روشنی اور نمی سے محفوظ رکھیں۔ اسے ۱۵ سے ۳۰ ڈگری

سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائے گی

R-N-12/NA/07/2021