

PAINO[®]

Aceclofenac film coated tablet

DESCRIPTION

PAINO[®] is the preparation of Aceclofenac. Aceclofenac, a phenylacetic acid derivative, is peripherally acting, non-steroidal anti-inflammatory analgesic with anti-inflammatory, antiarthritic and antipyretic activities. It is converted to active metabolites intracellularly that inhibit the production of prostaglandins. Aceclofenac demonstrates better gastric tolerance and consequently offers greater potential security than other NSAIDs such as indomethacin and diclofenac.

INDICATIONS

PAINO[®] is used in the management of pain and inflammation in osteoarthritis rheumatoid arthritis, and ankylosing spondylitis.

DOSAGE AND ADMINISTRATION

Adult: The recommended dose is 200 mg daily in two divided doses, one tablet in the morning and one in the evening. The initial dose should be reduced to 100 mg daily in patients with hepatic impairment.

Children: It is not recommended

CONTRAINDICATIONS

Aceclofenac should not be administered to patients previously sensitive to aceclofenac or in whom aspirin or NSAIDs precipitate attacks of asthma, acute rhinitis or urticaria or who are hypersensitive to these drugs. It should not be administered to patient with active or suspected peptic ulcer or gastro-intestinal bleeding, moderate or severe renal impairment.

SIDE- EFFECTS

The side effects of aceclofenac correspond to those from ibuprofen, however the substance is, compared with other non-opioid analgesics somewhat to be better compatible.

USE IN PREGNANCY AND LACTATION

There is no information in the use of aceclofenac during pregnancy. The use of aceclofenac should therefore be avoided in pregnancy and lactation unless the potential benefits to the mother outweigh the possible risk to the fetus.

INTERACTIONS

Aceclofenac is highly protein-bound. Concomitant use of other protein-binding drugs, e.g. anticoagulants, sulphonamides, hydantoins might

necessitate modification of dosage in order to avoid increased levels of such drugs resulting from competition for plasma protein-binding sites. Similar acting drugs such as aspirin, or other non-steroidal anti-inflammatory agents should not be administered concomitantly with aceclofenac as the potential for adverse reactions is increased. Serious interactions have been recorded after the use of high dose methotrexate with non-steroidal anti-inflammatory agents including aceclofenac.

OVERDOSE

Like other propionic acid derivatives, aceclofenac is of low toxicity in overdose; symptoms after acute aceclofenac intoxication are largely limited to drowsiness, abdominal pain and vomiting, but adverse effects seen after over dosage with propionic acid derivatives such as hypotension, bronchospasm and gastrointestinal haemorrhage should be anticipated. Treatment should be symptomatic and may include gastric washout and the use of activated charcoal.

PRECAUTIONS

Cautions must be taken in renal, cardiac, hepatic impairment, and elderly patients. The dose should be kept as low as possible and renal function should be monitored.

WARNINGS

Gastro-intestinal disorders, with a history suggestive of gastro-intestinal ulceration, with ulcerative colitis or with Crohn's disease, bleeding diathesis or haematological abnormalities, severe impairment of hepatic function. Gastro-intestinal bleeding or ulcerative perforation, haematemesis and melaena may occur at any time during the treatment. As with other NSAIDs allergic reactions, including anaphylactic reactions can also occur without earlier exposure to the drug.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

PAINO[®] 100 mg tablet: Box containing 10 strips of 10 tablets each.
Each film coated tablet contains Aceclofenac BP 100 mg.

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Manufactured by
ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

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