

210mm

Erwin[®] 50mg/75mg Tablets

(Diclofenac Sodium+ Misoprostol)

COMPOSITION:

Erwin[®] 50mg Tablets

Each tablet contains:

Diclofenac sodium BP (enteric coated)50mg
Misoprostol MS.....200mcg

Erwin[®] 75mg Tablets

Each tablet contains:

Diclofenac sodium BP (enteric coated)75mg
Misoprostol MS.....200mcg

PHARMACOLOGICAL ACTION:

Diclofenac is a non-steroidal anti-inflammatory drug with anti-inflammatory and analgesic properties. Misoprostol is used for the prophylaxis of NSAIDs induced gastric and duodenal ulceration. The pharmacokinetic profiles of diclofenac and misoprostol administered are similar to the profiles when the two drugs are administered as separate tablets

INDICATIONS:

Diclofenac is indicated for the treatment of sign and symptoms of osteoarthritis, rheumatoid arthritis, acute musculoskeletal disorders. Misoprostol is indicated for the prevention of NSAID induced gastric and duodenal ulceration

DOSAGE AND DIRECTIONS FOR USE:

Adults

Erwin[®] 50mg Tablets: One tablet to be taken with food, two to three times daily

Erwin[®] 75mg Tablets: One tablet to be taken with food, two times daily

Tablet to be swallowed whole with water

OR

As directed by the physician

CONTRA-INDICATIONS:

Erwin[®] is contra-indicated in patients with active gastro-intestinal bleeding and in patients with known gastric and/or duodenal ulceration

Erwin[®] is contra-indicated in pregnancy as it may increase uterine tone and contractions in pregnancy which could produce miscarriage. Also, it may cause premature closure of the ductus arteriosus

Erwin[®] is contra-indicated during lactation

Erwin[®] is contra-indicated in patients with a known hypersensitivity to diclofenac, aspirin, other NSAIDs and misoprostol

WARNINGS:

Erwin[®] should not be used in pre-menopausal women unless they use effective contraception and have been advised of the risks of taking the product if pregnant

Elderly/Renal Impairment/Hepatic Impairment

No adjustment of dosage is necessary in the elderly or in patients with hepatic impairment or mild to moderate renal impairment as pharmacokinetics are not altered to any clinically relevant extent. Nevertheless, patients with severe renal or hepatic impairment should be closely monitored

Children

The safety and efficacy of **Erwin[®]** in children has not been established

SIDE-EFFECTS:

Gastro-intestinal: Abdominal pain, diarrhoea, nausea, dyspepsia, flatulence, vomiting, gastritis, constipation, eructation and gastro duodenal ulcerations/erosions
Magnesium containing antacids may aggravate the diarrhoea caused by **Erwin[®]**

Liver: Clinically significant elevations of SGPT, SGOT, alkaline phosphatase or bilirubin have been observed in association with **Erwin[®]** without symptomatic evidence of hepatic disease

Kidney: As a class, NSAIDs have been associated with renal pathology such as papillary necrosis and interstitial nephritis

Female reproductive system: Menorrhagia, intermenstrual bleeding and vaginal bleeding have been reported in pre-menopausal women and vaginal bleeding in post-menopausal women

Other adverse effects: Headache, dizziness, skin rashes and allergic reactions including anaphylaxis may occur

SPECIAL PRECAUTIONS:

Erwin[®] may decrease platelet aggregation and prolong bleeding time. This effect should be considered when bleeding times are determined
Fluid retention and edema have been observed in patients taking NSAIDs, including **Erwin[®]**. Therefore, **Erwin[®]** should be used with caution in patients with compromised cardiac function or conditions predisposing to fluid retention

In patients with renal, cardiac or hepatic impairment, caution is required since the use of NSAIDs, including **Erwin[®]**, may result in deterioration of renal function. The dose should be kept as low as possible and renal function should be monitored

All patients who are receiving long-term treatment with NSAIDs, including **Erwin[®]**, should be monitored as a precautionary measure (e.g. renal, hepatic function and blood counts)

DRUG INTERACTIONS:

Erwin[®] may attenuate the natriuretic efficacy of diuretics due to inhibition of intrarenal synthesis of prostaglandins. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels

Hence serum potassium should be monitored

Steady state plasma lithium and digoxin levels may be increased

Pharmacodynamic studies with diclofenac have shown no potentiation of oral hypoglycemic and anticoagulant drugs. However, as interactions have been reported with other NSAIDs, caution and adequate monitoring are nevertheless advised

Caution is advised when methotrexate is administered concurrently with **Erwin[®]** because of possible enhancement of its toxicity as a result of an increase of methotrexate plasma levels

120mm

PREGNANCY AND LACTATION:

Erwin® is contra-indicated in pregnancy (see Contra-indications) and during lactation

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

The toxic dose of **Erwin®** has not been determined and there is no experience of over-dosage, intensification of the pharmacological effects may occur with over-dosage. Management of acute poisoning with **Erwin®** essentially consists of supportive and symptomatic measures. It is reasonable to take measures to reduce absorption of any recently consumed drug by forced emesis, gastric lavage or activated charcoal

STABILITY: See expiry on pack

PRESENTATION:

Erwin® 50mg tablets are available in a pack of 20 tablets

Erwin® 75mg tablets are available in a pack of 20 tablets

INSTRUCTIONS:

To be swallowed whole with water

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

ایرون

(ڈکلو فینک سوڈیم + مینسو پروسٹول)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

ہدایت: ثابت ٹیبلٹ چبائے بغیر پانی سے نگل لیں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں ۱۵ سے ۳۰ ڈگری سینٹی گریڈ

کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی



Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

210mm

P000664/S

R-N-04/HA/05/16/Pampac

120mm