

Voren® Injection

(Diclofenac Sodium)

ورین انجکشن

Voren®, the brand of diclofenac sodium, is an anti-inflammatory, analgesic and antipyretic agent. Chemically it is sodium [O-[(2,6-dichlorophenyl)amino] phenyl] acetate.

COMPOSITION

Each 3ml **Voren®** ampoule contains 75mg of diclofenac sodium.

ACTIONS

1. **Voren®** is a nonsteroidal anti-inflammatory agent that possesses analgesic and antipyretic activities. Its mode of action, like that of other nonsteroidal anti-inflammatory agents, is not known; however, its therapeutic action is not due to pituitary adrenal stimulation, but may be from the inhibitory action in the synthesis of prostaglandin.
2. **Voren®** exhibits very marked antirheumatic, anti-inflammatory, analgesic, and antipyretic properties and is thus suitable for use in inflammatory and degenerative rheumatic disease, as well as for the treatment of post-traumatic inflammation and swelling.
3. In patients treated with **Voren®** for rheumatoid arthritis and osteoarthritis, the anti-inflammatory action of **Voren®** has been shown by reduction in joint swelling, reduction in pain, also reduction on duration of morning stiffness.

INDICATIONS

Inflammatory and degenerative forms of rheumatism, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis.

- Painful syndromes of the vertebral column.
- Non-Articular rheumatism.
- Acute attack of gout.
- Painful post-traumatic and post-operative inflammation and swelling of orthopedic surgery.
- Painful and inflammatory condition in gynaecology, e.g. primary dysmenorrhea & adnexitis.
- As an adjuvant therapy in severe painful inflammatory infection of ear, nose and throat.
- Painful post-operative, inflammatory condition of dental surgery.

DOSAGE AND ADMINISTRATION

By intramuscular injection:

75mg, once daily (twice daily in severe cases). Intramuscular injection should be given deeply into the gluteal muscle to ensure intramuscular delivery. Use alternate sites for subsequent injections.

By intravenous infusion (in hospital setting):

75mg over 30~120 minutes repeated if necessary after 4~6 hours for maximal 2 days. Prevention of postoperative pain, initially after surgery 25~50mg over 15~60 minutes then 5mg/hour for maximal 2 days.

To be used by a physician.

SIDE EFFECTS

At the start of treatment, patients may complain of epigastric pain, eructation, nausea and diarrhoea, headache, or dizziness. These side effects, however, are usually of a mild nature and generally disappear after a few days despite continuation of the medication. Skin rashes may also occur very occasionally.

DRUG INTERACTIONS

Aspirin:

As with other NSAIDs, concomitant administration of diclofenac and aspirin is not generally recommended because of the potential of increased adverse effects.

Methotrexate:

Caution should be used when NSAIDs are administered concomitantly with methotrexate. Methotrexate plasma levels may be increased and result in increased toxicity.

Cyclosporine:

Concomitant therapy with **Voren®** may increase cyclosporine's nephro-toxicity. Caution should be used when **Voren®** is administered with cyclosporine.

ACE Inhibitors:

Reports suggest that NSAIDs may diminish the anti-hypertensive effect of ACE inhibitors. This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE inhibitors.

Furosemide:

Voren® can reduce the natriuretic effect of furosemide and thiazides in some patients. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure, as well as to assure diuretic efficacy.

Warfarin:

The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that users of both drugs together have a risk of serious GI bleeding higher than users of either drug alone.

PRECAUTIONS

- In accordance with currently accepted views on the employment of drugs during pregnancy, **Voren®** should not be prescribed in the first three months of pregnancy unless its use is strictly indicated.
- Diclofenac sodium should not be used concomitantly with diclofenac potassium since both exist in plasma as the same active organic ion.
- Patients on long-term diclofenac sodium treatment should have their hemopoietic system evaluated periodically.
- Administration of NSAIDs may precipitate overt renal decompensation due to a dose-dependent reduction in prostaglandin formation. Patients at greatest risk are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics, and the elderly.
- During long-term therapy, kidney function should be monitored periodically.
- Liver function should be monitored during long-term treatment with this drug.
- Caution is called for when using diclofenac sodium in patients with hepatic porphyria, since diclofenac sodium may trigger an attack.

- As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can occur without prior exposure to drug.

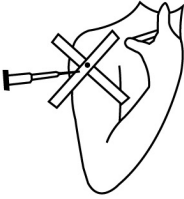
WARNINGS

- Caution is required if administered to patients suffering from, or with a previous history of bronchial asthma since NSAIDs have been reported to cause bronchospasm in such patients.
- NSAIDs should only be given with care to patients with a history of gastrointestinal disease.
- Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration.
- NSAIDs should be given with care to patients with a history of heart failure or hypertension since oedema has been reported in association with NSAID administration.

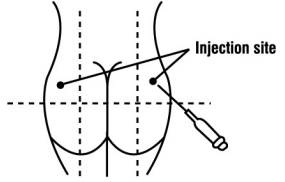
CONTRAINDICATIONS

- Patients with known hypersensitivity to diclofenac, or other non-steroidal anti-inflammatory medicines.
- Asthmatic patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid, or other medicines with prostaglandin synthetase inhibiting activity.
- Diclofenac sodium is contra-indicated in patients with a history of active gastro-intestinal bleeding or peptic ulceration, or severe hepatic or renal impairment. Patients with porphyria.
- Last trimester of pregnancy.
- Severe hepatic, renal and cardiac failure.

Voren® is injected sagittally into the upper outer quadrant of the gluteal muscle, with the needle directed towards the iliac crest, or into the ventral part of the M. glut. med. and the subjacent M. glut. min. injection site; see illustration. The muscles are then gently rubbed to spread the preparation, this favours absorption. Strict asepsis.



Prevent injecting at this site.



I.M. injection into upper outer quadrant.

ورین انجکشن ہڈیوں، پٹھوں اور جوڑوں کے شدید درد کو رفع کرنے میں انتہائی مفید ہے۔ ورین انجکشن سرجری کے بعد شدید درد میں بھی بہت مؤثر دوا ہے۔

انجکشن کو لہے کے عضلات میں گہرا لگانا چاہیے۔ بار بار لگانے کی صورت میں انجکشن کی جگہ بدلنا ضروری ہے۔

خوراک: بالغ افراد کے لئے

انٹراسکوپل: ایک اینپیول (۵ ملٹی گرام) روزانہ کو لہے کی جگہ پر لگائیں۔ ضرورت پڑنے پر دوا انجکشن روزانہ دے سکتے ہیں۔

انٹراونیس انفیوژن: (زیادہ سے زیادہ دورانیہ دودن) ایک اینپیول (۵ ملٹی گرام) ۳۰ سے ۱۲۰ منٹ میں۔

انجکشن ۴ سے ۶ گھنٹے میں دوبارہ دہرایا جاسکتا ہے۔

بعد از آپریشن درد کے لئے: (زیادہ سے زیادہ دورانیہ دودن) سرجری کے بعد ۲۵ سے ۵۰ ملٹی گرام ۱۵ سے ۶۰ منٹ میں،

اس کے بعد ہر گھنٹے ۵ ملٹی گرام۔

انجکشن ڈاکٹر کی ہدایت کے مطابق دیں۔

انٹراونیس انفیوژن ڈاکٹر کی نگرانی میں دینا چاہیے۔

ہدایات:

دوا کو روشنی اور گرمی سے محفوظ رکھیں۔

دوا کو منجمد ہونے سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

PACKAGING

Voren® Injection : 3ml x 10's / Pack

Voren® Injection : 3ml x 100's / Pack.

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Detailed prescribing information available on request.



Manufactured by:
AsianContinental (Pvt.) Ltd.
D-32, S.I.T.E. II, Super Highway,
Karachi-Pakistan.



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TACHIA, TAIWAN, R.O.C.

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