

Vologen Injection 75mg/3ml

(Diclofenac Sodium Injection)

PA 73/133/5

Summary of Product Characteristics

(Clean)

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Clean SPC
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Summary of Product Characteristics

Product Name: Vologen Injection 75mg/3ml

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PRODUCT NAME: VOLOGEN INJECTION 75MG/3ML

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

VOLOGEN Injection (Diclofenac Sodium Injection 75mg in 3ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3ml contains 75mg of Diclofenac Sodium.

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

Colourless or almost colourless aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In the management of acute exacerbations of rheumatoid arthritis, or osteoarthritis, in acute back pain, acute gout, post-operative pain. Relief of pain in acute traumatic musculo-skeletal disorders and fractures. In the acute management of renal colic.

4.2 Posology and method of administration

Intramuscular injection.

One ampoule once (or in severe cases twice) daily intramuscularly by deep intragluteal injection into the upper outer quadrant. If two injections daily are required, it is advised that the alternate buttock be used for the second injection. Diclofenac Sodium Injection should not be given for more than 2 days; if necessary, treatment can be continued with tablets. Diclofenac Sodium Injection should not be administered by the intravenous route.

Renal Colic: 1 x 75mg ampoules intramuscularly. A further ampoule may be administered after 30 minutes if necessary. The total daily dose should not exceed 150mg.

Elderly: Although the pharmacokinetics of diclofenac are not impaired to any clinically relevant extent in elderly patients, non-steroidal anti-inflammatory drugs should be used with particular caution in such patients who generally are more prone to adverse reactions. In particular, it is recommended that the lowest effective dosage be used in frail elderly patients or those with a low body weight (see also "Precautions").

Children: Diclofenac Sodium Injection is not recommended for use in children.

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4. CLINICAL PARTICULARS cont/d.

4.3 Contra-indications

Hypersensitivity to diclofenac.

Use in patients with active or suspected peptic ulceration or with gastrointestinal bleeding.

Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents.

Hypersensitivity to the excipients sodium metabisulphite, benzyl alcohol, or propylene glycol.

4.4 Special warnings and special precautions for use

The product should only be used with great caution in patients with a history of peptic ulcer, gastrointestinal bleeding, hepatic or renal insufficiency, bleeding diathesis, or haematological abnormalities, or intestinal inflammation, including ulcerative colitis or Crohn's disease.

The importance of prostaglandins in maintaining renal blood flow should be taken into account in patients with impaired cardiac or renal function, those being treated with diuretics or recovering from major surgery. Effects on renal function are usually reversible on withdrawal of diclofenac sodium.

All patients on long term non-steroidal anti-inflammatory treatment should be kept under regular surveillance with monitoring of renal and hepatic function, and of haematological parameters. This is particularly important in the elderly. Any evidence of progressive deterioration in function should be regarded as a reason for discontinuing therapy.

Diclofenac sodium, in common with other non-steroidal anti-inflammatory drugs, can reversibly inhibit platelet aggregation.

Use of diclofenac sodium in patients with hepatic porphyria may trigger an attack.

Concurrent use with aspirin results in reduced serum levels of diclofenac sodium and of aspirin and salicylates.

4.5 Interactions with other medicinal products and other forms of interaction

This product is strongly protein bound. Studies to date show no potentiation of oral hypoglycaemic or anticoagulant drugs.

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4. **CLINICAL PARTICULARS cont/d.**

4.5 Interactions with other medicinal products and other forms of interaction cont/d.

Diclofenac sodium may increase plasma levels of concurrently administered digoxin or lithium.

Various non-steroidal anti-inflammatory drugs are liable to inhibit the activity of diuretics. Concomitant treatment with potassium sparing diuretics may be associated with increased serum potassium levels, hence serum potassium should be monitored.

Concurrent therapy with other systemic non-steroidal anti-inflammatory drugs may increase the frequency of side effects.

Caution should be exercised if non-steroidal anti-inflammatory drugs and methotrexate are administered within 24 hours of each other, since non-steroidal anti-inflammatory drugs may increase methotrexate plasma levels, resulting in increased toxicity.

Cyclosporin nephrotoxicity may be increased by the effect of non-steroidal anti-inflammatory drugs on renal prostaglandins.

4.6 Pregnancy and lactation

The product should not be used in pregnancy or lactation unless considered essential by the physician. Use of PG synthetase inhibitors in the third trimester may result in premature closure of the ductus arteriosus. Traces of drug are detectable in breast milk but are not clinically significant.

4.7 Effects on ability to drive and use machines

Patients who experience dizziness or other central nervous system disturbances while taking NSAIDs should refrain from driving or operating machinery.

4.8 Undesirable effects

The following side effects have been reported in association with diclofenac: -

Blood and Lymphatic system disorders: Blood dyscrasias.

Central nervous system: Occasional: headache, dizziness, or vertigo. Rare: drowsiness, tiredness, malaise. In isolated cases: disturbances of sensation (paraesthesia), memory disturbance, disorientation, confusion, disturbance of vision (blurred vision, diplopia), impaired hearing, tinnitus, insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reactions. Taste alteration disorders. Optic neuritis has been reported in association with NSAID therapy.

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4. CLINICAL PARTICULARS cont/d.

Respiratory, thoracic and mediastinal disorders: Bronchospasm

Gastro-intestinal tract: Occasional: epigastric pain, other gastro-intestinal disorders (e.g. nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia).

Rare: gastro-intestinal bleeding, peptic ulcer (with or without bleeding or perforation), bloody diarrhoea.

In isolated cases: lower gut disorders (e.g. non-specific haemorrhagic colitis and exacerbations of ulcerative colitis or Crohn's proctocolitis), pancreatitis, aphthous stomatitis, glossitis, oesophageal lesions, constipation.

Kidney: In isolated cases: acute renal insufficiency, urinary abnormalities (e.g. haematuria, proteinuria), interstitial nephritis, nephrotic syndrome, papillary necrosis.

Skin: Occasional: rashes or skin eruptions. Rare: urticaria. In isolated cases: bullous eruptions, eczema, erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome, (acute toxic epidermolysis), erythroderma (exfoliative dermatitis), loss of hair, photosensitivity reactions, purpura including allergic purpura.

Metabolism and Nutrition Disorders- Fluid retention

General disorders and administration site conditions:

Injection site reaction

Injection site necrosis

Injection site pain

Very Rare: injection site abscess sterile.

Immune System disorders: Anaphylactic reaction.

Hepato-biliary signs and symptoms: Hepatitis

4.9 Overdose

There is no typical clinical picture associated with acute overdosage, and treatment should be symptomatic and supportive.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties and 5.2 Pharmacokinetic properties

A non-steroidal anti-inflammatory agent and inhibitor of PG synthetase, the drug is well absorbed with peak plasma levels in 30 minutes. It is extensively metabolised in the liver and excreted through bile and urine. The drug is strongly protein bound. It has a half-life of 1 – 2 hours.

In patients with impaired renal function accumulation of diclofenac sodium has not been reported.

Diclofenac sodium in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to the concentration reached in humans.

5.3 Preclinical safety data

No further relevant information other than that, which is included in other sections of the Summary of Product Characteristics.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulphite
Propylene glycol
Benzyl alcohol
Sodium hydroxide
Water for injections.

6.2 Incompatibilities

Other injection solutions.

6.3 Shelf life

Unopened: 3 years.
The product should be used immediately after opening.

6.4 Special precautions for storage

Keep the ampoules in the outer carton.
Do not store above 25°C.

6.5 Nature and contents of container

3ml, clear glass ampoules, glass type 1 Ph. Eur. packed in cardboard cartons to contain 5 x 3ml ampoules or 10 x 3ml ampoules.

6.6 Instructions for use and handling

If only part of an ampoule is used, discard the remaining solution.
For single use only.

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7. MARKETING AUTHORIZATION HOLDER

Antigen Pharmaceuticals Ltd.,
Roscrea,
County Tipperary,
Ireland.

8. MARKETING AUTHORIZATION NUMBER

PA 73/133/5

**9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE
AUTHORIZATION**

13th November 1995 / 13th November 2000

10. DATE OF (PARTIAL) REVISION OF THE TEXT

November 2006.