SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the drugproduct:
JUSTIN
Diclofenac Sodium Injection

Strength:
25 mg/ml – 3 ml

Pharmaceutical dosage form
Solution for Injection.

2. Qualitative and quantitative composition:

Sr. No.	Particulars	Grade	Qty. / ml	O.A. %	Function
1.	Diclofenac Sodium	BP	25 mg	--	Active

For a full list of excipients, see section 6.1

3. Pharmaceutical form:
A clear, colorless to yellowish solution.

4. Clinical Particulars:

4.1 Therapeutic indications:
Treatment of:
- Exacerbation of inflammatory and degenerative forms of rheumatism rheumatoid arthritis, ankylosing spondylitis, osteoarthritis
- Acute attacks of gout
- Renal colic
- Painful post-traumatic and postoperative pain, inflammation and swelling

4.2 Dosage and method of administration: Adults:
Diclofenac ampoules should not be given for more than 2 days; if necessary treatment can be continued with Diclofenac tablets.
The following directions for intramuscular injection must be followed in order to avoid damage to a nerve or other tissue at the injection site. The dosage is generally one 75 mg ampoule daily, given by deep intragluteal injection into the upper outer quadrant. In severe cases (e.g. colic) the daily dose can exceptionally be increased to two injections of 75 mg, separated by an interval of a few hours (one into each buttock). Alternatively, one ampoule of 75 mg can be combined with Diclofenac tablets, upto a maximum daily dosage of 150 mg. Diclofenac should not be mixed with other injection solutions.
Children:
Diclofenac Sodium Injection are not recommended for use in children.

Not to be used in newly born or premature infants

4.3 Contraindications:

Gastric or intestinal ulcer: Known hypersensitivity to the active substance or sodium metabisulphite and other excipients. Like other non-steroidal anti-inflammatory drugs (NSAIDs), Diclofenac Sodium Injection is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other drugs with prostaglandin-synthetase inhibiting activity.

4.4 Precautions and Warnings:

Warnings: Gastrointestinal bleeding or ulceration/perforation can occur at any time during treatment, with or without warning symptoms or a previous history. They generally have more serious consequences in the elderly. In the rate cases where gastrointestinal bleeding or ulceration occurs in patients receiving the drug should be withdrawn.
As with other NSAIDs allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur in rate cases without earlier exposure to the drug. The sodium metabisulphite in the ampoules can also lead to isolated hypersensitivity reactions. Like other NSAIDs, Diclofenac Sodium Injection may mask the signs and symptoms of infection due to its pharmacodynamic properties.

PRECAUTIONS

Close medical surveillance is imperative in patients with symptoms indicative of gastrointestinal disorders or a history suggestive of gastric or intestinal ulcer, patients with ulcerative colitis or Crohn's disease, and patients suffering from impaired hepatic function.
As with other NSAIDs, values of one or more liver enzymes may increase. During prolonged treatment with Diclofenac Sodium Injection (e.g. in the form of tablets), monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (e.g. eosinophilia, rash etc) Diclofenac Sodium Injection should be discontinued. Hepatitis may occur without prodromal symptoms.
Caution is called for when using Diclofenac Sodium Injection in patients with hepatic porphyria, since Diclofenac Sodium Injection may trigger an attack.
Owing to the importance of prostaglandins in maintaining renal blood flow, particular caution is called for in patients with impaired cardiac or renal function, the elderly, patients being treated with diuretics, and patients with substantial extracellular volume depletion of any cause, e.g. before or after major surgery. Monitoring of renal function is recommended as a precautionary measure when using Diclofenac Sodium Injection in such cases. Discontinuation of therapy is usually followed by a return to the pretreatment state.
During prolonged treatment with Diclofenac Sodium Injection as with other NSAIDsmonitoring of the blood count is recommended. Like other NSAIDs, Diclofenac Sodium Injection may temporarily inhibit platelet aggregation. Patients with haemostatic disorders should be carefully monitored.
Special caution is recommended when Diclofenac Sodium Injection is used parenterally in patients with bronchial asthma because symptoms may be exacerbated.
Caution is indicated in elderly on basic medical grounds. In particular it

is recommended that the lowest effective dosage should be used in frail elderly patients or those with a low body weight.

4.5 Interaction with other drugs:

(including interactions observed with other pharmaceutical forms of Diclofenac Sodium Injection) Lithium, digoxin : Diclofenac Sodium Injection may raise plasma concentrations of lithium and digoxin. **Diuretics**: Like other NSAIDs Diclofenac Sodium Injection may inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, which should therefore be monitored.

NSAIDs: Concomitant administration of systemic NSAIDs may increase the frequency of side effects.

Anticoagulants: Although clinical investigations do not appear to indicate that Diclofenac Sodium Injection affects the action of anticoagulants, there are isolated reports of an increased risk of haemorrhage in patients receiving Diclofenac Sodium Injection and anticoagulants concomitantly. Close monitoring of such patients is therefore recommended.

Antidiabetic: Clinical studies have shown that Diclofenac Sodium Injection can be given together with oral antidiabetic agents without influencing their clinical effect. However, isolated cases have been reported of both hypoglycaemic and hyperglycaemic effects necessitating changes in the dosage of hypoglycaemic agents during treatment with Diclofenac Sodium Injection.

Methotrexate: caution is called for if NSAIDs are administered less than 24 hours before or after treatment with methotrexate, since blood concentrations of methotrexate may rise and the toxicity of this substance be increased.

Cyclosporin: The effects of NSAIDs on renal prostaglandins may increase the nephrotoxicity of cyclosporin.

Quinolone antibacterials: There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.

4.6 Pregnancy and Lactation:

Because of insufficient data, administration of Diclofenac Sodium Injection during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and operate machine:

Dizziness, drowsiness, visual disturbances or headaches are possible undesirable effects after taking NSAIDs, if affected, patients should not drive or operate machinery

4.8 Adverse effects:

GASTROINTESTINAL TRACT:

Occasional: epigastric pain; other gastrointestinal disorders such as

nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence and anorexia.
Rare: gastrointestinal bleeding (haematemesis, melaena, bloody diarrhoea), gastric or intestinal ulcer with or without bleeding or perforation.
Isolated cases: aphthous stomatitis, glossitis, oesophageal lesions, diaphragm like intestinal strictures, lower gut disorders such as non-specific haemorrhagic colitis or Crohn's disease, constipation, pancreatitis.

CENTRAL NERVOUS SYSTEM
Occasional: headache, dizziness, vertigo.
Rare: drowsiness
Isolated cases: sensory disturbances, including paraesthesia, memory disturbances, disorientation, insomnia, irritability convulsions, depression, anxiety, nightmares, tremor, psychotic reactions, aseptic meningitis.

SPECIAL SENSES
Isolated cases: disturbances of vision (blurred vision, diplopia), impaired hearing, tinnitus, taste disturbances.

SKIN
Occasional: rashes or skin eruptions.
Rare: urticaria
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.

KIDNEY
Rare: oedema
Isolated cases: acute renal failure, urinary abnormalities such as haematuria and proteinuria, interstitial nephritis, nephrotic syndrome, papillary necrosis.

LIVER
Occasional: elevation of serum aminotransferase values.
Rare: hepatitis with or without jaundice.
Isolated cases: fulminant hepatitis

BLOOD
Isolated cases: thrombocytopenia, leucopenia, haemolytic anaemia, aplastic anaemia, Agranulocytosis.

HYPERSENSITIVITY
Rare: hypersensitivity reactions such as asthma, systemic anaphylactic/anaphylactoid reactions including hypotension.
Isolated cases: vasculitis, pheumonitis.

CARDIOVASCULAR SYSTEM
Isolated cases: palpitation, chest pain, hypertension, congestive heart failure, other organ systems
Occasional: intramuscular injection site reactions such as local pain and induration.
Isolated cases: local abscesses and necrosis at the intramuscular

injection site.

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org '

4.8 Over dosage:

Management of acute poisoning with NSAIDs consists essentially of supportive and symptomatic measures. There is no typical clinical picture associated with overdosage of Diclofenac.
The following therapeutic measures should be taken in cases of overdosage: Supportive and symptomatic treatment are indicated for complications such as hypotension, renal failure, convulsions, gastrointestinal irritation, and respiratory depression.
Specific measures such as forced diuresis, dialysis, or haemoperfusion are unlikely to
be helpful in eliminating NSAIDs because of their high protein-binding rate and extensive metabolism.

5. Pharmacological properties :

5.1 Pharmacodynamic properties :

Diclofenac Sodium Injection contains Diclofenac sodium, a non-steroidal compound with pronounced antirheumatic, anti-inflammatory, analgesic and antipyretic properties. Inhibition of prostaglandin biosynthesis, which has been demonstrated in experiments, is considered fundamental to its mechanism of action. Prostaglandins play a major role in causing inflammation, pain and fever. Diclofenac sodium in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to those reached in humans. In rheumatic diseases, the anti- inflammatory and analgesic properties of Diclofenac elicit a clinical response characterised by marked relief from signs and symptoms such as pain at rest, pain on movement, morning stiffness, and swelling of the joints, as well as by an improvement in function.
Diclofenac Sodium Injection has also been found to exert a pronounced analgesic effect in moderate and severe pain of non-rheumatic origin, an effect which sets in within 15-30 minutes.
In post-traumatic and postoperative inflammatory conditions, Diclofenac Sodium Injection rapidly relieves both spontaneous pain and pain on movement and reduces inflammatory swelling and wound oedema. When used concomitantly with opioids for the management of postoperative pain, Diclofenac Sodium Injection significantly reduces the need for opioids. Diclofenac Sodium Injection ampoules are particularly suitable for initial treatment of inflammatory and degenerative rheumatic diseases, and of painful conditions due to inflammation of non-rheumatic origin.

5.2 Pharmacokinetic properties:

Absorption: After administration of 75 mg Diclofenac by intramuscular injection, absorption sets in immediately, and mean peak plasma concentrations of about 2.5 ug/ml (8umol/L) are reached after about 20 minutes. The amount absorbed is in linear proportion to the size of the dose.

Plasma concentrations decline rapidly once peak levels have been reached following intramuscular injection.
The area under the concentration curve (AUC) after intramuscular administration is about twice as large as it is following oral administration, because about half the active substance is metabolised during its first passage through the liver ("first pass" effect) when administered via the oral route.
Pharmacokinetic behavior does not change after repeated administration. No accumulation occurs provided the recommended dosage intervals are observed.

Distribution: 99.7% of Diclofenac binds to serum proteins, mainly to albumin (99.4%). The apparent volume of distribution calculated is 0.12-0.17L/kg.
Diclofenac enters the synovial fluid, where maximum concentrations are measured 2-4 hours after peak plasma values have been attained.
The apparent half-life for elimination from the synovial fluid is 3 to 6 hours. Two hours after reaching peak plasma levels, concentrations of the active substance are already higher in the synovial fluid than in the plasma, and they remain higher for up to 12 hours.

Biotransformation: Biotransformation of Diclofenac takes place partly by glucuronidation of the intact molecule, but mainly by single and multiple hydroxylation and methoxylation, resulting in several phenolic metabolites (3- hydroxy-, 4-hydroxy-, 5-hydroxy-, 4',5-dihydroxy-, and 3'-hydroxy-4'-methoxy-diclofonac), most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, but to a much lesser extent than Diclofenac.

Elimination: Total systemic clearance of Diclofenac from plasma is 263 ± 56 mL/min (mean vlaue ± SD). The terminal half-life in plasma is 1-2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1-3 hours. One metabolite, 3'-hydroxy-4' – methoxy-Diclofenac, has a much longer plasma half-life.
However, this metabolite is virtually inactive.
About 60% of the administered dose is excreted in the urine as the glucuronide conjugate of the intact molecule and as metabolites, most of which are also converted to glucuronide conjugates. Less than 1% is excreted as unchanged substance. The rest of the dose is eliminated as metabolites through the bile in the faeces.

Characteristics in patients: No relevant age-dependent differences in the drug's absorption, metabolism or excretion have been observed after oral administration. However, in a few elderly patients a 15 minutes intravenous infusion resulted in 50% higher plasma concentrations than expected from the data on young healthy subjects.
In patients suffering from renal impairment, no accumulation of unchanged active substance can be inferred from the single-dose kinetics when applying the usual dosage schedule. At a creatinine clearance of less than 10 mL/Min, the calculated steady-state plasma levels of the hydroxy metabolites are about 4 times higher than in normal subject. However, the metabolites are ultimately cleared through

the bile.
In patients with chronic hepatitis or non-decompensated cirrhosis, the kinetics and metabolism of Diclofenac are the same as in patients without liver disease.

NOTE: Medicines should be kept out of the reach of children.

5.3 Pre-clinical Safety Data:
Not applicable

6. Pharmaceutical particulars:

6.1 List of Excipients:
Disodium Edetate B.P.
Anhydrous Sodium
Sulphite B.P.
Potassium Dihydrogen Phosphate
B.P. Sodium Hydroxide B.P.
Benzyl Alcohol B.P.
Water for Injection BP (Bulk)

6.2 Incompatibilities:
No further relevant information other than that mentioned above.

6.3 Shelf – life:
24 Months

6.4 Special precautions for storage:
Store below 30°C., protected from light. Do not freeze.

6.5 Nature and contents of container:
3 ml Flint Ampoule Purple OPC Dotted.

6.6 Special Precautions for Handling and Disposal:
Medicines should be kept out of the reach of children.

7. Marketing authorization holder:
M/s. NEON LABORATORIES LIMITED
140, Damji Shamji Industrial Complex,
28, Mahal Indl. Estate, Mahakali Caves
Road, Andheri (East), Mumbai - 400 093

8. Marketing authorization number:
H2015/CTD2446/332

9. Date of first authorization / Renewal of the authorization:
18/01/2026

10. Date of revision of the text: December 2025
18/01/2026