AKIS® (DICLOFENAC SODIUM) 75mg/mL SOLUTION FOR INJECTION

PRESCRIBING INFORMATION: Please refer to Summary of Product Characteristics before prescribing.

ACTIVE INGREDIENT: Each 1 mL ampoule contains 75 mg diclofenac sodium.

INDICATIONS: By intravenous bolus injection for treatment, or prevention, of post-operative pain in hospital settings. **By intramuscular and subcutaneous injection** in acute forms of pain, including renal colic, exacerbations of osteo- and rheumatoid arthritis, acute back pain, acute gout, acute trauma and fractures, and post-operative pain.

DOSAGE AND ADMINISTRATION: **Adults:** by intramuscular, subcutaneous or intravenous bolus injection. Not to be given by i.v. infusion. Use the lowest effective dose for the shortest duration necessary. For severe pain a dose of 75mg may be needed. Exceptionally, and in severe cases, a second dose of 75mg can be administered after 4- 6 hours. Lower doses may suffice for mild and moderate pain, where freedom from the usual side-effects of NSAIDs is a priority and in the elderly particularly if frail or underweight. Maximum daily dose 150mg. Maximum treatment duration two days. **Elderly:** Maximum daily dose 150mg. Monitor regularly for GI bleeding. **Children and adolescents**: Not recommended.

CONTRAINDICATIONS: Haemostasis disorders or current anticoagulant treatment (**i.m. use only**), hypersensitivity to active substance or excipients, active gastric or intestinal ulcer, bleeding or perforation, historic NSAID-related gastrointestinal bleeding or perforation, active or history of recurrent peptic ulcer/haemorrhage, last trimester of pregnancy, severe hepatic, renal or cardiac failure, history of NSAID or acetylsalicylic acid precipitated asthma, urticaria, or acute rhinitis, established congestive heart failure, ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease. **Specifically for i.v. use:** Concomitant NSAID or anticoagulant use (including low dose heparin), history of haemorrhagic diathesis or asthma, history of confirmed or suspected cerebrovascular bleeding, operations associated with high risk of haemorrhage, moderate or severe renal impairment, any cause of hypovolaemia or dehydration.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE: Avoid use with systemic NSAIDs or COX-2 inhibitors. Caution in the elderly particularly if frail or underweight. Monitor for anaphylactic/anaphylactoid reactions and signs and symptoms of infection. Adhere to instructions for intramuscular injection to avoid adverse events at injection site including injection site necrosis and embolia cutis medicamentosa (Nicolau syndrome). Caution and close medical surveillance with symptoms indicative of gastrointestinal disorders or with a history suggestive of gastric or intestinal ulceration, bleeding or perforation. Consider combination therapy with protective agents for these patients and those requiring concomitant medications likely to increase gastrointestinal risk. Discontinue immediately if gastrointestinal bleeding or ulceration occurs or at first appearance of skin rash, mucosal lesions, or other signs of hypersensitivity. Close medical surveillance and caution in patients with ulcerative colitis, Crohn's disease, after gastro-intestinal surgery, impaired hepatic function, hepatic porphyria, impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function and patients with substantial extracellular volume depletion from any cause. Monitor for fluid retention and oedema in patients with history of hypertension and/or mild to moderate congestive heart failure. Caution in patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking).
Careful monitoring in patients with defects of haemostasis. Monitor haemoglobin and

haematocrit levels if symptoms of anaemia are detected. Risk of hyperkalaemia in diabetic patients or those taking potassium-sparing drugs. Special precaution recommended in patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa, COPD, chronic infections of the respiratory tract, and patients allergic to other substances. Increased risk of aseptic meningitis in patients with SLE and mixed connective tissue disorders.

INTERACTIONS: Lithium, digoxin, diuretics, ACE inhibitors, angiotensin-II antagonists, other NSAIDs, corticosteroids and acetylsalicylic acid, anticoagulants and heparin (administered in the elderly or at curative doses), thrombolytics and anti-platelet agents, SSRIs, antidiabetics, methotrexate, pemetrexed in patients with normal renal function, calcineurin inhibitors (e.g. ciclosporin, tacrolimus), deferasirox, quinolone antibacterials, phenytoin, colestipol and cholestyramine, potent CYP2C9 inhibitors, (e.g. sulfinpyrazone and voriconazole), mifepristone, tacrolimus, zidovudine.

PREGNANCY, LACTATION AND FERTILITY: Avoid during first and second trimester of pregnancy unless clearly necessary. Consider antenatal monitoring for oligohydramnios resulting from foetal renal dysfunction and ductus arteriosus constriction after exposure to diclofenac for several days from week 20 onward; discontinue if found. Contraindicated during the third trimester of pregnancy.Not be administered during lactation. May impair female fertility.

DRIVING: May cause visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances. Driving or use of machines should be avoided if affected.

UNDESIRABLE EFFECTS: AKIS Post-marketing experience: Very common: injection site reactions. **Common:** nausea, limb discomfort**. Serious:** hypersensitivity reaction, ischaemic colitis, Nicolau syndrome **NSAID class effects: Common:** headache,dizziness, vertigo, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, transaminases increased, rash, injection site reaction, injection site pain, injection site induration. **Serious:** Thrombocytopenia, leukopenia, anaemia (including haemolytic and aplastic anaemia), agranulocytosis, anaphylactic and anaphylactoid reactions, psychotic disorder, convulsion, aseptic meningitis, cerebrovascular accident, cardiac failure, myocardial infarction, Kounis syndrome, hypertension, vasculitis, asthma, pneumonitis, gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, melaena, gastrointestinal ulcer, colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), stomatitis, diaphragm-like intestinal strictures, pancreatitis, hepatitis, hepatic necrosis, hepatic failure, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis. Prescribers should consult the summary of product characteristics in relation to other adverse reactions.

PHARMACEUTICAL PRECAUTIONS: Store below 25°C. Do not refrigerate or freeze. Store in the original packaging to protect from light. Do not use if crystals or precipitates are observed.

DATE OF REVISION OF PRESCRIBING INFORMATION: March 2023

LEGAL CATEGORY: POM.

BASIC NHS PRICE: £24.00 (5x75mg/1 mL ampoules).

MARKETING AUTHORISATION HOLDER: IBSA Farmaceutici Italia Srl, Via Martiri di Cefalonia 2, 26900 Lodi (Italy).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Flynn Pharma Ltd. Medical information: Tel 01438 727822

MARKETING AUTHORISATION NUMBER: PL 21039/0042.

Marketed in the UK by Flynn Pharma Limited, Hertlands House, Primett Road, Stevenage, Herts SG1 3EE, Tel: 01438 727822, E-mail:medinfo@flynnpharma.com.

Information about this product, including adverse reactions, precautions, contraindications and method of use can be found at http://medicines.org.uk/emc/.