VKT5
Insert
Draft :
12 Oct 2018

VOKAM FILM COATED TABLET 50MG

Ingredient(s):
Vokam Film Coated Tablet 50mg
Each tablet contains:
Diclofenac Potassium 50mg

Pharmacodynamic :
Diclofenac is a non-steroidal agent with pronounced anti-inflammatory, analgesic and antipyretic activity. Prostaglandins play an important role in the pathogenesis of inflammation, pain and fever. Diclofenac is a potent inhibitor of prostaglandin bio-synthesis. Besides, diclofenac is also a modulator of arachidonic acid release and uptake.
Vokam Film Coated Tablets have a rapid onset of action and are, therefore, suitable for the treatment of acute episodes of pain and inflammation.
In migraine attacks diclofenac has been shown to be effective in relieving the headache and in improving the accompanying symptom of nausea.
Diclofenac in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to the concentrations reached in human beings.

Pharmacokinetics :
Absorption: Diclofenac is rapidly and completely absorbed from the coated tablet. Food intake does not affect absorption.
Distribution: The plasma concentrations show a linear relationship to the size of the dose. Diclofenac is 99.7% bound to serum protein, mainly bound to albumin (99.4%).
Metabolism: Diclofenac undergoes first-pass metabolism and is extensively metabolised. The biotransformation of diclofenac involves partly glucuronidation of the intact molecule but mainly single and multiple hydroxylation followed by glucuronidation.
Elimination: The total system clearance of diclofenac in plasma is 263 +/- 56ml/ min. The terminal half life in plasma is 1- 2 hours. Approximately 60% of the dose administered is excreted via renal in the form of metabolites, and less than 1% as unchanged substance. The remainder of the dose is eliminated in the form of metabolites via bile into the faeces.
The age of the patient has no influence on the absorption, metabolism, or excretion of diclofenac.
In patients suffering from renal impairment, no accumulation of the unchanged active substance can be inferred from the single-dose kinetics when applying the usual dosage schedule. At a creatinine clearance of <10 ml/min the theoretical steady-state plasma levels of metabolites are about four times higher than in normal subjects. However, the metabolites are ultimately cleared through the bile.
In the presence of impaired hepatic function (chronic hepatitis, non-decompensate cirrhosis) the kinetics and metabolism are the same as for patients without liver disease.

Indication(s):
As short-term treatment for the following acute conditions in cases where particular importance is attached to a prompt onset of effect (within 30 minutes) :
- Painful post-traumatic inflammatory states, e.g. due to sprains.
- Post-operative inflammation and pain, e.g. following dental or orthopaedic surgery.
- Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis.
- Acute migraine attacks. Vokam should not be used for migraine prophylaxis.
- Painful syndromes of the vertebral column.
- Non-articular rheumatism.
- As an adjuvant in severe painful inflammatory infections of the throat, nose, or ears, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.

Dosage and Administration:
Adults: As a rule, the daily dosage for adults is 100-150 mg. In milder cases, as well as for children over 14 years of age, 75-100 mg daily is usually sufficient. The daily dosage should always be prescribed in 2-3 fractional doses. In primary dysmenorrhoea the daily dosage, which should be individually adapted, is generally 50-150 mg. Initially a dose of 50-150 mg should be given ; if necessary, this can be raised in the course of several menstrual cycles up to a maximum of 200 mg daily. Treatment should be started upon appearance of the first symptoms and depending on the symptomatology, continued for a few days. The tablets should be taken with liquid, preferably before meals. In migraine an initial dose of 50 mg should be taken at the first signs of an impending attack. In cases where pain relief within 2 hours after the first dose is not sufficient, a further dose of 50 mg may be taken. If needed, further dose of 50 mg may be taken at intervals 4-6 hours, not exceeding a total dose of 200 mg in any 24-hours period.

Children: The dosage strengths are such that VOKAM tablets are not recommended for use in children.

L
260mm

Route of Administration: Oral.

Contraindications:
Known hypersensitivity to the active substance or any of the other excipients.
- Active gastric or intestinal ulcer, bleeding or perforation
- Last trimester of pregnancy
- Hepatic failure.
- Renal failure.
- Severe cardiac failure
- Like other non-steroidal anti-inflammatory drugs (NSAIDs), VOKAM is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs .

Precaution(s) / Warning(s):

Cardiovascular effects: Treatment with NSAIDs including diclofenac, particularly at high dose and in long term, maybe associated with an increased risk of serious cardiovascular thrombotic events (including myocardial infraction and stroke).
Treatment with diclofenac is generally not recommended in patients with established cardiovascular diseases (congestive heart failure, established ischemic heart diseases, peripheral arterial diseases) or uncontrolled hypertension. If needed, patients with established cardiovascular diseases, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellilitus and smoking) should be treated with diclofenac only after careful consideration and only at doses ≤100mg daily when treatment continues for more than 4 weeks.
As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the lowest effective daily dose should be used for the shortest duration possible. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially when treatment continues for more than 4 weeks.
Patients should remain alert for the signs and symptoms of serious arteriothrombotic events (e.g. chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a physician immediately in case of such an event.
Hypertension: NSAIDs may lead to the onset of new hypertension or worsening the pre-existing hypertension and patients taking antihypertensive with NSAIDs may have an impaired antihypertensive response. Caution is advised when prescribing NSAIDs to patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and at regular intervals thereafter.
Heart Failure: Fluid retention and oedema have been observed in some patients taking NSAIDs, hence caution is advised in patients with fluid retention of heart failure.
Gastrointestinal Events: All NSAIDs can cause gastrointestinal discomfort and rarely serious, potentially fatal gastrointestinal effects such as ulcers, bleeding and perforation which may increase with dose or duration of use, but can occur at any time without warning. Caution is advised in patients with risk factors for gastrointestinal events e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism. When gastrointestinal bleeding or ulcerations occur in patients receiving NSAIDs, the drug should be withdrawn immediately. Doctors should warn patient about signs and symptoms of serious gastrointestinal toxicity. The concurrent use of aspirin and NSAIDs also increases the risk of serious gastrointestinal adverse events.
Severe Skin Reactions: Severe cutaneous reactions, including Stevens-Johnson Syndrome and toxic epidermal necrolysis (Lyell's syndrome), have been reported with diclofenac. Patients treated with diclofenac should be closely monitored for signs of hypersensitivity reactions. Discontinue diclofenac immediately if rash occurs.
Hepatic: Close monitoring is necessary in patients suffering from severe impairment of hepatic function when using this drug. If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), Vokam tablet should be discontinued. Hepatitis may occur without prodromal symptoms. Use of diclofenac in patients with hepatic porphyria may trigger an attack.
Renal: Patients with renal impairment, especially the elderly, should be kept under surveillance, since the use of NSAIDs may result in deterioration of renal function.
Haematological: Diclofenac may reversibly inhibit platelet aggregation. Patients with defects of haemostasis should be carefully monitored.
Long term treatment: All patients who are receiving long term treatment with non-steroidal anti-inflammatory agents should be monitored as a precautionary measure e.g. renal function, hepatic function (elevation of liver enzymes may occur) and blood counts.

WARNINGS
RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (eg. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.

Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious adverse events and other risk factors associated with peptic ulcer disease (eg. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

W
110mm

260 x 110mm

Pregnancy and Lactation:
Although animal studies have not demonstrated teratogenic effects, Vokam film coated tablets should not be prescribed during pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used.
Congenital abnormalities have been reported in association with the administration of NSAIDs in man.
In view of the known effects of NSAIDs on the foetal cardiovascular system (e.g. a premature closure of the ductus arteriosus) and in causing uterine intertia, use in third trimester is contraindicated.
Like other NSAIDs, diclofenac passes into breast milk in small amounts. Therefore Diclofenac should not be administered during breast feeding in order to avoid undesirable effects in the infant.

Interaction with Other Medicaments:

Drug	Interaction
Lithium and digoxin	Diclofenac may increase their plasma concentrations.
Anticoagulants	Although clinical investigations do not appear to indicate that diclofenac has an influence on the effect of anticoagulants, there are isolated reports of an increased risk of haemorrhage with the combined use of diclofenac and anticoagulant therapy. Therefore to be certain that no change in anticoagulant dosage is needed; close monitoring of such patients is required. As with other non-steroidal anti-inflammatory agents, diclofenac can reversibly inhibit platelet aggregation.
Antidiabetic agents	Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However there have been isolated reports of hypoglycaemic and hyperglycaemic effects which have required adjustment to the dosage of hypoglycaemic agents.
Cyclosporine	The effects of NSAIDs on renal prostaglandin may increase the nephrotoxicity of cyclosporine.
Methotrexate	Caution should be taken when NSAIDs are administered <24 hours before or after treatment with methotrexate, since the blood concentration of methotrexate may increase and raise the risk of toxicity.
Quinolone Antibacterials	There have been reports of incidence of convulsion during the concurrent use of quinolone with NSAIDs.
Other NSAIDs and corticosteroids	The concomitant use of different systemic NSAIDs or of glucocorticoids may increase the occurrence of adverse effects.
Diuretics	Concomitant treatment with potassium sparing diuretics may be associated with increased serum potassium levels, which should therefore be monitored frequently.
Anti-hypertensives	Antagonism of antihypertensive effect on administration together with indomethacin and possibly other NSAIDs.

Side Effect(s) / Adverse Reaction(s):
Gastro-intestinal tract
Occasional: Epigastric pain, other gastro-intestinal disorders (e.g. nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia).
Rare: Gastro-intestinal bleeding (haematemesis, melaena, bloody diarrhoea), gastro-intestinal ulcers with or without bleeding or perforation.
In isolated cases: Aphthous stomatitis, glossitis, oesophageal lesions, lower gut disorders (e.g. non-specific haemorrhagic colitis and exacerbations of ulcerative colitis or Crohn's proctocolitis, colonic damage and stricture formation), pancreatitis, constipation.
Central nervous system
Occasional: Headache, dizziness.
Rare: Somnolence, tiredness.
In isolated cases: Paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident.
Dermatological
Occasional: rashes or skin eruptions
In isolated cases: hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.
Kidney
In isolated cases: Acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis.
Liver
Occasional: Elevation of serum amino-transferase enzymes (ALT, AST).
Rare: Liver function disorders including hepatitis with or without jaundice.
In isolated cases: Fulminant hepatitis.
Blood
In isolated cases: Thrombocytopenia, leucopenia, agranulocytosis, haemolytic anaemia, aplastic anaemia.
Hypersensitivity
Rare: Hypersensitivity reactions (e.g. bronchospasm, anaphylactic/ anaphylactoid systemic reactions including hypotension).
Cardiovascular system
Isolated cases: Uncommon*: Myocardial infraction, cardiac failure, palpitations, chest pain.
*The frequency reflects data from long-term treatment with a high dose (150mg/day).
Description of selected adverse drug reactions
Arteriothrombotic events
Meta-analysis and pharmacoepidemiological data point towards an increased risk of arteriothrombotic events (for example myocardial infarction) associated with the use of diclofenac, particularly at a high dose (150mg daily) and during long-term treatment (see section Precaution/Warning)., hypertension, congestive heart failure.

Effects on ability to drive and use machines.
Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.
Symptoms and Treatment for Overdosage, and Antidote(s):
Management of acute poisoning with NSAIDs essentially consists of supportive and symptomatic measures. There is no typical clinical picture resulting from diclofenac overdose. The therapeutic measures to be taken are: absorption should be prevented as soon as possible after overdosage by means of gastric lavage and treatment with activated charcoal; supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression; specific therapies such as forced diuresis, dialysis or haemoperfusion are unlikely to be helpful in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

Storage Condition(s):
Keep in a tight container. Store at temperature below 25°C. Protect from light and moisture.

Shelf-Life:
3 years from the date of manufacture.

Product Description:
A round reddish – brown color film coated tablet, in the shape of "◯ ◯".

Packing(s):
Blister packing of 10's x 2

Y. S. P.®
Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (192593 U)
Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor Darul Ehsan, Malaysia.
Ordering Line: 1 800 88 3027
Product Info: 1 800 88 3679

xxxxxx printing code xxxxxx
Date of revision: 12 Oct 2018

L
260mm

W
110mm

260 x 110mm