OFLAM®

(Diclofenac Potassium)

PRESENTATION

Oflam 50 mg Powder : Diclofenac Potassium 50 mg/Sachet.

INDICATIONS

Oflam is indicated for short-term treatment (maximum 2 weeks) of the following acute conditions:

- Postoperative inflammation and pain, e.g. following acute orthopaedic surgery.
- Painful post-traumatic pain, inflammatory states, e.g. due to sprains.
- Painful and/or inflammatory gynaecological conditions, e.g. primary dysmenorrhoea. or adnexitis.
- Migraine attacks.
- As an adjunct in severe painful inflammatory infections of the ear, nose, or throat. e.g. pharyngotonsillitis, otitis.
- Painful syndromes of the vertebral column.
- Non-articular rheumatism.
- Fever alone is not an indication.

DOSAGE AND ADMINISTRATION

In post-traumatic pains, postoperative cases and in the treatment of severe acute osteoaticular rheumatic pain, the attack dose in adults is in the range of 100-150mg per day divided into 2-3 administrations. In milder cases as well as for adolescents over 14 years of age, a dose ranging between 50 to 100 mg daily will generally sufficient. In primary dysmenorrhoea, the daily dosage, which should be individually adjusted, is generally between 50 to 150 mg and, if necessary, it may be raised over the course of other menstrual cycles until it reaches a maximum of 200 mg daily. It is advisable to start treatment upon onset of the early symptoms and continue it for a few days depending on symptomatology. Migraine: An initial dose of 50 mg is recommended at the first sign of an impending attack. In cases where pain relief is inadequate approx. 2 hours after ingestion of the first dose a further dose of 50 mg may be taken. If necessary, further 50 mg doses may be taken at intervals of 4-6 hours, although a total dose of 200 mg must not be exceeded within a 24-hours period. Don't exceed the doses recommended: The content of the sachet is to be melted in a half glass of natural water preferably before meals possible opaiescence of the solution does not indicate impairement of the efficacy of the preparation.

CONTRAINDICATIONS

Peptic and/or gastric ulcers, hypersensitivity to the components and/or other substances chemically strictly correlated to them and in particular hypersensitivity to acetyl salicylic acid and in general to the non-steroidal analgesic ,antipyretic, anti-inflammatory drugs, progressive liver diseases and grave renal dysfunction (insufficiency). Oflam is contraindicated in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated or worsened by acetylsalicylic acid or other drugs with prostaglandin-synthetase inhibiting activities. Due to the presence of aspartame, Oflam granulated soluble in mouth is contraindicated in patients with phenylketonuria. Oflam is also contraindicated in children (less than 14 years of age). It is generally contraindicated in pregnancy, particularly during the third trimester (see special warnings) and during lactation.

PRECAUTIONS

The physician must take great care in case of treatment of patients with gastrointestinal symptoms, a history of peptic/gastric ulcer, ulcerative colitis, Crohn's disease or grave impaired hepatic function. In all such cases, treatment shall be kept under close medical supervision. In general, gastrointestinal bleeding or ulceration/perforation have been more serious consequences in the elderly. They can occur at any time durig treatment, without warning symptoms or previous hsitory. In the rare events of gastrointestinal bleeding or ulceration, the drug should be withdrawn. Owing to the importance of prostaglandins in maintaining renal blood flow, particular caution is called in patients with impaired renal or cardiac blood flow, the elderly, patients being treated with diuretics and those with extracellular volume depletion. In such cases, monitoring or renal function during treatment with Oflam is recommended. With drawal of the drug is usually followed by a return to the pretreatment state. In any case, particular caution is indicated in old patients or those with a low bodyweight; in particular it is recommended to administer the lowest effective dosage.

As with other NSAIDs, values of one or more liver enzymes may increase. As a precautionary measure, it is recommended to monitor the hepatic function. The treatment with this drug should be discontinued if tests should show that liver function disturbance persists or worsen or if other grave manifestations or symptoms consistent with liver disease develop or if other grave manifestations occur. Particular care is called in patients with hepatic porphyria, since diclofenac may trigger an attack. Treatment with Oflam in the indications listed above is recommended only for limited periods. If, however, there should be a necessity for using this medicine for a long period, it is advisable to perform blood counts. As with other NSAIDs, the use of Oflam can cause allergic reactions even in the absence of previous exposure. Like other NSAIDs, the use of Oflam may mask the symptoms of infective diseases, thus delaying sound diagnosis and sound treatment.

DRUG INTERACTIONS

When given concemitantly with preparations containing digoxin or lithium, diclofenac may increase their plasma concentrations. Many NSAIDs are capable of inhibiting the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, these should necessarily be checked regularly. Although no data in clinical investigations suggested that diclofenac could have an anticoagulant effect, there have been isolated reports of an increased risk of hemorrhage in patients receiving Oflam and an anticoagulant therapy concomitantly. Close monitoring of such patients is therefore recommended. Like other NSAIDs, Diclofenac at high dosage (200mg) may temporarily inhibit platelet aggregation. 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 both hypoglycaemic and hyperglycaemic effects during treatment with diclofenac, necessaitating changes in the antidiabetic drug dosage. Special caution is required when NSAIDs are administrated less than 24 hours before treatment with methotrexate, as blood concentrations of methorexate can rise, increasing its toxicity. The effects of NSAIDs on renal prostaglandins may increase the nephrotoxicity of cyclosporin.

WARNINGS

Concomitant use of diclofenac with other non-steroidal anti-inflammatory agents can increase incidence of side effects as in the case of use of Oflam concomitantly with cortisones which can accentuate gastrointestinal side effects. As with most other NSAIDs the potential for increase risk of cardiovascular (CV) events should be considered.

USE IN PREGNANCY AND LACTATION

During pregnancy, this drug may be administred only after careful evaluation of risk/benefit analysis and in any case, with the lowest effective dosage. This drug may not be used during the third trimester or pregnancy owig to the possibility of delaying delivery and slackening labour. It is necessary to underline the risk of haemorrhage that can arise from administration of NSAIDs during the terminal phase of pregnancy. After oral dosage of 50mg every 8 hours, diclofenac excreted in breast milk is os small that adverse effects in the neonate are likely. Effects on the capacity to guide motorocares or operate machines; those patients who have experienced vertigo, cars or operating machines requiring attention. It is recommended not to use Oflam concomitantly with other medicines without consulting physician.

SIDE EFFECTS

Gastrointestinal tract: Occassionally: disturbances like nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia (loss of appetite). Rarely: gastrointes tinal bleeding, haematemesis, melena, peptic ulceration with or without bleeding or perforation. bloody diarrhoea in isolated cases: lower gastrointestinal disorders (such as haemorrhagic inflammation and ulcerative colitis) pancreatitis (the cause/effect relationship is not known well), aphthous stomatitis, glossitis, oesophageal lesions, diaphragm disease. Special attention must be paid to possible appearance of superficial lesions or ulcers in the stomach. Sometimes these lesions happen without previous warning symptoms other than those noted above, namely loss of occult blood or emission of black faecas.

CENTRAL AND PERIPHERAL NERVOUS SYSTEM

Occasionally: headache, vertigo. Rarely: drowsiness. in isolated cases: sensory disturbances, Paraesthesias, memory disturbances, disorientation, disturbances of vision, impaired hearing, tinnitus, insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reactions, taste alteractions.

SKIN: Occasionally: skin eruption. Rarely: urticaria. In isolated cases: bullous eruptions, eczema, erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome, erythroderma, hair loss, photosensitivity reactions, purpura, allergic purpura.

UROGENITAL SYSTEM: In isolated cases: acute renal failure, haematuria, proteinuria, interstitial nephritis, nephrotic syndrome, papillary necrosis. In most cases, renal affections are due to chronic use of Oflam. Particular attention must be paid to the appearance of renal complications, particularly in elderly patients.

LIVER: Occasionally: increase in serum aminotransferase enzymes levels. Rarely: Hepatitis with or without jaundice. In isolated cases: fulminate hepatitis.

BLOOD: In isolated cases: thrombocytopenia, leucopenia, anemia, agranulocytosis.

HYPERSENSITIVITY: Rarely: asthma, systemic anaphylactic/anaphylactoid reactions.

OTHERS: Rarely: oedema. In isolated cases: impotence (connection with diclofenac is doubtful), palpitations, chest pain, hypertension. In case of appearance of undersired effects, even if different from those described in this illustrative leaflet, the patient is advised to report them to his doctor.

OVERDOSAGE

The procedure of management to be adopted in case of acute poisoning with NSAIDs is essentially a procedure of supportive or symptomatic measures. No typical clinical picture associated with overdosage of diclofenac exists. In case of overdosage, it is necessary to prevent absorption as soon as possible by means of gastric lavage and activated charcoal. Adequate symptomatic or supportive measures to combat hypotension, renal damage, convulsions, gastriotestinal lesions and respiratory depression must be employed and taken.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children

Manufactured by:
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