Olfen®-100 SR *Depocaps®*

Antirheumatic agent with anti-inflammatory and antipyretic properties

Composition

Each Olfen-100 SR Depocaps® contains:
Diclofenac sodium 100mg
(as sustained-release pellets)

Properties and actions

Olfen contains the sodium salt of diclofenac, a non-steroidal active substance having pronounced anti-rheumatic, anti-inflammatory, analgesic and anti-pyretic properties.
Inhibition of prostaglandin biosynthesis, which has been demonstrated experimentally, is thought to be important for the mechanism of action. Prostaglandins play an essential role in the development of inflammation, pain and fever. The anti-inflammatory and analgesic properties become clinically evident in the case of rheumatic disorders in that the symptoms, such as rest pain, pain on motion, morning stiffness, swelling of the joints, are significantly improved and functional ability increases. In post- traumatic/post-operative inflammations, diclofenac causes a rapid reduction in spontaneous pain and pain on motion and reduces inflammatory swelling and wound oedema.
For moderate and severe states of pain of a non-rheumatic type, as well, the pronounced analgesic effect was demonstrated in clinical trials. In cases of primary dysmenorrhoea, diclofenac can alleviate pain and reduce the extent of bleeding.

Pharmacokinetics

After oral administration, diclofenac is rapidly and completely absorbed. The plasma concentrations are linearly dose-dependent. Plasma protein binding amounts to more than 97%. Peak plasma concentrations are attained 1-4 hours after taking the enteric-coated Lactab tablets. The therapeutic plasma concentration range is 0.7-2mcg/ml.
Diclofenac undergoes first pass metabolism. Elimination is about 2/3 renal and about 1/3 via the bile in metabolized form (about 90% of the administered dose in 96 hours). The greater amounts of the hydroxyl-glucuronide and sulphated metabolites are biologically inactive. Only about 1% is renally excreted in unchanged form.
The plasma half-life is about 2 hours and is not affected by kidney failure.
Peak plasma concentration after administration of Depocaps is in the same range as after a single dose of 25 mg, but lasts longer in proportion to the higher content of active agent in Depocaps. The pharmacokinetics do not vary with the age of patients.
On administration of two 75mg Olfen SR per day, the mean maximum plasma concentrations reached in steady state are approximately 489 ± 237ng/ml.

Indications

- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis;
- Painful syndromes of the vertebral column;
- Acute gout attack;
- Non-rheumatoid inflammatory pain.

Normal doses

100mg SR Depocaps
Adults: One Depocaps daily, taken whole with liquid. The Depocaps are to be taken unchewed with a glass of water before meals.
As a general recommendation, the dose should be individually adjusted. Adverse effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see section WARNINGS AND PRECAUTIONS).
Established cardiovascular disease or significant cardiovascular risk factors
Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus and smoking) should be treated with diclofenac only after careful consideration and only at dose ≤100mg daily if treated for more than 4 weeks (see section WARNINGS AND PRECAUTIONS)

Contraindications

Olfen must not be used in the presence of peptic ulcers, hypersensitivity (e.g. with asthma attacks, skin reactions, acute rhinitis) to acetylsalicylic acid or other nonsteroid anti-inflammatory agents, severe disorders of liver function or haemopoiesis disorders.
Severe cardiac failure (see section WARNINGS AND PRECAUTIONS)

Adverse effects

Gastrointestinal upsets, upper abdominal pain, eructation, nausea, diarrhoea, light-headedness or headaches at the start of treatment. These adverse effects are generally mild and usually regress after a few days.
Hypersensitivity reactions such as skin rash and pruritus, asthma attacks and a tendency to oedema may arise.
Gastrointestinal bleeding and ulceration, hearing disturbances, photosensitivity, haematuria, blood disorders and renal failure were reported in isolated cases.
Adverse effects: Dermatological: Occasional – rashes or skin eruptions, cases of hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.
Cardiac disorders
Uncommon*: Myocardial infarction, cardiac failure, palpitations, chest pain
*The frequency reflects data from long-term treatment with a high dose (150 mg/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 (150 mg daily) and during long-term treatment (see section WARNINGS AND PRECAUTIONS).

Warnings and Precautions

Patients with evidence of peptic ulcers in their history, those with unexplained gastrointestinal disorders, those with liver or kidney damage and those with high blood pressure as well as elderly patients require attentive medical supervision.
Blood counts are recommended during prolonged treatment with Olfen, as is the case with other NSAIDs there is a risk of coagulation defects.
Note: NSAIDs may mask the signs and symptoms of infection and should be used cautiously in patients with existing infections.
Precaution:
Severe cutaneous reactions, including Stevens-Johnson Syndrome and toxic epidermal necrolysis (Lyell's syndrome), have been reported with diclofenac sodium. Patients treated with diclofenac sodium should be closely monitored for signs of hypersensitivity reactions. Discontinue diclofenac sodium immediately if rash occurs.

Warnings

Risk of GI ulceration, bleeding and perforation with NSAID therapy.
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 GI problems (e.g. 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 (e.g. 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 of fatal GI events.

Warnings:
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 infarction and stroke).
Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established

cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus 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.

Heart Failure - fluid retention and oedema have been observed in some patients taking NSAIDs, there caution is advised in patients with fluid retention or 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 - NSAIDs may very rarely cause serious cutaneous adverse events such as exfoliative dermatitis, toxic epidermal necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), which can be fatal and occur without warning. These serious adverse events are idiosyncratic and are independent of dose or duration of use. Patients should be advised of the signs and symptoms of serious skin reactions and to consult their doctor at the first appearance of a skin rash or any other sign of hypersensitivity.

Interactions

The simultaneous use of Olfen with lithium products or digoxin products increases the lithium or digoxin levels in the blood.

In the case of simultaneous treatment with potassium-sparing diuretics, particular monitoring of serum potassium levels is required since Olfen, like other (nonsteroid) antirheumatics, can lead to an increase in potassium values (hyperpotassaemia).

The simultaneous administration of corticoids or other anti-inflammatory agents increases the risk of gastrointestinal bleeding.

An inhibition of the action of diuretics such as furosemide or etacrynic acid is possible, as is a weakening of the action of antihypertensive drugs.

The simultaneous administration of acetylsalicylic acid leads to a decrease in the blood concentration of the active agent diclofenac.

Pregnancy/breastfeeding

In general, Olfen should be used with caution in first and second trimester of pregnancy. Animal studies have shown no risk for the fetus, but no controlled studies in pregnant women are available. Olfen should not be giving during the third trimester owing to the risk of premature closure of the ductus arteriosus and suppression of uterine contractility. Following oral doses of 50mg given at 8-hour intervals, the active substance of diclofenac sodium passes into the breast milk, but in such small quantities that no unwanted effects on infant are likely to occur.

Overdosage

Management of acute poisoning with NSAIDs consists essentially in supportive and symptomatic measures. Overdosage of diclofenac produces no typical clinical pictures. The following therapeutic measures should be taken in cases of overdosage. Absorption should be prevented as soon as possible after the overdosage by performing gastric lavage and giving activated charcoal. Supportive and symptomatic treatment is indicated for complications such as hypotension, renal failure, convulsions, gastrointestinal irritation, and respiratory depression. It is unlikely that specific measures such as forced diuresis, dialysis, or haemoperfusion are helpful in eliminating NSAIDs owing to their high protein-binding rate and extensive metabolism.

Other information

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

Storage: Do not store above 30°C.

Expiry: The preparation should not be used after the date marked "EXP" on the pack.

Presentation

Olfen-100 SR Depocap (Hard gelatin, pink coloured cap size 1, colourless, transparent body imprinted "Olfen 100 mepha", white pellets content)

Packing of 100 Depocaps

The information contained here is limited. Further information can be obtained from your doctor or pharmacist

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for Acino, Liesberg, Basel-Land, Switzerland

acino Switzerland