Painreliefer capsule

analgesic & anti-inflammatory

Warning:
Cardiovascular risk:
NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors
for cardiovascular disease may be at greater risk. NSAIDs is contraindicated for the treatment of peri-operative pain in the setting of coronary artery by pass graft (CABG) Surgery
Gastrointestinal risk:
NSAIDs cause an increased risk of serious gastrointestinal adverse events including inflammation, bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

COMPOSITION:

Each capsule of Painreliefer contains:

Diclofenac sodium	50 mg
(Vitamin B 1)	50 mg
(Vitamin B6)	50 mg
(Vitamin B 12)	0.25 mg

INDICATIONS:

Neuritis and neuralgia, such as cervical syndrome, lumbago, ischialgia.
Painful degenerative forms of rheumatism of an inflammatory nature or activated by an inflammation, e.g.
- arthrosis
- spondylarthrosis
- chronic polyarthritis
- spondylitis ankylosans (Bechterew's disease)
- acute attacks of gout non-articular rheumatism non-rheumatic inflammatory pain.

CONTRA-INDICATIONS:

Painreliefer should not be used in gastric or duodenal ulcer, porphyria, in patients with a hypersensitivity to any of the active constituents, in disturbances of liver function and of haematopoiesis. In patients reacting to acetylsalicylic acid or other non-steroidal anti- inflammatory agents with hypersensitivity in the form of, e.g. asthma attacks, skin reactions, or acute rhinitis Painreliefer may only be used with certain precautions (emergency service). Patient suffering from asthma, hay fever, swelling of the nasal mucosa (nasal polyps) or chronic infections of the respiratory tract are especially threatened by hypersensitivity reactions (analgesic into lerance/analgesic asthma).
Careful medical monitoring is required in patients with a history of gastric or intestinal ulcer, with gastrointestinal disorders, as well as in patients with liver or kidney damage, hypertension and/or heart failure, and in elderly patients.
Painreliefer must not be administered in the last trimester of pregnancy, during the lactation period, or to infants.
Although so far there have been no indications of any teratogenic effects (malformations), Painreliefer should not be taken during the first and second trimester of pregnancy either.
Painreliefer is not recommended for children under 6 years of age.
Painreliefer is not indicated in vitamin B deficiency.

ADVERSE REACTIONS:

GASTROINTESTINAL TRACT:

Gastrointestinal disorders, such as nausea, diarrhea, and slight gastrointestinal bleeding which in exceptional cases may cause anaemia be frequent.
Occasionally, gastric and intestinal ulcers may develop under certain circumstances accompained by bleeding and perforation.
Single cases of abdominal complaints have been reported (e.g. hemorrhagic inflammation of the large intestine).
If severe pain, in particular in the epigastric region, and/or black discolouration of the faces should occur, the doctor should be informed immediately.

CENTRAL NERVOUS SYSTEM:

Central nervous disorders, such as headaches, excitation, irritability, insomnia, tiredness and dizziness may occasionally occur. There have been isolated cases of disturbed sensibility or vision (blurred or double vision), tinnitus and spasm.

SKIN:

Hypersensitivity reactions, such as rashes and pruritus, have occasionally been observed, so have in rare cases, urticaria and loss of hair, Hypersensitivity to light, rashes with blister formation, eczema, erythema and severe forms of skin reactions (stevens-johnson syndrome, Lyell's syndrome) may occur in isolated cases.

LIVER:

With long-term therapy, liver is to be expected only in rare cases.

KIDNEY:

Kidney damage may develop in rare cases.

BLOOD:

Haematopoietic disorders (anaemia, leukopenia, agranulocytosis, thrombocytopenia) may occur in rare cases. In long-term therapy, blood count, liver values and renal function should be monitored regularly.

OTHER ORGAN SYSTEMS:

In particular in hypertensive patients, there may in rare cases be a tendency towards accumulation of water in the body (e.g. peripheral oedema). Severe hypersensitivity reactions are possible. In isolated cases outbreaks of sweat, tachycardia, skin reactions with pruritus and urticaria have been described after administration of vitamin B 1.

NOTE:

INTERACTIONS:

Simultaneous use of Painreliefer and digoxin or lithium preparations may increase the serum concentrations of digoxin or lithium.
Painreliefer may diminish the effect of dehydrant and blood-pressure- lowering agents (diuretics and antihypertensives). Simultaneous administration on Painreliefer and potassium sparing diuretics may lead to an increase in the potassium values (hyperkalaemia).
Simultaneous administration of glucocorticoids or other anti- inflammatory agents increases the risk of gastrointestinal haemorrhage.
The administration of Painreliefer within 24 hours before or after a dose of metnotrexate may increase the concentration of methotrexate and its toxic effects.
Simultaneous ingestion of acetylsalicylic acid causes a reduction of the diclofenac concentration in the blood. So far, clinical trials have not shown any interactions between diclofenanc and anti-coagulants.
Nevertheless, in cases of simultaneous administration it is recommended to monitor the coagulation status as a precautionary measure.
Patients treated with L-dopa should not be given any preparations containing high vitamin-B6 doses, i.e. no Painreliefer capsules either, since vitamin B6 diminishes the effect of L-dopa.

DOSAGE INSTRUCTIONS:

Depending on the severity of the disease, the recommended dose lies between 2xl and 3x2 capsules of Painreliefer, equivalent to 50 and 150 mg of diclofenac, per day. Unless otherwise prescribed, adults initially take 3x2 Painreliefer capsules daily.
3xl Painreliefer capsule daily is generally sufficient as a maintenance dose. Children under 6 years of age are definitely to be excluded from therapy. The usual daily dose for children over 6 years of age is 2 mg of diclofenac per kg body weight; distributed over several doses.

MODE AND DURATION OF APPLICATION:

The capsules should be swallowed whole, best with some water, during or after meals. The therapy period is fixed by the doctor.

NOTES:

The drug should not be used after the expiry date.
Store at temperature not exceeding 30°C in a dry place, protected from moisture.

PRESENTATION AND PACKAGE SIZES PAINRELIEFER:

Package of 30 capsules

Produced by
D B K for pharmaceutical industries
(D B K Pharma)

Ver(02)