1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information for the patient

CLOFAINS 500 mg/50 mg tablets
Paracetamol /diclofenac sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this package leaflet:

1. WHAT CLOFAINS IS AND WHAT IT IS USED FOR
Clofains contains the non-steroidal anti-inflammatory drug (NSAID) diclofenac and paracetamol. This medicine is used in adults to reduce inflammation and pain in:
- sprains, strains and other injuries
- pain and inflammation following surgery
- musculo-skeletal inflammatory conditions such as backache, rheumatoid arthritis, osteoarthritis, ankylosing spondilytis, gout.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CLOFAINS
Do not take CLOFAINS in the following cases:
- history of gastrointestinal bleeding or perforation related to the use of NSAIDs,
- history of allergy to paracetamol or to diclofenac or to any component of the tablet (see section 6),
- history of allergy, asthma or acute rhinitis triggered by taking a related medicine, particularly other non-steroidal anti-inflammatory drugs (NSAIDs), acetylsalicylic acid,
- stomach or duodenal ulcer,
- liver disease, moderate or severe renal insufficiency, heart failure, ,
- pregnancy, particularly in the last trimester of pregnancy,
- if you have established heart disease and /or cerebrovascular disease e.g. if you have had a heart attack, stroke, mini-stroke (TIA) or blockages to blood vessels to the heart or brain or an operation to clear or bypass blockages,
- if you have or have had problems with your blood circulation (peripheral arterial disease).

Make sure your doctor knows, before you are given Clofains
- If you smoke
- If you have diabetes
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides

Side effects may be minimised by using the lowest effective dose for the shortest duration necessary.

Warnings and precautions:

- Medicines containing diclofenac may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose nor duration of treatment.
- If you have had heart problems, have had a previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.
- Gastro-intestinal haemorrhage or ulcers and perforations can occur at any time during treatment, with or without any signal or antecedent. These reactions are usually more severe in elderly patients. In such rare cases, the treatment should be discontinued.
- As with similar medicines, diclofenac can lead to allergic reactions even without previous administration. NSAIDs can mask some symptoms of infectious diseases with a risk of postponing the diagnosis and adequate treatment.
- A medical monitoring is strongly recommended in patients with symptoms of gastro-intestinal disorders or with a history of gastro-intestinal ulcers, or in patients with ulcerative colitis, Crohn disease, or with liver impairment.
- During treatment, elevated hepatic enzyme levels can be detected. Liver inflammation can occur without any alerting signs.
- Caution should be exercised when administered to patients suffering from liver porphyria as diclofenac can trigger a porphyria crisis.
- Cautious administration is especially recommended in patients with heart or renal diseases, in patients treated with diuretics or in patients with low extracellular volume (for instance after an important surgery).
- Complete blood controls are required in long treatment period. Patients with abnormal coagulation should be closely monitored.
- In elderly patients, gastro-intestinal or renal adverse reactions should be closely monitored. The minimal dose should be administered, particularly in case of weakness or low body weight.
- Some abnormal laboratory tests results can be observed.
- If you are taking other medicines, please read section «Taking other medicines".
- If you suffer from liver failure (including Gilbert's syndrome), acute hepatitis, kidney failure, chronic alcoholism, dehydration, chronic malnutrition or if you weigh less than 50 kg.
- If you are treated with drugs influencing the liver function.

This medicine contains a non-steroidal anti-inflammatory drug: **diclofenac**.
You must not take this medicine at the same time as other medicines containing non-steroidal anti-inflammatory drugs (NSAIDs) and/or acetylsalicylic acid.
Read carefully the package leaflets of the other medicines that you take to make sure they do not contain NSAIDs and/or acetylsalicylic acid.

IF YOU HAVE ANY DOUBT DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Other medicines and CLOFAINS
In order to prevent any drug interactions, particularly with oral anticoagulants, other NSAIDs including acetylsalicylic acid and its derivatives, diuretics, anti-hypertensive drugs, methotrexate, cortisone, cyclosporine, certain drugs targeting the reduction of blood cholesterol (colestyramine),

metoclopramide, domperidon, chloramphenicol, enzyme-inducing agents (barbiturates, primidone, isoniazid, rifampicin, alcohol), probenecid, zidovudine and lamotrigine.
You must systematically report any other treatment you are currently taking or have taken recently to your doctor or pharmacist.

Pregnancy and Breastfeeding
In case of use during pregnancy, strictly follow your doctor's advice. In any case, administration of Clofains should be avoided during the last 3 months of pregnancy because delivery can be postponed and labour reduced. Risk of haemorrhage also exists in case of use of drugs containing diclofenac at the end of pregnancy.
Clofains can be used in breastfeeding mothers.
IN GENERAL, ALWAYS ASK YOUR DOCTOR OR PHARMACIST BEFORE TAKING ANY MEDICINE DURING PREGNANCY OR WHILE BREASTFEEDING.

Driving and using machines
In case of dizziness or of other adverse reaction affecting the nervous system, driving vehicles and use of machines is not recommended.

3. HOW TO TAKE CLOFAINS
Clofains should be taken orally and is for adults only.
Adults: 1 tablet 2 to 3 times daily. If symptoms are more severe during the night or in the morning, the tablet can be taken in the evening. Take the tablets with a glass of water, preferably during or just after the meals particularly if you have a long duration treatment or a history of gastro-intestinal ulcers, this will reduce the risk of ulcers.
Children: tablet and strength are not recommended for children.
Elderly: dose should be reduced and monitoring of biological parameters is recommended.

If you have taken more CLOFAINS tablets than you should:
In the event of overdose or accidental intoxication, inform your doctor immediately.
Massive absorption requires an urgent hospitalisation.
Following symptoms can occur: headache, agitation, muscular contractions, irritability, ataxia, vertigo, seizures mainly in children, gastric pain, nausea, vomiting, loss of appetite, excessive sweating, hematemesis, diarrhoea, gastro-intestinal ulcers, hepatic function disorders and oliguria.
Signs of hepatic damage can be observed after several hours or even days after intake. It is therefore important to determine the number of tablets taken in order to take appropriate measures.
Treatment:
Vomiting and gastric lavage should be performed as early as possible. Administration of activated charcoal should be considered. Administration of N-acetylcysteine should be initiated by a doctor as principal counter measure against paracetamol overdose.

4. POSSIBLE SIDE EFFECTS
Like all medicines, CLOFAINS tablets may cause side effects, although not everybody gets them:

Medicines containing diclofenac may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

Gastro-intestinal:
Occasionally: gastric pain, gastro-intestinal disorders (nausea, vomiting, diarrhoea, abdominal cramp, digestive disorders, flatulence, loss of appetite).
Rarely: gastro-intestinal haemorrhage (blood vomiting, black stools containing digested blood, blood in faeces), gastric ulcer with or without haemorrhage or perforation.

Isolated cases: aphtous stomatitis, glossitis, oesophageal lesions, intestinal stenosis, low abdominal disorders such as haemorrhagic or ulcerative colitis, pancreatitis, constipation.

Central nervous system:

Occasionally: headache, dizziness, vertigo

Rarely: somnolence, dizziness, uneasiness.

Isolated cases: sensory function disorders including paresthesia, memory loss, disorientation disorders, insomnia, irritability, seizures, depression, anxiety, nightmares, tremor, psychotic reactions, meningitis.

Special senses:

Isolated cases: vision troubles (blurred or double vision), hearing disorders, tinnitus, taste perversion.

Skin:

Occasionally: eruption, irritation, rash.

Rarely: urticaria, anaphylactic reaction, pruritus, sweating, angioedeme, hypes.

Very rarely: bullous eruption, eczema, erythema multiforme, Stevens-Johnson syndrome, Lyell syndrome (acute toxic epidermolysis), hair loss, photosensitivity reaction, purpura, skin reaction requiring stopping the treatment.

Any allergic reaction requires the discontinuation of the treatment.

Kidneys and urinary tract:

Rarely: oedema

Very rarely: renal impairment, blood in urines, proteinuria, interstitial nephritis, nephrotic syndrome, renal necrosis, cloudy urines. Most of the time, chronic use is the cause of nephropathy. Renal disorders should be closely monitored in elderly patients.

Liver:

Occasionally: elevated hepatic enzyme levels.

Rarely: hepatitis with or without jaundice, troubles liver function, liver failure, liver necrosis, icterus.

Very rarely: fulminant hepatitis, hepatotoxicity.

Blood:

Very rarely: blood formula alteration.

Hypersensitivity reactions:

Rarely: hypersensitivity reactions such as asthma, generalised allergic reactions including hypotension.

Very rarely: vasculitis, lung inflammation.

Cardiovascular system:

Very rarely: palpitation, chest pain, hypertension, cardiac insufficiency.

Chronic use of Clofains can lead to hypertension.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

5. HOW TO STORE CLOFAINS

Keep out of the sight and reach of children.

Do not use CLOFAINS after the expiry date stated on the outer pack.

Store at a temperature not exceeding 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist what you should do with unused medicines. These measures are to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What does CLOFAINS contain?

The active substances are paracetamol (500 mg) and diclofenac sodium (50 mg)

The other ingredients are: sodium starch glycolate, maize starch, microcrystalline cellulose, dibasic calcium phosphate, sodium benzoate (E211), povidone K-30, tartrazine (E102), magnesium stearate, talc.

What CLOFAINS looks like and contents of the pack?

This medicine is presented in the form of yellow, elongated, scored tablets. Boxes of 10 tablets in blister pack.

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