



Package leaflet: Information for the patient

CATAFLAM® 25 mg sugar-coated tablets.

CATAFLAM® 50 mg sugar-coated tablets.

diclofenac potassium

Read all of this leaflet carefully before you start using 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 affects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Cataflam Tablets are and what they are used for
- 2 What you need to know before you take Cataflam Tablets
- 3 How to take Cataflam Tablets
- 4 Possible side effects
- 5 How to store Cataflam Tablets
- 6 Contents of the pack and other information

1 What Cataflam Tablets are and what they are used for

Diclofenac potassium, the active ingredient in Cataflam Tablets, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation by blocking synthesis of the molecules (prostaglandins).

Cataflam Tablets relieve pain, reduce swelling, reduce fever and ease inflammation in:

- Painful syndromes of the vertebral column for example low back pain
- Migraine
- Conditions affecting the joints and muscles such as sprains and strains, soft tissue sports injuries, frozen shoulder, dislocations, and fractures, and other forms of soft-tissue rheumatism.
- Conditions affecting the tendons for example tendonitis, tenosynovitis bursitis.
- Painful inflammatory conditions in gynaecology, including painful menstrual periods.
- Infections of the ear, nose, or throat.

They are also used to treat pain and inflammation associated with orthopaedic, dental and other minor surgery.

2 What you need to know before you take Cataflam Tablets

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using Cataflam, as Cataflam can sometimes worsen wound healing in your gut after surgery.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

Do not take Cataflam Tablets:

- If you think you may be allergic to diclofenac potassium aspirin, ibuprofen or any NSAID, or to any of the other ingredients of Cataflam Tablets. (These are listed at the end of the leaflet. Signs of a hypersensitivity reaction may include asthma, runny nose, skin rash, swelling of the face and mouth, lips, tongue, throat and/or extremities (signs of angioedema), breathing problems, chest pain or any other allergic type reaction. If you think you may be allergic, ask your doctor for advice. If you have now, or have ever had, stomach (gastric) or duodenal (peptic) ulcer, perforation, or bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces)
- If you have had stomach or bowel problems after you have taken other NSAIDs
- If you have kidney or liver failure.
- If you are more than six months pregnant.
- If you think you may be allergic, ask your doctor for advice.
- If you have or have had problems with your blood circulation (peripheral arterial disease)
- If you have established heart disease and/or cerebrovascular disease e.g. if 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.

It is generally important to take the lowest dose of Cataflam that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Cataflam Tablets

- If you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn’s disease
- If you have kidney or liver problems, or are you elderly
- If you have a condition called porphyria
- If you suffer from any blood or bleeding disorder, your doctor may ask you to go for regular check-ups while you are taking these tablets.
- If you have ever had asthma or hay fever (seasonal allergic rhinitis).
- If you are breast-feeding
- If you have intolerance to some sugars such as sucrose (Cataflam Tablets contain sucrose).

- If you could be suffering from dehydration (e.g. by sickness, diarrhea, before or after major surgery)
- If you have swollen feet
- If you smoke, have diabetes, have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides you must not increase the dose above 100mg per day if treated for more than 4 weeks

If any of the above apply to you, **tell your doctor before you take Cataflam.**

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

If, at any time while taking Cataflam you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness or slurring of speech, contact your doctor immediately.

Use of Cataflam tablets is recommended only for short term treatment.

Monitoring during your treatment with Cataflam

If you have established heart disease or significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Cataflam, especially in case you are treated for more than 4 weeks. If you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor either your liver function (level of transaminases) or your kidney function (level of creatinine) or your blood count (level of white and red blood cells and platelets). Your doctor will take these blood tests into consideration to decide if Cataflam needs to be discontinued or if the dose needs to be changed.

Other medicines and Cataflam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- Medicines (such as metformin) to treat diabetes
- Anticoagulants (blood thinning tablets like warfarin).
- Diuretics (water tablets).
- Lithium (used to treat some mental problems).
- Methotrexate (for some inflammatory diseases and some cancers).
- Ciclosporin, Tacrolimus (primarily used to treat some inflammatory diseases and after transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibiotics (for infections)
- Any other NSAID, for example aspirin or ibuprofen.
- Cardiac glycosides (for example digoxin) used to treat heart problems
- Medicines known as SSRIs used to treat depression
- Oral steroids (an anti-inflammatory drug)

- Medicines used to treat heart conditions or high blood pressure, for example beta-blockers or ACE inhibitors
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures)
- Colestipol and cholestyramine (medicines used to lower cholesterol levels).
 - Rifampicin (an antibiotic medicine used to treat bacterial infections).

Always tell your doctor or a pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as medicines on prescription from your doctor.

Pregnancy, breast-feeding and fertility

Are you are pregnant or planning to become pregnant? Although not common, abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. You should not take Cataflam Tablets during the last 3 months of pregnancy, as it may affect the baby's circulation.

Are you trying for a baby? Taking Cataflam Tablets may make it more difficult to conceive. You should talk to your doctor if you are planning to become pregnant, or if you have problems getting pregnant. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Cataflam during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. From 20 weeks of pregnancy, Cataflam can cause kidney problems in your unborn baby, if taken for more than a few days, which can lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios). If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Are you breast-feeding? Since the drug can pass into the breast milk in small amounts, it is advisable not to take medication during breast feeding.

Ask your doctor or pharmacist for advice before taking any medicines.

Your doctor will discuss with you the potential risk of taking Cataflam during pregnancy or breast-feeding.

Other special warnings

- You should take the lowest dose of Cataflam for the shortest possible time, particularly if you are underweight or elderly.
- There is an increased risk of heart attack or stroke when you are taking any medicine like Cataflam. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for.
- Whilst you are taking these medicines your doctor may want to give you a check-up from time to time. Blood tests are recommended when taking treatment for a long time.
- If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms since you may need to stop treatment.
- Because it is an anti-inflammatory medicine, Cataflam may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Cataflam.

- Cataflam 25 mg and 50 mg sugar-coated tablets contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Cataflam Tablets

The doctor will tell you how many Cataflam Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist. Keep taking your tablets for as long as you have been told, unless you have any problems. In that case, check with your doctor.

It is recommended to take Cataflam sugar-coated tablets before meals or an empty stomach.

Cataflam Tablets are specially formulated to act quickly. Swallow the tablets whole with a glass of water preferably before meals or on an empty stomach. Do not crush or chew them.

The doctor may also prescribe another drug to protect the stomach to be taken at the same time, particularly if you have had stomach problems before, or if you are elderly, or taking certain other drugs as well.

The recommended doses are:

Adults

The usual daily dose at the start of the treatment is generally 100 to 150 mg. In milder cases, 75 to 100 mg daily is usually sufficient. The total daily dose should usually be taken in 2 or 3 separate doses, as applicable. Do not exceed 150 mg per day.

In painful menstrual periods, start treatment with a single dose of 50mg as soon as you feel the first symptoms. Continue with 50 mg up to three times a day for a few days, as needed. If 150 mg a day does not provide sufficient pain relief over 2 to 3 menstrual periods, your doctor may recommend you to start with a dose. Do not exceed 200 mg per day.

In migraine, start treatment with a single dose of 50 mg, as soon as you feel 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 doses of 50 mg may be taken at intervals of 4 to 6 hours. Do not exceed 200 mg per day.

Elderly

Your doctor may advise you to take a dose that is lower than the usual adult dose if you are elderly. Your doctor may also want to check closely that the Cataflam Tablets are not affecting your stomach.

Use in children and adolescents over 14 years

For adolescents aged 14 years or over, a daily dose of 75 to 100 mg is usually sufficient. The total daily dose should usually be taken in 2 to 3 separate doses. Do not exceed 150 mg per day.

In migraine, Cataflam sugar-coated tablets must not be used by children and adolescents (below 18 years of age).

Cataflam Tablets are not recommended for children and adolescents under 14 years of age. Cataflam must not be given to children aged less than 1 year old. They are not recommended

for the treatment of migraine in children of any age.

How long to take Cataflam

If you take Cataflam sugar-coated tablets for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects

If you forget to take Cataflam

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, just take the next dose and forget about the one you missed. Do not double up on the next dose to make up for the one you missed. Do not take more than 150mg (three 50mg tablets or six 25mg tablets) in 24 hours.

If you take more Cataflam than you should

If you or anyone else accidentally takes too many tablets, tell your doctor or your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Cataflam Tablets and tell your doctor straight away if you notice:

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick) or vomiting (being sick)
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry faeces
- Allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering
- Wheezing or shortness of breath (bronchospasm)
- Swollen face, lips, hands or fingers
- Yellowing of your skin or the whites of your eyes
- Persistent sore throat or high temperature
- An unexpected change in the amount of urine produced and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Cataflam and followed by rectal bleeding or bloody diarrhea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data).
- **Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome**

If you notice that you are bruising more easily than usual or have frequent sore throats or infections, tell your doctor.

Some side effects could be serious

These uncommon side effects may affect between 1 and 10 in every 1000 patients, especially when taking a high daily dose (150mg) for a long period of time

- Sudden and oppressive chest pain (signs of myocardial infarction or heart attack)

- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure).

These rare or very rare side effects may affect from less than 1 to 10 in every 10,000 patients

- Spontaneous bleeding or bruising (signs of thrombocytopenia).
- High fever, frequent infections, persistent sore throat (signs of agranulocytosis).
- Difficulty of breathing or swallowing, rash, itching, hives, dizziness (signs of hypersensitivity, anaphylactic and anaphylactoid reactions).
- Swelling mainly of the face and throat (signs of angioedema).
- Disturbing thoughts or moods (signs of psychotic disorders).
- Impaired memory (signs of memory impairment).
- Seizures (signs of convulsions).
- Anxiety.
- Stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis).
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, weakness or paralysis of limbs or face (signs of cerebrovascular accident or stroke).
- Difficulty of hearing (signs of impaired hearing).
- Headache, dizziness (signs of high blood pressure, hypertension).
- Rash, purplish-red spots, fever, itching (signs of vasculitis).
- Sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma or Pneumonitis if fever).
- Vomiting of blood (signs of hematemesis) and/or black or bloody stools (signs of gastrointestinal hemorrhage).
- Bloody diarrhea (signs of hemorrhagic diarrhea).
- Black stools (signs of melena).
- Stomach pain, nausea (signs of gastrointestinal ulcer).
- Diarrhea, abdominal pain, fever, nausea, vomiting (signs of colitis, including hemorrhagic colitis, ischaemic colitis and exacerbation of ulcerative colitis or Crohn`s disease).
- Severe upper stomach pain (signs of pancreatitis).
- Yellowing of the skin or eyes (signs of jaundice), nausea, loss of appetite, dark urine (signs of hepatitis/liver failure).
- Flu-like symptoms, feeling tired, muscles aches, increased liver enzymes in blood test results (signs of liver disorders including fulminant hepatitis, hepatic necrosis, hepatic failure).
- Blister (signs of bullous dermatitis).
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with flaking or peeling (signs of erythema multiforme or if fever signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Skin rash with flaking or peeling (signs of exfoliative dermatitis).
- Increased sensitivity of the skin to sun (signs of photosensitivity reaction).
- Purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy).

- Swelling, feeling weak, or abnormal urination (signs of acute renal failure).
- Excess of protein in the urine (signs of proteinuria).
- Swollen face or abdomen, high blood pressure (signs of nephrotic syndrome).
- Higher or lower urine output, drowsiness, confusion, nausea (signs of tubulointerstitial nephritis).
- Severely decreased urine output (signs of renal papillary necrosis).
- Generalized swelling (signs of edema).
- Coincidental occurrence of chest pain and allergic reactions (signs of Kounis syndrome).

If you experience any of these, **tell your doctor straight away.**

Some side effects are common

These side effects may affect between 1 and 10 in every 100 patients

Headache, dizziness, vertigo, nausea, vomiting, diarrhea, indigestion (signs of dyspepsia), abdominal pain, flatulence, loss of appetite (signs of decreased appetite), abnormal liver function test results (e.g. level of transaminases increased), skin rash

Some side effects are rare

These side effects may affect between 1 and 10 in every 10,000 patients

Drowsiness (signs of somnolence), stomach pain (signs of gastritis), liver disorder, itchy rash (signs of urticaria)

Some side effects are very rare

These side effects may affect less than 1 in 10,000 patients

Acute kidney injury, low level of red blood cells (anaemia), low level of white blood cells (leukopenia), disorientation, depression, difficulty sleeping (signs of insomnia), nightmares, irritability, tingling or numbness of the hands or feet (signs of paraesthesia), trembling (signs of tremor), taste disorders (signs of dysgeusia), vision disorders* (signs of visual impairment, vision blurred, diplopia), noises in ears (signs of tinnitus), constipation, mouth sores (signs of stomatitis), swollen, red and sore tongue (signs of glossitis), disorder of the tube that carries food from the throat to the stomach (signs of esophageal disorder), upper abdomen cramp specially after eating (signs of intestinal diaphragm disease), palpitations, chest pain, itchy, red and burning rash (signs of eczema), skin reddening (signs of erythema), hair loss (signs of alopecia), itching (signs of pruritus), blood in urine (signs of haematuria)

***Vision disorders:** If symptoms of vision disorders occur during treatment with Cataflam, contact your doctor as an eye examination may be considered to exclude other causes.

If any of these affects you severely, **tell your doctor.**

Do not be alarmed by this list - most people take Cataflam Tablets without any problems.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly v ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Cataflam Tablets

Store below 30°C. Protect from moisture. Keep the tablets in their original pack.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton.

If your doctor tells you to stop taking the tablets, please take any unused tablets back to your pharmacist to be destroyed. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6 Contents of the pack and other information

What Cataflam contains

- The **active substance** in Cataflam sugar-coated tablets is diclofenac potassium.
- **Core:** Silica aerogel; calcium phosphate; magnesium stearate; pregelatinized maize starch; polyvidone; sodium carboxymethyl starch.
- **Sugar-coat:** Microcrystalline cellulose; polyethylene glycol 8000; red iron oxide (E172) and titanium dioxide (E171) (dispersed Anstead); povidone; talc; sucrose.
- **Polish:** polyethylene glycol 8000; sucrose.
- **Imprint** with printing ink brown for 25 mg and white for 50 mg.

What Cataflam looks like and contents of the pack

Your medicine is called Cataflam and is supplied in the form of a sugar-coated tablets.

Cataflam 25 mg sugar coated tablet is a pale red, round biconvex tablet.

Cataflam 50 mg sugar coated tablet is a reddish-brown, round biconvex tablet.

Each tablet contains 25 mg or 50 mg of the active substance diclofenac potassium.

The tablets come in blister packs containing 20, 28 or 30 tablets. Some of the pack sizes may not be marketed

Marketing Authorisation Holder and Manufacturer

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