

Package leaflet: Information for the patient**Catafast® 50mg Powder for oral solution**

diclofenac potassium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may want 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

What is in this leaflet

1. What Catafast is and what it is used for
2. What you need to know before you take Catafast
3. How to take Catafast
4. Possible side effects
5. How to store Catafast
6. Contents of the pack and other information

1 What Catafast is and what it is used for

Diclofenac potassium, the active ingredient in Catafast, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain and inflammation.

Catafast relieves pain, reduces swelling, by blocking the synthesis of the molecules (prostaglandins) responsible for pain and fever and eases 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.

Monitoring during your treatment with Catafast

If you have established heart disease or significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Catafast, 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 Catafast needs to be discontinued or if the dose needs to be changed.

2 What you need to know before you take Catafast

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 Catafast as Catafast can sometimes worsen wound healing in your gut after surgery.

Do not take Catafast:

- If you think you may be allergic to potassium diclofenac, aspirin, ibuprofen or any other NSAID, or to any of the other ingredients of Catafast. (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 ever had, a 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 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).

If any of these apply to you, **tell your doctor** without taking Catafast.

If you think you may be allergic, ask your doctor for advice.

It is generally important to take the lowest dose of Catafast 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 Catafast

- If you suffer from any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- If you have kidney or liver problems
- If you are over 65 years of age
- If you have a condition called porphyria
- If you suffer from any blood or bleeding disorder. If you do, your doctor may ask you to go for regular check-ups while you are taking these sachets.
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you are you breast-feeding
- If you smoke, have diabetes, angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides. If yes, you must not increase the dose above 100mg per day of you are treated for more than 4 weeks. If you could be suffering from dehydration (e.g. by sickness, diarrhea, before and after major surgery)
- If you have swollen feet
- If you have a phenylketonuria (Catafast contains aspartame, a source of phenylalanine which may be harmful for patients with phenylketonuria)

If any of these above apply to you, **tell your doctor before you take Catafast.**

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

One Catafast sachet contains 50 mg of aspartame. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains less than 1 mmol sodium (23 mg) in each sachet, that is to say essentially "sodium-free".

Other medicines and Catafast

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

- 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 (used to treat some inflammatory diseases 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 treat high 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 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 Catafast during the last 3 months of pregnancy, as it may affect the baby's circulation. 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 Catafast 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, Catafast 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 trying for a baby? Taking Catafast 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.
- 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 medicine.

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

Other special warnings

- You should take the lowest dose of Catafast 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 Catafast. 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.
- If, at any time while taking Catafast 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.
- 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, Catafast 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 Catafast.

3 **How to take Catafast**

The doctor will tell you how much Catafast to take and when to take them. Always follow his/her instructions carefully. If you are not sure, ask your doctor or pharmacist. Keep taking your sachets for as long as you have been told, unless you have any problems. If you have questions about how long to take Catafast, talk to your doctor or your pharmacist.

Dissolve the contents of the sachet by stirring in a glass of non carbonated water. The solution may remain slightly cloudy, but this should not influence the efficacy of the medicine. The solution should be swallowed preferably before a meal.

If you take Catafast 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.

The usual doses are:

Adults

50 mg to 150 mg daily divided into two or three doses. The number of sachets you take will depend on the strength the doctor has given you.

For the relief of migraine in adults:

Take 50 mg at the first signs of an attack. If the migraine has not gone after 2 hours, take another 50 mg. You can take further doses at intervals of 4 to 6 hours if necessary, but you must not take more than 200 mg in a day.

In painful menstrual periods:

Start treatment with a single dose of 50 to 100 mg 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 take up to 200 mg a day during your next menstrual periods. Do not exceed 200 mg per day.

Use in children and adolescents

For adolescents aged 14 years and over, 50 to 100 mg daily are usually sufficient given as 1 to 2 divided doses. Do not exceed 150 mg per day.

Catafast is not recommended for children under 14. It is not recommended for the treatment of migraine in children of any age.

Use in 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 Catafast is not affecting your stomach.

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.

If you take more Catafast than you should

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

If you forget to take Catafast

If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, though, 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 missed. Do not take more than 150mg (three 50mg sachets) in 24 hours.

4 Possible side effects

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

Stop using Catafast and tell your doctor straight away if you notice:

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Catafast and followed by rectal bleeding or bloody diarrhoea, 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

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 (150 mg) 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 are likely to 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 (anemia), 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 paresthesia), 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 hematuria).

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

Do not be alarmed by this list - most people take Catafast 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 via the national reporting system 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 Catafast

Store below 25°C. Protect from moisture and heat.

Keep the sachets 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 sachets, please take any unused sachets 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 Catafast contains

The active substance in Catafast powder for oral solution is diclofenac potassium.

The other ingredients are potassium hydrogen carbonate, mannitol SD 200, mannitol 35, aspartame, saccharin sodium, glyceryl dibehenate, mint flavour, anise flavour.

What Catafast looks like and contents of the pack

Catafast powder for oral solution is diclofenac potassium

Each sachet contains a homogeneous, white to light yellow powder.

The sachets contain 50mg of the active ingredient, diclofenac potassium. The sachets also contain the inactive **ingredients** potassium hydrogen carbonate, mannitol SD 200, mannitol 35, aspartame, saccharin sodium, glyceryl dibehenate, mint flavour, anise flavour.

Marketing Authorisation Holder and Manufacturer

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