



CATAFAST[®] (diclofenac potassium)

50 mg Powder for oral solution

Read all of this leaflet carefully before you start taking this medicine

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or pharmacist.

This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses.

If any of the side effects affects you severely, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1	What CATAFAST [®] is and what it is used for.....	1
2	Before you take Catafast [®]	2
3	How to take Catafast	6
4	Possible side effects.....	7
5	Storing Catafast	10
6	Further information	10

1 What Catafast is and what it is used for

What Catafast is

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

Catafast belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs), which are used to treat pain and inflammation.

What Catafast is used for

Catafast can be used for short-term treatment of the following conditions:

- Sprains, strains, or other injuries.
- Pain and swelling after surgery.
- Painful menstrual periods.
- Migraine attacks.
- Back pain, frozen shoulder, tennis elbow, and other forms of soft-tissue rheumatism.
- Infections of the ear, nose or throat.

In migraine attacks, Catafast is effective in relieving the headache as well as in improving the accompanying symptoms such as nausea and vomiting.

How Catafast works

Catafast relieves the symptoms of inflammation, such as pain and swelling, by blocking the synthesis of the molecules (prostaglandins) responsible for inflammation, pain and fever. It has no effect on the causes of inflammation or fever.

If you have any questions about how Catafast works or why this medicine has been prescribed to you, ask your doctor.

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 Before you take Catafast

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Do not take Catafast

- **If you are allergic** (hypersensitive) to diclofenac or to any of the other ingredients of Catafast listed at the end of this leaflet.
- **If you have** ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid, (diclofenac or ibuprofen). Reactions may include asthma, runny nose, skin rash, face swelling. If you think you may be allergic, ask your doctor for advice.
- **If you have** stomach or intestinal ulcer.

- **If you have** gastrointestinal bleeding or perforation, symptoms of which may include blood in your stools or black stools.
- **If you suffer** from severe kidney or liver disease.
- **If you suffer** from severe heart failure.
- **If you are** in the last three months of pregnancy.

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.

Take special care with Catafast

- If you have established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established ischemic heart disease, or peripheral arterial disease), as treatment with Catafast is generally not recommended.
- If you have established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe Catafast, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.
- 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.
- If you are taking Catafast simultaneously with other anti-inflammatory medicines including acetylsalicylic acid, corticosteroids, “blood thinners” or “SSRIs” (see “Taking other medicines”).
- If you have asthma or hay fever (seasonal allergic rhinitis).
- If you have ever had any gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.
- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn’s disease).
- If you have liver or kidney problems.
- If you could be dehydrated (e.g. by sickness, diarrhea, before or after major surgery).

- If you have swollen feet.
- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.

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

- 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.
- Catafast may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are taking Catafast.
- In very rare cases, Catafast, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash).

If you get any of the above described symptoms, **tell your doctor straight away**.

Taking other medicines

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is particularly important to tell your doctor if you are taking any of the following medicines:

- Lithium or selective serotonin-reuptake inhibitors (SSRIs) (medicines used to treat some type of depression).
- Digoxin (a medicine used for heart problems).
- Diuretics (medicines used to increase the amount of urine).
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure and heart failure).
- Other anti-inflammatory medicines such as acetylsalicylic acid or ibuprofen.
- Corticosteroids (medicines used to provide relief for inflamed areas of the body).
- “Blood thinners” (a medicine used to prevent blood clotting).
- Medicines used to treat diabetes, except insulin.
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis).
- Ciclosporin, Tacrolimus (medicines primarily used in patients who have received organ transplants).

- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibacterials (medicines used against infections).
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).

Taking Catafast with food and drink

It is recommended to take Catafast before meals.

Older people

Elderly patients may be more sensitive to the effects of Catafast than other adults. Therefore, they should follow the doctor's instructions particularly carefully and take the minimum number of sachets that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

Children and adolescents

Catafast must not be given to children and adolescents below 14 years of age. For pediatric use, other forms of diclofenac can be used.

The use of Catafast in migraine has not been established in children and adolescents.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or think that you may be pregnant. You should not take Catafast while pregnant unless absolutely necessary.

As with other anti-inflammatory medicines, you must not take Catafast during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

You should tell your doctor if you are breast-feeding.

You should not breast-feed if you are taking Catafast, as it might be harmful for your infant.

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.

Women of child-bearing potential

Catafast may make it more difficult to become pregnant. You should not take Catafast unless necessary if you are planning to become pregnant or if you have problems to become pregnant.

Driving and using machines

Catafast is unlikely to affect the ability to drive, use machines or carry out other activities that need careful attention.

Important information about some of the ingredients of Catafast

Catafast contains aspartame, a source of phenylalanine which may be harmful for patients with phenylketonuria.

3 How to take Catafast

Follow your doctor's instruction carefully. Do not exceed the recommended dose.

How much Catafast to take

Do not exceed the recommended dose prescribed by your doctor. It is important that you use the lowest dose that controls your pain and that you do not take Catafast for longer than necessary.

Your doctor will tell you exactly how many sachets of Catafast to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Adults

- For adults, the recommended dose to start the treatment is generally 100 to 150 mg daily (to be taken in 2 to 3 doses). In milder cases, 50 to 100 mg daily are usually sufficient (to be taken in 1 to 2 doses). Do not exceed 150 mg per 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.
- In migraine, take Catafast at the first symptoms of a migraine attack. The initial dose is 50 mg. If relief is not obtained within 2 hours, take a further dose of 50 mg. This may be repeated at intervals of 4 to 6 hours, but you should not take more than 200 mg per day.

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.

When to take Catafast

It is recommended to take Catafast before meals.

How to take Catafast

The contents of the sachet should be dissolved 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.

How long to take Catafast

Follow your doctor's instructions exactly.

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.

If you have questions about how long to take Catafast, talk to your doctor or your pharmacist.

If you take more Catafast than you should

If you have accidentally taken more Catafast than prescribed, tell your doctor or pharmacist or go to the hospital emergency unit at once.

You may require medical attention.

If you forget to take Catafast

Do not take a double dose to make up for forgotten individual doses.

4 Possible side effects

As with all medicines, patients taking Catafast can experience side effects, although not everybody gets them.

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 hearing impaired).
- 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 diarrhea hemorrhagic).
- Black stools (signs of melena).
- Stomach pain, nausea (signs of gastrointestinal ulcer).
- Diarrhea, abdominal pain, fever, nausea, vomiting (signs of colitis, including hemorrhagic colitis and exacerbation of ulcerative colitis or Crohn`s disease).
- Severe upon 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 dermatitis bullous).
- 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 dermatitis exfoliative).
- 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).

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

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).

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5 Storing Catafast

- Do not use after the expiry date shown on the box.
- Do not store above 25°C.
- Store in the original package, in order to protect from moisture.
- Keep out of the reach and sight of children.

6 Further information

What Catafast is

- The **active substance** in Catafast powder for oral solution is diclofenac potassium.
- The **other ingredients** are potassium hydrogen carbonate, mannitol, aspartame, saccharin sodium, glyceryl dibehenate, mint flavour, anise flavour.

This information might differ in some countries.

What Catafast is/looks like and contents of the pack

Catafast powder for oral solution is supplied in sachets.

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

Each sachet contains 50 mg of diclofenac potassium.

This information might differ in some countries.

Marketing Authorisation Holder

Saudi Pharmaceutical Distribution Company (Saphad)

Manufacturer

Manufactured by Mipharm S.p.A., Milan, Italy.

If you have any questions about this medicine, please contact your doctor or pharmacist.

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7. To report any side effect(s):

- **Saudi Arabia:**

- National Pharmacovigilance Center (NPC)
 - Fax: +966-11-205-7662
 - Toll-Free : 800249000
 - E-mail: npc.drug@sFDA.gov.sa
 - Website: www.sFDA.gov.sa/npc

8. Council of Arab Health Ministers

The following statements issued by the Council of Arab Health Ministers should be printed in the PIL.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists