NOVARTIS

CATAFLAM® D dispersible tablets

CATAFLAM® SACHETS powder for oral solution

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

PROPRIETARY NAME AND PHARMACEUTICAL FORM:

CATAFLAM® D dispersible tablets

CATAFLAM® powder for oral solution

Read all of this leaflet carefully because it contains important information for you. CATAFLAM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CATAFLAM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CATAFLAM with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after (number of) days.

What this leaflet contains:

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

1. What CATAFLAM is and what it is used for

What CATAFLAM is:

The active substance of CATAFLAM D is 46,5 mg of diclofenac free acid, which is equivalent to 50 mg diclofenac sodium.

The active substance of CATAFLAM SACHETS powder for oral solution is 50 mg diclofenac potassium.

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

What CATAFLAM is used for:

As short-term symptomatic treatment for a maximum of 5 days in the following acute conditions:

- Painful musculoskeletal conditions
- Acute attacks of gout
- Pain and swelling after surgery
- Flare-ups of degenerative joint pain (osteoarthritis)
- Painful menstrual periods
- Classical migraine attacks

2. What you need to know before you take or use CATAFLAM:

Before you take CATAFLAM:

Do not take CATAFLAM:

- If you are allergic to diclofenac or to any of the other ingredients of CATAFLAM listed at the beginning of this leaflet.
- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, (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 suffer from asthma attacks that are worsened by acetylsalicylic acid or by other medicines used to treat inflammation (e.g. acetylsalicylic acid/aspirin, (diclofenac or ibuprofen).

- If you have stomach or intestinal ulcer.
- If you have gastrointestinal bleeding, symptoms of this 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 have suffered from a stroke or have a condition called peripheral arterial disease (a narrowing of blood vessels in your body).
- If you are pregnant or breastfeeding.
- If you suffer from a condition called porphyria.

If any of these apply to you, tell your doctor and do not take CATAFLAM. Your doctor will decide whether this medicine is suitable for you.

Take special care with CATAFLAM

- If you are taking CATAFLAM simultaneously with other anti-inflammatory medicines including acetylsalicylic acid/aspirin, 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, such as diclofenac in the past.
- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn’s disease).
- If you have or have had heart problems or high blood pressure.
- If you have liver or kidney problems. Hepatitis may occur with the use of CATAFLAM without symptoms that go before the disease.
- If you could be dehydrated (e.g. by sickness, diarrhoea, 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.

CATAFLAM 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 CATAFLAM.

Avoid taking CATAFLAM together with other non-steroidal anti-inflammatory medicines (NSAIDs), including cyclooxygenase-2 selective inhibitors (such as aspirin, indomethacin and celecoxib), to avoid an increase in side effects.

CATAFLAM may cause severe allergic skin reactions (e.g. rash). Therefore, inform your doctor immediately if you experience such reactions.

Pay attention to signs and symptoms of the formation of blood clots within your blood vessels as a result of plaque build-up inside the blood vessels. These signs and symptoms can occur without warning and include chest pain, shortness of breath, weakness and slurring of speech. Inform your doctor immediately if you experience such an event.

Taking CATAFLAM with food and drink:

CATAFLAM D dispersible tablets should preferably be taken on an empty stomach. CATAFLAM D dispersible tablets should be dropped into a glass of water and the liquid stirred to aid dispersion before swallowing. Since a proportion of the active substance may remain in the glass after swallowing, it is advisable to rinse the glass with a small amount of water and to swallow again. The dispersible tablets must not be divided or chewed.

The contents of CATAFLAM SACHETS powder for oral solution should be dissolved with stirring in a glass of natural (non-carbonated) water. The solution may remain somewhat cloudy. The solution should be swallowed preferably before meals.

Pregnancy and Breastfeeding

The use of CATAFLAM during pregnancy is contraindicated. You cannot use CATAFLAM if you are pregnant or breastfeeding.

Driving and using machinery:

CATAFLAM is unlikely to affect the ability to drive and use machines or carry out activities that need careful attention.

Important information about some of the ingredients of CATAFLAM tablets

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

Important information about some of the ingredients of CATAFLAM Sachets

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

Taking other medicines with CATAFLAM:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

The effects of the following medicines in particular may be affected by CATAFLAM:

- Lithium (a medicine used to treat some types of depression and mood disorders) levels in the body may be increased, if it is taken together with CATAFLAM.
- Combination of CATAFLAM together with selective serotonin-reuptake inhibitors (SSRIs) such as fluoxetine, citalopram, paroxetine and sertraline, which are used to treat some types of depression, may increase the risk of bleeding in the stomach.
- Digoxin (a medicine used to treat heart problems) levels in the body may be increased, if it is taken together with CATAFLAM.
- The effect of diuretics (medicines used to increase the amount of urine) and other medicines that are used to decrease the blood pressure (such as ACE inhibitors or beta-blockers) may be reduced if they are taken together with CATAFLAM.
- Taking CATAFLAM together with medicines that are known to cause an increase in the potassium levels in the blood (such as potassium-sparing diuretics, ciclosporin, tacrolimus or trimethoprim), may further increase the potassium levels in the blood.
- Taking other anti-inflammatory medicines such as acetylsalicylic acid/aspirin or ibuprofen or diclofenac and corticosteroids may increase the risk of undesirable effects in the stomach and intestines.
- Taking CATAFLAM together with “blood thinners” (medicines used to prevent blood clotting) may increase the risk of bleeding.
- Your blood sugar levels must be monitored if you are taking CATAFLAM together with medicines used to treat diabetes.
- Blood levels of methotrexate (a medicine used to treat some kinds of cancer or arthritis) may rise and toxicity may increase if you take CATAFLAM less than 24 hours before or after treatment with methotrexate.
- Taking CATAFLAM with ciclosporin (a medicine primarily used in patients who have received organ transplants) may increase toxicity to the kidneys.
- Some medicines used to treat infection (quinolone antibacterials, trimethoprim, voriconazole).

- Phenytoin (a medicine used to treat seizures) blood levels may increase if it is taken with CATAFLAM.

If you are taking medicines on a regular basis, concomitant use of CATAFLAM may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

If you are pregnant while taking CATAFLAM, please consult your doctor, pharmacist or other health care professional for advice. If you are taking CATAFLAM, you should not breastfeed your baby.

3. How to take CATAFLAM:

Do not share medicines prescribed for you with any other person.

Always take CATAFLAM exactly as described in this leaflet or as your doctor or healthcare practitioner has told you. Check with your doctor or healthcare practitioner if you are not sure.

Children:

You should not give CATAFLAM to children under 14 years of age.

Adults:

CATAFLAM D dispersible tablets should preferably be taken on an empty stomach. CATAFLAM D dispersible tablets should be dropped into a glass of water and the liquid stirred to aid dispersion before swallowing. Since a proportion of the active substance may remain in the glass after

swallowing, it is advisable to rinse the glass with a small amount of water and to swallow again. The dispersible tablets must not be divided or chewed.

The contents of CATAFLAM SACHETS powder for oral solution sachets should be dissolved with stirring in a glass of natural (non-carbonated) water. The solution may remain somewhat cloudy, but this should not influence the efficacy of the preparation. The solution should be swallowed preferably before meals.

As a rule, the initial daily dose is 100 to 150 mg, in milder cases, 50 to 100mg daily is usually sufficient.

The maximum daily dose is 150 mg.

The daily dosage should generally be prescribed in two to three fractional doses.

In painful menstrual periods, start the 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.

In migraine, take CATAFLAM 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.

Do not share medicines prescribed for you with others.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

The elderly

Since elderly patients may react more strongly to the effects of CATAFLAM than other adults, they should use the lowest effective dose for their condition. It is especially important for elderly patients to report unwanted effects immediately to their doctor.

If you take more CATAFLAM than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take CATAFLAM:

If you forget to take CATAFLAM, take it as soon as you remember, then continue to take it at the usual times. Ask your doctor or pharmacist for advice.

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

4. Possible Side effects:

CATAFLAM can cause side effects.

Not all side effects reported for CATAFLAM are included in this leaflet. Should your general health worsen while taking CATAFLAM, please consult your doctor, pharmacist or other health care professional for advice.

Some rare or very rare side effects could be serious:

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

- Unusual bleeding or bruising.
- High fever or persistent sore throat.

- Allergic reactions with swelling of the face, lips, mouth, tongue or throat, often associated with rash and itching, which may cause difficulty to swallow, hypotension (low blood pressure) or fainting.
- Wheezing and feelings of tightness in the chest (signs of asthma).
- Chest pain (signs of heart attack).
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, paralysis (signs of cerebral attack).
- Stiff neck (signs of viral meningitis).
- Convulsions.
- Hypertension (high blood pressure).
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering lips, eyes and mouth, skin inflammation with flaking or peeling.
- Severe stomach pain, bloody or black stools, vomiting blood.
- Yellowing of the skin or eyes (signs of hepatitis, liver failure or liver necrosis).
- Blood in urine, excess of protein in the urine, severe decreased urine output (signs of kidney disorders).
- Higher or lower urine output combined with drowsiness, confusion, nausea (signs and symptoms of tubulointerstitial nephritis).
- Purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy).

Frequent side effects:

Headache, dizziness, nausea, vomiting, diarrhoea, indigestion, abdominal pain, flatulence, loss of appetite, change in liver function (e.g. level of transaminases), skin rash.

Less frequent side effects:

Drowsiness, stomach pain, swelling of arms, hands, legs and feet (oedema).

Disorientation, depression, difficulty sleeping, nightmares, irritability, psychotic disorder, tingling or numbness of the hands or feet, memory impairment, anxiety, trembling, taste disorders, vision or hearing disorders, constipation, mouth sores, ulcer of the oesophagus (the tube that carries food from the throat to the stomach), palpitations, hair loss, redness, swelling and blistering of the skin (due to increased sensitivity to sun).

Tell your doctor if you experience any of these side effects.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CATAFLAM D.

5. How to store CATAFLAM

Storing and disposing of CATAFLAM

CATAFLAM D: Store at or below 30 °C. Protect from moisture.

CATAFLAM SACHETS Powder for oral solution: Store at or below 30 °C. Protect from moisture and heat.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use the dispersible tablets after the expiry date printed on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Content of the pack and other information

What CATAFLAM contains:

CATAFLAM D dispersible tablets

One CATAFLAM D dispersible tablet contains 46,5 mg of diclofenac free acid, which is equivalent to 50 mg diclofenac sodium.

The other ingredients are microcrystalline cellulose; sodium starch glycollate; croscarmellose sodium; silica, colloidal anhydrous; castor oil, hydrogenated; talc.

CATAFLAM SACHETS powder for oral solution:

Each sachet contains 50 mg diclofenac potassium.

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

Presentation of CATAFLAM:

CATAFLAM D is supplied in packs of 15 dispersible tablets.

CATAFLAM SACHETS powder for oral solution sachets can be packed in cartons of 3 or multiples thereof. The sachets are white with the name and all relevant information printed on them. The sachets consist of 3 layers – paper, aluminium and plastic.

Identification of CATAFLAM:

CATAFLAM D dispersible tablets:

White, flat, triangular tablets with beveled edges. One side debossed with “CG” and the other side embossed with “V”. Width, measured from flattened vertex: approximately 9 mm. Thickness: approximately 3,9 mm.

CATAFLAM SACHETS Powder for oral solution:

Homogeneous, white to light yellow powder in a sachet. The powder is sweet with an anise-mint flavour. The reconstituted solution is clear to somewhat cloudy.

Holder of Certificate of Registration:

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