

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

# CATAFLAM® 50 mg Tablets

Each tablet contains: Diclofenac as potassium 50 mg  
Inactive ingredients and their quantities: see section 6 "Further information" and section 2 "Important information about some of the ingredients of the medicine".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.  
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

The preparation is intended for management of pain and premenstrual pain when rapid pain relief is desired.

#### Therapeutic group:

Non-steroidal anti-inflammatory drugs (NSAIDs), pain and inflammation reducers.

### 2. BEFORE USING THE MEDICINE

#### Do not use the medicine if:

- you think you might be allergic to diclofenac potassium, aspirin, ibuprofen or any other NSAID, or to any of the ingredients of Cataflam (listed in section 6 "Further information" and section 2 "Important information about some of the ingredients of the medicine" in this leaflet). Signs of hypersensitivity include: swelling of the face and mouth (angioedema), breathing problems, chest pain, runny nose, skin rash or any other allergic reaction.
- you are suffering, or have suffered in the past, from a gastric or intestinal ulcer, or bleeding in the digestive tract (including: blood in vomit, bleeding when emptying the bowels and passing stools, fresh blood in feces or black, tarry feces).
- you have suffered from stomach or bowel problems after taking other NSAIDs.
- you are suffering from heart, kidney or liver failure.
- you are suffering from a heart disease and/or cerebrovascular disease, e.g., if you have had a heart attack, stroke, transient ischemic attack (TIA) or blockage of the arteries that lead to

the heart or brain, or have undergone an operation to open or bypass a blockage.

- you are suffering, or have suffered in the past, from blood circulation problems (peripheral arterial disease).
- you are in the third trimester of pregnancy.

#### Special warnings regarding use of the medicine:

##### Before beginning treatment with Cataflam, tell the doctor if:

- you have gastric or intestinal disorders, including ulcerative colitis, or a chronic intestinal inflammatory disease (Crohn's disease).
- you have kidney or liver problems or you are elderly.
- you are suffering from a condition called porphyria, a porphyrin metabolism disturbance.
- you suffer from any blood disorders or bleeding. In such cases, your doctor may ask you to perform periodic tests while taking Cataflam.
- you are suffering, or have suffered in the past, from asthma.
- you are breastfeeding.
- you are suffering from angina, blood clots, high blood pressure, abnormal levels of blood fat (high cholesterol or high triglyceride levels).
- you have heart problems or have suffered from a stroke or think you may be at risk for these conditions (e.g., if you have high blood pressure, diabetes, high cholesterol or you smoke).
- you have diabetes.
- you smoke.
- you are suffering from systemic lupus erythematosus (lupus), or from a similar condition.

#### Children and adolescents

This medicine is not intended for children under the age of 14.

#### Drug interactions:

##### If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially if you are taking:

- Medicines to treat diabetes.
- Anticoagulants (blood-thinning medicines, like warfarin).
- Diuretics (to increase the amount of urine).
- Lithium (used to treat certain mental problems).
- Methotrexate (for treatment of inflammatory diseases and certain types of cancer).
- Ciclosporin and tacrolimus (used to treat inflammatory diseases and after transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections).
- Quinolone-type antibiotics (to treat infections).

- Other NSAIDs or COX-2 (cyclo-oxygenase-2) inhibitors, for example, aspirin or ibuprofen.
- Mifepristone (a medicine used to terminate pregnancy).
- Cardiac glycosides (for example: digoxin), used to treat heart problems.
- Medicines known as SSRIs, used to treat depression.
- Oral steroids (oral anti-inflammatory medicines).
- Medicines used to treat heart problems 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/cholestyramine (used to lower cholesterol).

#### Use of the medicine and food

Take the tablets with or after a meal. The tablet should be swallowed whole with liquid, do not chew or divide the tablet.

#### Pregnancy, breastfeeding and fertility

If you are pregnant or planning a pregnancy, even though the cases were not common, abnormalities have been reported in babies to mothers who took NSAIDs during pregnancy. Do not take Cataflam tablets during the last three months of pregnancy, as it may affect the blood circulation of the fetus.

Inform the doctor if you are breastfeeding. Small amounts of diclofenac pass into breast milk; therefore, to prevent unwanted effects in the infant, do not take diclofenac while breastfeeding.

If you are planning a pregnancy, taking Cataflam may cause difficulty in getting pregnant. You should consult your doctor if you are planning a pregnancy or if you have difficulties getting pregnant.

#### Driving and operating machinery

There have been occasional reports that use of the medicine may cause dizziness, fatigue or sleepiness. Visual disturbances have also been reported. If you experience these effects, you should avoid driving a car and operating machinery.

#### Important information about some of the ingredients of the medicine

Cataflam tablets 50 mg contain sucrose. If you have been told by the attending doctor that you have an intolerance to some sugars, inform your doctor before taking the medicine.

Each tablet contains approximately 68 mg sucrose.

Information about sodium content:

This medicine contains less than 1 mmol sodium (23 mg) per tablet, and is therefore considered to be 'sodium-free'.

#### Additional warnings

- Take the lowest dosage of Cataflam and for the shortest possible time, particularly if you are underweight or elderly.

- There is a slightly increased risk of heart attack or stroke when you are taking medicines like Cataflam. The risk increases if you are taking a high dosage for a long time. Always follow the doctor's instructions regarding how much to take and for how long.
- 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.
- Whilst you are taking the medicine, your doctor may want to check you from time to time.
- If you have a history of stomach problems while taking NSAIDs, particularly if you are elderly, you must inform the doctor immediately if you notice any unusual symptoms.
- Since the medicine is an anti-inflammatory, Cataflam may reduce the symptoms of infection, for example, headache and high fever. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Cataflam.

Before taking Cataflam, tell your doctor if you have recently had surgery or are due to undergo surgery in the abdomen or intestinal tract, since Cataflam may sometimes worsen a healing intestinal wound after surgery.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Your doctor will tell you how many Cataflam tablets to take and when to take them.

Keep taking the tablets for as long as you have been told to take them, unless problems arise. In such a case, consult your doctor.

The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

#### Adults

The daily dosage should usually be taken in 2 or 3 separate doses. Do not exceed a dosage of 150 mg per day, unless so instructed by the doctor.

#### Elderly

If you are elderly, the doctor may advise you to take a dosage that is lower than the usual adult dosage. The doctor may want to check closely that the Cataflam tablets are not affecting your stomach.

#### Children over the age of 14

**This medicine is not intended for children under the age of 14.**

For children aged 14 years or over, the daily dosage should usually be taken in 2 or 3 separate doses. Do not exceed a dosage of 150 mg per day.

The doctor may prescribe another medicine to protect the stomach, to be taken at the same time as this medicine, particularly if you experienced stomach problems before, if you are elderly, or if you are taking certain other medicines as well.

#### Do not exceed the recommended dose.

#### How and when to take the medicine

It is preferable to take the medicine during or after a meal.

Cataflam tablets have been specially designed to act rapidly. Swallow the tablet whole with a beverage or water.

Do not halve, crush or chew the tablet. There are no data in this regard.

#### If you accidentally take a higher dosage

If you, or someone else, accidentally took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Adhere to the treatment regimen as recommended by the doctor.

#### If you forget to take the medicine

If you forgot to take the medicine at the scheduled time, take a dose as soon as you remember. But, if it is nearly time for the next dose, do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time and consult the doctor. Do not exceed a dosage of 150 mg (3 tablets of 50 mg) over 24 hours.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

#### Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

#### If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

### 4. SIDE EFFECTS

As with any medicine, use of Cataflam may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

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

#### Some side effects could be serious

##### Stop taking Cataflam tablets and tell the doctor immediately if you notice:

- Sudden and crushing chest pain (sign of myocardial infarction or heart attack).
- Breathlessness, breathing difficulties when lying down, swelling of the feet or legs (signs of heart failure).
- Sudden weakness or numbness in the face, arms or legs, especially on one side of the body, sudden loss or disturbance

of vision, sudden difficulty in speaking or ability to understand speech, sudden migraine-like headaches that occur for the first time, with or without disturbed vision. These signs can be early signs of a stroke.

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick), vomiting (being sick).
- Any sign of bleeding in the stomach or intestine, for example, when emptying your bowels, blood in vomit or black, tarry feces.
- Allergic reactions which include skin rash, itching sensation, bruising, painful red areas, skin peeling or blistering.
- Breathing difficulties with wheezing or shortness of breath (bronchospasm).
- Swelling of the face, lips, hands or fingers.
- Yellowing of the skin or the whites of the eyes.
- Persistent sore throat or high fever.
- An unexpected change in urine output and/or its appearance.
- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Cataflam tablets and followed by rectal bleeding or bloody diarrhea, usually within 24 hours of the onset of abdominal pain.
- Chest pain, which can be a sign of a severe allergic reaction called Kounis syndrome.

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

#### Additional reported side effects:

##### Common side effects (effects occurring in 1-10 in 100 users):

- Stomach pains, heartburn, nausea, vomiting, diarrhea, indigestion, wind, loss of appetite
- Headache, dizziness, vertigo
- Skin rash or spots
- Raised levels of liver enzymes in the blood

##### Uncommon side effects (effects occurring in 1-10 in 1,000 users):

- Fast or irregular heartbeat (palpitations), chest pain, heart disorders, including heart attack or breathlessness, breathing difficulties when lying down, swelling of the feet and legs (signs of heart failure), especially if you took a high dosage (150 mg per day) for a long period of time

##### Rare side effects (effects occurring in 1-10 in 10,000 users):

- Stomach ulcers or bleeding (there have been very rare reported cases resulting in death, particularly in the elderly)
- Gastritis (inflammation, irritation or swelling of the stomach lining)
- Vomiting blood
- Bloody diarrhea or anal bleeding
- Black, tarry feces
- Drowsiness, tiredness
- Skin rash and itching
- Fluid retention, symptoms of which include swollen ankles

- Liver function disorders, including hepatitis and jaundice
- Asthma (signs include wheezing, breathlessness, coughing and a sensation of tightness in the chest)

*Very rare side effects (effects occurring in less than 1 in 10,000 users):*

##### Effects on the nervous system:

Inflammation of the lining of the brain (meningitis), tingling or numbness in the fingers, tremor, visual disturbances such as blurred or double vision, taste changes, hearing loss or impairment, tinnitus (ringing in the ears), insomnia, nightmares, mood swings, depression, anxiety, irritability, mental disorders, disorientation, memory loss, fits, headaches with sensitivity to bright light, fever and stiff neck.

##### Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, mouth ulcers, inflammation of the inside of the mouth or lips, lower gut disorders (including inflammation of the colon or worsening of ulcerative colitis or chronic intestinal inflammatory disease [Crohn's disease]), inflammation of the pancreas.

##### Effects on the chest or blood system:

High blood pressure, low blood pressure (signs of low blood pressure include faintness, dizziness or lightheadedness), inflammation of blood vessels (vasculitis), inflammation of the lungs, blood disorders (including anemia).

##### Effects on the liver or kidneys:

Kidney disorders or severe liver disorders, including liver failure, presence of blood or protein in the urine.

##### Effects on the skin or hair:

Facial swelling, serious skin rashes including Stevens-Johnson syndrome and Lyell's syndrome and other skin rashes which worsen upon exposure to sunlight, hair loss.

##### Effects on the reproductive system:

Impotence

##### Additional side effects that have been reported with unknown frequency include:

Throat disorders, confusion, hallucinations, malaise (general feeling of discomfort), inflammation of the nerves in the eye, disturbances of sensation.

Medicines such as Cataflam may be associated with a slightly increased risk of heart attack or stroke.

#### If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

#### Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 30°C. Protect from moisture.
- If the doctor has told you to stop taking Cataflam tablets, give the remaining tablets to the pharmacist, for disposal. Do not dispose of the tablets into the wastewater or waste bin. This is in order to protect the environment

### 6. FURTHER INFORMATION

Each tablet contains 50 mg of the active ingredient diclofenac potassium.

- In addition to the active ingredient, the tablet also contains inactive ingredients:
  - Calcium phosphate; Maize starch; Sodium starch glycolate; Silica, colloidal anhydrous; Povidone; Magnesium stearate
- The sugar coating contains: Sucrose; Talc; Povidone; Dispersed Red 15881 (Iron oxide red EEC 172; Titanium dioxide EEC 171); Macrogol 8000; Cellulose, microcrystalline
- Also see in section 2 "Important information about some of the ingredients of the medicine".

- What the medicine looks like and the contents of the package: Cataflam 50 mg is supplied in the form of sugar-coated tablets. Cataflam packages contain 10 or 20 tablets (not all package sizes may be marketed).
- Cataflam tablets are sugar-coated, reddish-brown, round and biconvex.

#### Registration Holder and Importer and its Address:

Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in January 2021 according to MOH guidelines.

#### Registration number of the medicine in the National Drug Registry of the Ministry of Health: 069 40 28459