

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 and allergenic ingredients in the preparation: see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

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 additional ingredients contained in the medicine (listed in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information" 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 more than six months pregnant (in the third trimester of pregnancy).

Special warnings regarding use of the medicine:

Before 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.

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.

Do not take Cataflam if you are in the last 3 months of pregnancy (last trimester) as it could harm your unborn child or cause problems at delivery. It may cause kidney and heart problems in your unborn baby, affect your and your baby's tendency to bleed and cause labor to be later or longer than expected.

• 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 should not take Cataflam during the first 6 months of pregnancy unless absolutely necessary and advised by your attending doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dosage for the shortest time possible should be used.

• 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 and adolescents 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).
- Cyclosporin 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 medicine).

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.

• Swallow the tablet whole with a beverage or water. Do not halve, crush or chew the tablet. There are no data in this regard.

Effects on the nervous system:

It is preferable to take the medicine during or after a meal. Cataflam tablets have been specially designed to act rapidly.

• 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.

• 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.

Effects on the stomach and digestive system:

It is preferable to take the medicine during or after a meal. Cataflam tablets have been specially designed to act rapidly.

Effects on the heart or blood system:

Effects on the liver or kidneys:

Effects on the skin or hair:

Effects on the reproductive system:

Driving and operating machinery:

Adults

Important information about some of the ingredients of the medicine

Elderly

Some side effects could be serious

Registration Holder and Importer and its address:

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

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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'.

Children and adolescents over the age of 14
This medicine is not intended for children and adolescents under the age of 14.

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).

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, 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).

Do not exceed the recommended dose.

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.

How and when to take the medicine

Effects on the nervous system:

Effects on the stomach and digestive system:

Effects on the heart or blood system:

Effects on the liver or kidneys:

Effects on the skin or hair:

Effects on the reproductive system:

Driving and operating machinery:

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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) 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; 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 May 2023 according to MOH guidelines.