S3

Profenid® 100mg / 2ml Injection I.M.

ketoprofen

sanofi aventis

Read this entire leaflet before taking this medicine.
It contains important information about your treatment. If you have further questions, if you are unsure, ask your doctor or pharmacist.
This medicine has been prescribed for you. Never give it to someone else, even if they have similar symptoms, it may harm them.
Keep this leaflet; you may need to read it again.

This product contains benzyl alcohol not for use in neonates and infants

Drug identification
Composition:
Ketoprofen ..... 100 mg
Excipients:
arginine, benzyl alcohol, citric acid monohydrate, water for injection, for one ampoule.

Pharmaceutical form and presentation
Injectable solution (I.M.). Box of 3 ampoules each of 2 ml.

Pharmacotherapeutic Class
Anti-inflammatory, antirheumatic, non-steroidal

When to use this medication
This medication contains an anti-inflammatory drug: ketoprofen. It is indicated in adults (over 15 years), for short-term treatment of:
•Some severe inflammatory rheumatism
•Acute back pain,
•Acute pain related to irritation of a nerve, such as sciatica,
•Some intense pain,
•Attacks of renal colic (painful attacks in the lower back following a urinary tract blockage).
This drug is usually administered by injection when oral and rectal routes can not be used.
WARNING!
In which case not to use this medicine
This medicine should not be used in the following cases:
-History of allergy to ketoprofen or any of its other ingredients,
-History of asthma triggered by taking this drug or related drugs, including other non-steroidal anti-inflammatory drugs, as aspirin,
-Gastrointestinal bleeding, cerebral hemorrhage or other active bleeding
-Ongoing ulcer of the stomach or intestine
-Severe liver, kidney or heart diseases,
-Bleeding disorders or concurrent anticoagulant therapy (intramuscular related contraindication),
- This product contains benzyl alcohol which is potentially toxic when administered locally to neural tissue.
-Pregnancy, Nursing mothers & Pediatric use, do not administer injections preserved with benzyl alcohol to premature infants, neonates, infants below 13 years, pregnant women or nursing mothers. Benzyl alcohol has been associated with serious adverse events & death, particularly in pediatric patients (it may cause Gasping syndrome). Injections preservative free should be used in these populations.

Special warnings
This medication should be taken under medical supervision. Undesirable events may be minimized by using the lowest effective dose for the shortest possible duration necessary to control symptoms.
Cardiovascular Risk:
NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. NSAIDs is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
Gastrointestinal Risk
NSAIDs cause an increased risk of serious gastrointestinal adverse events including inflammation, bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.
•Before treatment
Tell your doctor in case of:
-A history of asthma associated with chronic rhinitis, chronic sinusitis or nasal polyps. The administration of this drug can cause difficulty of breathing or an attack of asthma, especially in some subjects allergic to aspirin or other non-steroidal anti-inflammatory drugs (see Who should not use this medication),
-Disorders of coagulation, treatment with anticoagulants or antiplatelets because concomitant drugs can cause serious gastrointestinal manifestations,
-Gastrointestinal history (peptic or old duodenal ulcer, ulcerative colitis, Crohn's disease),
-History of skin reaction when exposed to sunlight or UV rays,
-Heart, liver or kidney disease,
-Treatment with diuretics or recent surgery.
Taking this drug in combination with oral anticoagulants, other anti-inflammatory drugs, including aspirin in high doses and selective inhibitors of cyclo-oxygenase 2 (cox-2), heparin, lithium, methotrexate (at doses above 20 mg/week), or pemetrexed in patients with low to moderate renal insufficiency, should be avoided (see Drug interactions and other interactions).
- This product is contraindicated for use in premature infants because the formulation contains benzyl alcohol.
•During treatment
In case of:
-Signs of infection, CALL YOUR DOCTOR
-Signs suggesting allergy to this drug, including asthma, urticaria, sudden swelling of the face and neck, stop treatment and call a doctor or emergency medical service.
-Gastrointestinal bleeding (discharge of blood through the mouth, presence of blood in stool or black colored stools), stop treatment and call a doctor or emergency medical service.

Usage Precautions
This medication contains a non-steroidal anti-inflammatory drug: ketoprofen.
You should not take this medication along with other medications containing non-steroidal anti-inflammatory drugs and / or aspirin.
Read the instructions for the other drugs you take to ensure the absence of non-steroidal anti-inflammatory drugs and /or aspirin.

Drug interactions and other interactions
To avoid possible interactions with other drugs, including oral anticoagulants, other non-steroidal anti-inflammatory drugs, including aspirin in high doses, and selective inhibitors of cyclo-oxygenase 2 (cox-2), heparin, lithium, methotrexate (at doses above 20 mg/week), pemetrexed in case of low to moderate renal insufficiency, you must systematically report any other treatment to your doctor or your pharmacist.

Pregnancy – Breastfeeding
Should not be used in pregnancy & nursing mothers. Generally, during pregnancy and breastfeeding, you should always consult your doctor or pharmacist before taking your medicine.

Drivers and machine operators
In rare cases, taking this medicine may cause dizziness, drowsiness, seizures or visual disturbances. It is advisable not to drive or operate machinery if any of these symptoms occurs.

List of excipients of which knowledge is necessary for safe use in some patients
Benzyl alcohol

How to use this medication
Dosage:
The dosage varies from 1 to 3 ampoules per day, according to the indication.
In all cases strictly follow your doctor's orders.
Mode and route of administration:
Strictly Intramuscular.
The injections should be made in a strictly aseptic manner in the outer part of the upper outer quadrant of the buttock, deeply and slowly. When repeated, it is recommended to switch sides with each injection. It is important to aspirate before injecting to make sure the tip of the needle is not in a vessel. In cases of severe pain at the injection, stop it immediately.
In case of a hip prosthesis, the injection should be made on the opposite side.
Frequency and time at which the drug should be administered:
The daily dose is preferably divided into 2 to 3 injections.
Duration of treatment:
The duration of treatment is 2 to 3 days. Beyond that, continue on oral or rectal treatment.
What to do in case of overdosage:
In case of overdosage or accidental poisoning, immediately notify a doctor.
What to do if you missed the administration of one or more doses:
Do not take a double dose to make up for the single dose that you missed.

Undesirable effects
Like all medicines, this product may, in some people, lead to more or less annoying effects:
- *Allergic reactions may occur:*
•Skin: skin rash, itching, hives, worsening of chronic urticaria,
•Respiratory: asthma, difficult breathing especially in patients allergic to aspirin or non-steroidal anti-inflammatory drugs,
•General: Very rarely, sudden swelling of the face and throat (angioedema), allergic shock.
- *Can also occur:*
•Gastrointestinal bleeding (see Special Warnings). This is even more common when the dose used is high,
•A skin reaction when exposed to sunlight or UV rays,
•Exceptionally, serious peeling of the skin which rapidly spreads throughout the body.
In all of these cases, immediately discontinue treatment and notify your doctor.
- *During treatment, it may also occur:*
•Digestive disorders: nausea, vomiting, diarrhea, constipation, stomachache, gastrointestinal discomfort, more rarely, inflammation of the intestine.
•Headache, dizziness, drowsiness, convulsions and exceptionally mood disorders, tinnitus, blurred vision, hypertension, hair loss or bristle hair, edema,
•Other effects related to the route of administration: in some cases, pain and burning sensation at the injection site.
In all of these cases, you must tell your doctor.
- Cases of gastric ulcer, intestinal perforation, renal impairment and hepatitis were observed.
- Some biological changes may require blood and renal tests to control.
Medications such as Profenid 100 mg / 2 ml solution for injection (IM), may increase the risk of heart attack (myocardial infarction) or stroke.
Do not hesitate to seek advice from your doctor or your pharmacist and report any undesirable effect that is not mentioned in this leaflet.

Conservation
Store at room temperature.
Do not use after the expiry date listed on the outer packaging.
Special precautions for storage
This medication should be kept away from light.

Keep all medicines out of reach of children

sanofi-aventis

This insert was last approved in february 2012