Profenid® 100mg

ketoprofen

Suppository

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT PROFENID 100 mg suppositories ARE AND WHAT THEY ARE USED FOR

ANTI-INFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS (M : musculo-skeletal system)

This medicine contains a non-steroidal anti-inflammatory: ketoprofen. It is indicated for use in adults (over 15 years of age):
- the long-term treatment of:
  - o certain types of chronic inflammatory rheumatism,
  - o certain types of severe osteoarthritis.
- the short-term treatment of:
  - o certain types of inflammation around the joints (tendonitis, bursitis, acute painful shoulder),
  - o certain types of joint inflammation caused by crystal deposits, such as gout,
  - o acute osteoarthritic pain,
  - o acute lower back pain,
  - o acute pain related to nerve irritation, such as sciatica,
  - o trauma-related pain and edema.

2. BEFORE YOU USE PROFENID 100 mg suppositories

Never use Profenid 100 mg suppositories in the following cases:
- after 5 full months of pregnancy (i.e. 24 weeks of amenorrhea),
- history of allergy to ketoprofen or to any other ingredients in the medicine,
- history of asthma caused by the medicine or related medicines, particularly other non-steroidal anti-inflammatory drugs or aspirin,
- history of digestive tract bleeding or ulcers related to previous treatment with non-steroidal anti-inflammatory drugs,
- active or recurrent digestive tract bleeding or ulcer,
- digestive tract bleeding, bleeding in the brain or any other active bleeding,
- serious liver disease,
- serious kidney disease,
- serious heart disease,
- recent rectal inflammation or bleeding (contraindication related to the route of administration).

Take special care with PROFENID 100 mg suppositories:

Warnings

THIS MEDICINE MUST ONLY BE USED UNDER MEDICAL SUPERVISION.

Medicines such as PROFENID may increase the risk of heart attack ("myocardial infarction") or stroke. The risk increases with the dose and duration of treatment.

Do not exceed the prescribed dose or treatment duration.

If you have heart problems, if you have had a stroke or think you may have risk factors for this type of disorder (e.g. if you have high blood pressure, diabetes, high cholesterol or if you smoke), talk to your doctor or pharmacist.

Precautions for use

Since it may be necessary to adjust your treatment, it is important that you inform your doctor before using PROFENID if:
- you have a history of asthma associated with chronic rhinitis, chronic sinusitis or nasal polyps. Using this medicine may induce breathing difficulties or an asthma attack, particularly in certain subjects allergic to aspirin or non-steroidal anti-inflammatory drugs (see Section "Never use Profenid 100 mg suppositories"),
- you have heart disease (high blood pressure and/or heart failure), liver or kidney disease or if you retain water,
- you have coagulation disorders, or if you are taking anticoagulant treatment, as this medicine may cause serious digestive effects,
- you have a disease involving chronic inflammation of the intestine (such as Crohn's disease or ulcerative colitis),
- you have a history of digestive disorders (previous stomach or duodenal ulcer),
- you are currently being treated with other medicines that increase the risk of peptic ulcer or digestive bleeding, such as glucocorticoids, antidepressants (SSRIs, i.e. selective serotonin reuptake inhibitors), medicines that prevent the formation of blood clots such as aspirin or anticoagulants such as warfarin. If one of these cases applies to you, consult your doctor before using PROFENID (see Section "Taking or using other medicines"),
- you have a history of skin reactions on exposure to the sun or UV rays (tanning beds).

During treatment, if:
- you have signs of infection or if your symptoms worsen, INFORM YOUR DOCTOR. As with any non-steroidal anti-inflammatory drug, ketoprofen can mask the symptoms (such as fever) of an underlying infection,
- you have signs indicating allergy to this medicine, particularly an asthma attack, hives or sudden swelling of the face and neck, STOP TREATEMENT AND IMMEDIATELY CONTACT A DOCTOR OR EMERGENCY MEDICAL SERVICE,
- you have digestive tract bleeding (expulsion of blood from the mouth or blood in stools, or dark stools), STOP TREATMENT AND IMMEDIATELY CONTACT A DOCTOR OR EMERGENCY MEDICAL SERVICE.

For women: PROFENID can affect your fertility. Therefore, you should not use this medicine if you wish to become pregnant, if you have difficulty conceiving or if you are undergoing fertility tests.

Elderly subjects have a higher risk of experiencing side effects, in particular digestive bleeding, ulcers and perforations. In these patients, kidney, liver and cardiac function must be closely monitored, and the doses reduced.

This medicine contains a non-steroidal anti-inflammatory drug: ketoprofen.
You must not use this drug at the same time as other medicines containing non-steroidal anti-inflammatory drugs and/or aspirin.
Read the package leaflet of any other medicines you may be taking carefully to ensure that they do not contain non-steroidal anti-inflammatory drugs and/or aspirin.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, because some medicines should not be taken together and others require a change in dose when they are taken together.

Before using PROFENID, you must always inform your doctor or pharmacist if you are taking or being given one of the following medicines:
- acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs,
- corticosteroids,
- oral anticoagulants such as warfarin, injectable heparin, anti-platelet agents or other thrombolytics such as ticlopidine,
- lithium,
- methotrexate,
- angiotensin converting enzyme inhibitors, diuretics, beta-blockers and angiotensin II receptor antagonists,
- certain antidepressants (selective serotonin reuptake inhibitors),
- deferasirox,
- cyclosporin, tacrolimus.

Pregnancy and breast-feeding

Pregnancy

During the first trimester of pregnancy (12 weeks of pregnancy, i.e. 12 weeks after the first day of your last period), your doctor may prescribe this medicine if necessary.

Between 2.5 and 5 full months of pregnancy (12 to 24 weeks of pregnancy), this medicine should only be used if advised by your doctor, and only for a short time. Prolonged use of this medicine is strongly inadvisable.

After 5 full months of pregnancy (after 24 weeks of pregnancy), you should UNDER NO CIRCUMSTANCES use this medicine, as its effects on your unborn baby may have serious consequences, in particular on the heart, lungs and kidneys, even after only one dose.

If you have used this medicine when you were more than five months pregnant, talk to your obstetrician/gynaecologist who will recommend appropriate monitoring.

Breast-feeding

This medicine passes into breast milk. As a precaution, you should avoid using this medicine while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

In rare cases, this medicine may cause dizziness, drowsiness, seizures or visual disturbances. You should not drive or use machines if any of these effects occur.

3. HOW TO USE Profenid 100 mg suppositories

How many PROFENID 100 mg suppositories should be used

Dosage may vary depending on the condition being treated.

It ranges from one to two 100 mg suppositories, i.e. 100 to 200 mg per day.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

How PROFENID 100 mg suppositories should be used

Rectal use.

How often PROFENID 100 mg suppositories should be used

The daily dose should be taken as 1 dose or 2 divided doses.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

How long PROFENID 100 mg suppositories should be used

These suppositories should be used for as short a time as possible due to the risk of rectal side effects in addition to those which occur with oral forms.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

If you use more PROFENID 100 mg suppositories than you should

In the event of overdose or accidental poisoning, STOP TREATMENT AND IMMEDIATELY CONSULT A DOCTOR.

If you forget to use Profenid 100 mg suppositories

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, PROFENID 100 mg suppositories can cause side effects, although not all patients have them.

Medicines such as PROFENID may increase the risk of heart attack ("myocardial infarction") or stroke.

- The following allergic reactions may occur:

o skin reactions: skin rash, itching, hives, exacerbation of chronic hives,
o respiratory reactions: asthma attack, difficulty breathing, particularly in subjects allergic to aspirin or non-steroidal anti-inflammatory drugs,
o general reactions: very rarely, sudden swelling of the face and neck (angioedema), and allergic shock.

- The following effects may also occur:

o digestive tract bleeding (see Section "Warnings").This occurs more often with higher doses.
o skin reactions on exposure to the sun or UV rays (tanning beds),
o in exceptional cases, skin detachment which may rapidly and very seriously spread over the whole body.

If any of these occur, stop treatment immediately and inform your doctor.

- The following effects may also occur during treatment:

o digestive disorders: nausea, vomiting, diarrhoea, constipation, stomach pain, digestive discomfort and, more rarely, intestinal inflammation,
headache, dizziness, drowsiness and, in exceptional cases, seizures and mood disorders, ringing in the ears, visual disturbances, high blood pressure, edema, hair or body hair loss,
local effects, related to the route of administration: rectal irritation, such as burning sensations. These effects are more intense and occur more often with longer treatment duration, more frequent use and higher doses.

If any of these occur, inform your doctor.

- Cases of stomach ulcer, intestinal perforation, kidney damage and hepatitis have been observed.
- Some abnormal laboratory test results may require blood and kidney function tests.

If you notice any side effects not mentioned in this package leaflet, or if certain side effects become serious, please inform your doctor or pharmacist.

5. HOW TO STORE PROFENID 100 mg suppositories

Keep out of the reach and sight of children.

Do not use PROFENID after the expiry date indicated on the box. The expiry date is the last day of the month indicated.

Store at a temperature no higher than 25°C.

Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist how to dispose of unused medicines. These measures will help to protect the environment.

6. FURTHER INFORMATION

What PROFENID 100 mg suppositories contain

The active substance is:

Ketoprofen.....100 mg
For one 2.7 g suppository.

The other ingredients are:

Hydrophobic silica, hard fat (semi-synthetic glycerides, e.g. Suppocire® A).

What PROFENID 100 mg suppositories look like and contents of the pack

Suppositories. Box of 12.

Marketing Authorization holder and operating company
sanofi-aventis France
1-13, boulevard Romain Rolland
75014 Paris
France

Manufacturer
UNITHER LIQUID MANUFACTURING
1-3, allée de la Neste, Z.I. d'En Sigal
31770 COLOMIERS
France

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