

## PACKAGE LEAFLET: Information for the patient

### PIROCUTAN

Tablets – 20 mg

(Piroxicam)

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, or if you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.

#### **In this leaflet:**

1. What Pirocutan is and what it is used for?
2. What you need to know before you take Pirocutan?
3. How to take Pirocutan?
4. Possible side effects
5. How to store Pirocutan?
6. Other information

#### **1. WHAT PIROCUTAN IS AND WHAT IT IS USED FOR?**

Pirocutan contains the active substance piroxicam, which is an analgesic and antiinflammatory medicine (nonsteroidal antiinflammatory).

Before prescribing Pirocutan, the doctor should evaluate the need for this medicine versus the risk of occurrence of possible side effects. In certain circumstances the doctor may control you several times and tell you how often you should do controls during treatment with piroxicam.

### **Indications:**

Pirocutan 20 mg is indicated for the symptomatic relief of swelling, tenderness and joint pain in active arthritis, rheumatoid arthritis and Morbus Bechterew / Spondylitis ankylosans (rheumatic disease of the backbone).

Piroxicam does not cure arthritis, it only helps you as long as you use it.

Your doctor should prescribe piroxicam only if other nonsteroidal antiinflammators (NSAIDs) have not reached sufficient symptoms relief.

Since constant effective levels are reached late, Pirocutan is not indicated for the treatment of diseases which require a rapid onset of action.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PIROCUTAN?**

### **Do not take Pirocutan:**

- if you are hypersensitive (allergic) to piroxicam or to any of the other ingredients of Pirocutan;
- if you have had previously or have actually gastrointestinal ulcer, bleeding or gastrointestinal perforation;
- if you have actual or have had previous gastrointestinal disorders (gastric or intestinal inflammation), which predispose to bleeding, such as: ulcerative colitis, Crohn's disease, gastrointestinal cancer or diverticulitis (inflamed or infected protuberances or „pockets“ in the colon);
- if you use concomitantly NSAIDs, including COX-2-selective NSAIDs and acetylsalicylic acid (aspirin, which is present in many analgesic and antipyretic preparations);
- if you use anticoagulant medicines, such as. warfarin, to prevent blood coagulation;
- if you have experienced previously a severe allergic reaction to piroxicam, other NSAIDs or other medicines, mainly serious skin reactions (regardless of their gravity) e.g. exfoliative dermatitis, skin reactions with blister formation (Stevens-Johnson syndrome) or toxic epidermal necrolysis;
- if you develop a rash or skin symptoms; in this case you should stop taking Pirocutan immediately, seek prompt medical advice and tell your doctor that you are taking this medicine;
- in unexplained hematopoietic or blood-clotting disorders;

- in cerebral hemorrhage or other active hemorrhages;
- in severe disorders of hepatic or renal function;
- in moderated or severe heart failure;
- in the last trimester of pregnancy (see „Pregnancy and lactation“).

Children and adolescents under 15 years should not take Pirocutan because the active substance content is too high.

If you have any of these conditions, you should not use piroxicam. Talk immediately to your doctor.

### **Take special care with Pirocutan**

Cases of life-threatening skin reactions (Stevens - Johnson syndrome, toxic epidermal necrolysis) have been reported in association with the use of piroxicam. Initially, these appear as red circular spots (often with a blister in the middle). Rash may lead to blister formation in a large surface or to peeling. Other symptoms for which caution is required are: painful ulcers in the mouth, throat, nose and genital area, and also conjunctivitis. These skin reactions which may be life-threatening are often associated with flu-like symptoms (headache, fever and pain).

The risk for the occurrence of these reactions is highest in the first weeks of treatment. If you get Stevens-Johnson syndrome or toxic epidermal necrolysis after using piroxicam, you should never be re-treated with piroxicam. If you experience skin rash or other mentioned skin symptoms, discontinue the use of piroxicam and inform immediately your doctor.

Special care is required during use of Pirocutan 20 mg, so always inform your doctor before taking it.

Concomitant use of Pirocutan 20 mg and other nonsteroidal antiinflammatories should be avoided, including COX-2 inhibitors (cyclooxygenase inhibitors).

Side effects may be reduced by using minimal effective doses for the shortest time necessary to control the symptoms.

## Safety in the gastrointestinal tract

### *Elderly patients:*

In elderly patients, special medical care is required since in these patients during NSAID therapy, adverse effects are more common, especially gastrointestinal bleeding and perforation, which in certain conditions may be fatal.

Like all nonsteroidal antiinflammators, Pirocutan 20 mg may cause severe gastrointestinal reactions, like: pain, hemorrhage, ulcer and perforation.

You should discontinue immediately the use of piroxicam and should inform your doctor if you have stomach pain or signs of a gastrointestinal hemorrhage, like black or bloody stools or vomits with blood.

You should discontinue immediately the use of piroxicam and should inform your doctor if you experience an allergic reaction, like: rash, face swelling, wheezing or breathing difficulties.

If you are over 70 years old, your doctor may reduce the duration of treatment.

If you are over 70 years old or use other medicines, such as: glucocorticoids, selective serotonin reuptake inhibitors [SSRI] or acetylsalicylic acid (to prevent clot formation), your doctor may give you combination therapy of Pirocutan 20 mg and a gastroprotective medicine.

You should not use Pirocutan 20 mg if you are over 80 years old.

If you have had previously problems with medicines or with allergy, or if you are not sure if you can use piroxicam, talk to your doctor before using this medicine.

## Cardiovascular system effects

Medicines like Pirocutan are thought to be associated with a small increased risk for heart attack or stroke. Every risk is more possible in high doses and long-term treatment. Do not exceed the recommended doses and duration of treatment!

If you have heart problems, have had a stroke, or you think you may be at risk for these diseases (e. g. you have high blood pressure, diabetes or high cholesterol or if you smoke), you should discuss your treatment with your doctor or pharmacist.

## Other instructions

Pirocutan 20 mg may be used only after a strict evaluation of the benefit-risk ratio:

- in some congenital blood disorders (e.g. intermittent acute porphyria).

Special medical care is required:

- immediately after major surgeries;
- in allergy (e. g. skin reactions from other medicines, asthma, hay fever, chronic swelling of nasal mucosa or chronic obstructive pulmonary disease);
- in impaired renal or liver function.

During long-term treatment of Pirocutan 20 mg, regular controls of liver values, renal function and blood formula are necessary.

Piroxicam may temporarily inhibit platelet aggregation. Patients with coagulation disorders should be carefully monitored.

If Pirocutan 20 mg is taken before surgical procedures, the doctor or dentist should be informed.

During long-term use of painkillers, headaches may occur, which may not be treated by increased doses of the drug. Ask your doctor for advice if you suffer from headache in spite of taking Pirocutan!

Generally, the habitual intake of analgesics, especially when different analgesic agents are combined, can lead to permanent kidney damage with the risk of renal failure (analgesic nephropathy).

Like other medicines which inhibit prostaglandin synthesis, Pirocutan may make it difficult to get pregnant. You should inform your doctor if you are planning to get pregnant or if you have problems to get pregnant.

#### Care in children and adolescents

As a rule, Pirocutan 20 mg should not be used in children and adolescents under 18 years old because there is no sufficient experience.

Children and adolescents under 15 years old should not take Pirocutan 20 mg because the active ingredient content is too high (see section 2 "Do not take Pirocutan 20 mg").

#### **Taking Pirocutan with other medicines**

Inform your doctor for every medicine you take / use or have recently (last week) taken / used, even for medicines taken without a prescription. Sometimes drugs may interfere in each other's effect. It is particularly important for your doctor to know that you use the following medicines:

- acetylsalicylic acid or other nonsteroidal antiinflammatories, which are used to relieve pain;

- glucocorticoids;
- anticoagulant drugs, like warfarin;
- medicines to treat depression, known as selective serotonin reuptake inhibitors (SSRI);
- medicines like acetylsalicylic acid to avoid platelet aggregation.

If you use any of these medicines, talk immediately to your doctor.

Concomitant use of Pirocutan 20 mg and phenytoin (drug to treat epilepsy) or lithium (to treat mental-emotional disorders) can increase the blood concentration of these medicines. It is necessary to control serum lithium levels. It is recommended to control serum phenytoin levels. Pirocutan may reduce the effect of diuretics and antihypertensives.

Pirocutan may reduce the effect of ACE-inhibitors. Furthermore, during concomitant use, the risk for occurrence of renal function disorders may increase.

The simultaneous use of Pirocutan 20 mg and potassium-sparing diuretics may lead to increased potassium blood levels.

The simultaneous use of Pirocutan 20 mg with other nonsteroidal antiinflammatories or with glucocorticoids increases the risk for gastrointestinal ulcers or bleeding.

Antiplatelets, such as acetylsalicylic acid and some antidepressants (selective serotonin reuptake inhibitors [SSRI]), or iron chelators (deferasirox), may increase the risk for gastrointestinal bleeding.

Taking Pirocutan 20 mg within 24 hours before or after taking methotrexate, may lead to rised concentration of methotrexate and enhanced side effects.

During concomitant use of cyclosporin with some non-steroidal antiinflammatories, the risk for renal impairing effect is increased. This effect can not be ruled out for the combination of cyclosporin with piroxicam.

Medicines which contain probenecid (to treat gout) or cimetidine (to treat gastrointestinal ulcers), may slow down the elimination of piroxicam. In this way, the piroxicam content in the body may increase leading to enhanced side effects.

The concomitant take of phenobarbital causes a decrease in piroxicam serum concentration, reducing in such way the effect of the latter.

The simultaneous take of Pirocutan 20 mg and anticoagulants (e.g. coumarine derivatives), can increase the anticoagulant effect. The use of piroxicam in combination with anticoagulants like warfarin, is contraindicated (see paragraph 2. “Do not take Pirocutan 20 mg”).

Clinical studies have shown interactions between non-steroidal antiinflammators and sulfonylureas (antidiabetic drugs). Even though till now, interactions between piroxicam and sulfonylureas have not been described, as a precaution, during concomitant use, blood sugar levels should be controlled.

The risk for seizures may increase during simultaneous use of non-steroidal antiinflammators with quinolones.

### **Taking Pirocutan with food and drinks**

During use of Pirocutan you should possibly not drink alcohol.

### **Pregnancy and lactation**

Talk to your doctor or pharmacist before taking / using any medicine.

#### Pregnancy

If during use of Pirocutan you become pregnant, the doctor should be informed. Piroxicam may be used during the first and second trimester of pregnancy only after talking with the doctor. In the last trimester of pregnancy Pirocutan should not be used because of the increased risk for complications for the mother and the child.

#### Lactation

The active substance piroxicam passes in small amounts in breast milk. Thus, Pirocutan should not be taken during breastfeeding.

## **Driving and operating machinery**

Since during use of Pirocutan 20 mg in high doses, side effects in central nervous system may occur, like fatigue and dizziness, sometimes the ability to react may change, affecting the ability to drive or to operate machinery. This is enhanced if concomitantly is consumed alcohol. You may not react with the right velocity in unexpected situations. In such case, you should not drive or operate machinery.

## **Important informations about some of the excipients of Pirocutan**

This medicinal product contains lactose. Take Pirocutan only after talking to your doctor if you know that you suffer from intolerance to some sugars.

### **3. HOW TO TAKE PIROCUTAN?**

#### **If not otherwise prescribed by the doctor, follow these dosage recommendations:**

Always take Pirocutan as your doctor has told you. Talk to your doctor or pharmacist if you are not sure.

Your doctor will check you regularly for being sure that you take the right dose of piroxicam. You should never, in any circumstance, change the dose by yourself without consulting prior your doctor.

#### **Adults and elderly people**

The maximum daily dose is 20 mg piroxicam as single dose.

If you are over 70 years old, your doctor may prescribe a lower dose or may reduce the duration of treatment.

Your doctor may prescribe Pirocutan 20 mg at the same time with another medicine to protect the stomach and intestine from gastrointestinal side effects.

Adults take 1 tablet Pirocutan 20 mg daily (corresponding to 20 mg piroxicam).

The dose should not be increased. If you have the impression that the medicinal product has not the right effect, talk to your doctor.

Take Pirocutan 20 mg whole, with a considerable quantity of liquid (e. g. a glass of water) during or after food.

Your doctor will decide the duration of treatment.

In rheumatic diseases may be necessary to take Pirocutan for a longer period.

### **If you take more Pirocutan than you should**

Signs of an overdose may be: abdominal pain, nausea and vomiting, bleeding, headache, dizziness, lightheadedness, convulsions and loss of conscience. Other symptoms of an overdose may be: impaired renal function (blood and / or proteins in urine, acute failure) and impaired liver function.

There is no specific antidote.

The use of antiacids and activated charcoal reduces plasmatic levels.

If you suspect for an overdose with Pirocutan, inform your doctor, who will decide, depending on the overdose, for the measures to be taken.

### **If you forget to take Pirocutan**

Take the dose as soon as you remember. If it is almost time for the next dose, skip the forgotten dose and continue the treatment according the recommendations. The dose should not be doubled.

If you have any further questions on the use of this medicine, ask your doctor.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, piroxicam can cause side effects, although not everybody gets them. If you notice the following side effects, talk to your doctor to know what to do.

For the evaluation of side effects, the following frequencies have been used:

Very common:	More than 1 patient among 10
Common:	1 to 10 patients among 100
Uncommon:	1 to 10 patients among 1,000
Rare:	1 to 10 patients among 10,000
Very rare:	Less than 1 patient among 10,000
Unknown:	Frequency cannot be estimated from the available data.

For the following side effects, it should be kept in mind that they are dose-related and vary from patient to patient.

The most common side effects occur in the gastrointestinal tract. Especially in the elderly, gastroduodenal ulcers, perforations or bleeding, sometimes fatal, may occur.

Nausea, vomiting, diarrhea, bloating, constipation, digestive disorders, abdominal pain, stools with blood, vomiting with blood, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported. Less commonly has been noticed inflammation of the gastric mucosa.

Edema, high blood pressure and heart failure have been reported following treatment with NSAID.

Medicines like Pirocutan 20 mg may be associated with a small increased risk for heart attack or stroke.

#### Cardiac disorders

Very rare: palpitations, water retention (edema), heart failure, heart attack.

#### Blood and lymphatic system disorders

Very rare: blood disorders (anaemia, leucopenia, thrombocytopenia, pancitopenia, agranulocytosis).

The first signs may be: temperature, sore throat, superficial wounds in the mouth, flu-like symptoms, severe fatigue, nose bleeding and bruising.

The duration and severity of bleeding may increase from piroxicam.

In long-term treatment, blood count should be checked regularly.

#### Nervous system disorders

Common: central nervous disorders, such as: headache, dizziness and fatigue.

Very rare: convulsions.

#### Psychiatric disorders

Frequency not known: confusion, depression, hallucinations, sleep disorders, mood altered.

## Eye disorders

Uncommon: visual disturbances.

Frequency not known: eye irritation, eye swelling.

## Ear and labyrinth disorders

Common: tinnitus.

## Gastrointestinal tract disorders

Very common: gastrointestinal symptoms, such as: heartburn, abdominal pain, nausea, vomiting, bloating, diarrhea, constipation and small gastrointestinal bleeding, which in some cases may cause anaemia.

Common: gastric / duodenal ulcers, sometimes with hemorrhage and perforation, ulcerative stomatitis, exacerbation of ulcerative colitis and Crohn's disease.

Uncommon: inflammation of the gastric mucosa (gastritis).

Very rare: esophagitis and pancreatitis, discomfort in the lower part of the abdomen e.g. nonspecific, hemorrhagic inflammation of the intestine.

If you experience severe pain in the upper part of the abdomen, vomiting with blood, stools with blood and / or dark stools, you should stop taking Pirocutan and immediately contact your doctor.

## Renal and urinary tract disorders

Common: raise of blood urea.

Uncommon: edema, particularly in patients with hypertension or impaired renal function (renal failure).

Very rare: renal tissue damage (interstitial nephritis, papillary necrosis), which may be associated with acute renal failure, proteinuria and / or blood in urine (hematuria); nephrotic syndrome (edema and increased elimination of proteins in urine).

Urine reduction, edema, usually of the lower leg, which do not respond to treatment with diuretics, and general malaise may be signs of renal disease, even renal failure.

The renal function should be regularly monitored.

## Skin and subcutaneous tissue disorders

Common: rash.

Uncommon: photosensitivity of the skin with itching, redness and rash till vesicular rash, allergic edema.

Very rare: severe skin reactions, potentially life - threatening (Stevens-Johnson syndrome and toxic epidermal necrolysis), hair loss (alopecia), nail growth disorders.

Not known: fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching.

## Infections and infestations

Very rare: a deterioration of the inflammation caused by infection (e.g. development of necrotizing fasciitis) has been described with long-term use of non-steroidal anti-inflammatory drugs, where Pirocutan is part.

If during use of Pirocutan, signs of an infection occur (e. g. redness, swelling, pain, fever) or are exacerbated, you should immediately consult a doctor.

## Vascular disorders

Very rare: high blood pressure, ecchimosis (purpura Schoenlein-Henoch), vasculitis, oral and mucosal bleeding.

## Immune system disorders

Very rare: severe hypersensitivity reactions.

The first signs may be: swelling of the face, tongue and larynx, edema, breathing difficulties, palpitations, severe circulatory disorders till life-threatening shock. If any of these signs occur, which may be even at the beginning of the treatment, medical aid should be required immediately.

## Metabolism and nutrition disorders

Common: hyperglycaemia

Uncommon: hypoglycaemia

### General disorders and administration site conditions

Common: weight changes.

### Hepatobiliary disorders

Common: raise of liver values (raise of transaminases and alkaline phosphatases)

Rare: jaundice (cholestatic syndrome), acute liver inflammation (hepatitis)

Very rare: toxic liver failure.

If you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.

## **5. HOW TO STORE PIROCUTAN?**

Keep this medicine out of the sight and reach of children!

Do not store above 25°C!

Do not use this medicine after the expiry date which is stated on the package.

## **6. OTHER INFORMATION**

### **What Pirocutan – tablets 20 mg contain.**

The **active substance** is piroxicam.

1 tablet contains 20 mg piroxicam.

The **excipients** are: lactose monohydrate, hyprolose, magnesium stearate, microcrystalline cellulose.

### **Content of the pack**

Box with 30 tablets.

**Marketing Authorization Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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