FELDENE®

Piroxicam

FELDENE 20 mg/1 ml, solution for injection in ampoule (IM)

Reference Market : France

PACKAGE LEAFLET

Information for the user
FELDENE 20 mg/1 mL solution for injection in ampoule (IM)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. WHAT FELDENE 20 MG/1 ML SOLUTION FOR INJECTION IN AMPOULE (IM) IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: NON-STEROIDAL ANTI-INFLAMMATORIES – ATC code: M01AC01.

Before prescribing you piroxicam, your doctor must evaluate the benefits that this medicine could have for you compared to the risk of developing side effects. Your doctor will only prescribe you piroxicam if your symptoms are not sufficiently relieved with other non-steroidal anti-inflammatories (NSAIDs).

FELDENE 20 mg/1 mL solution for injection in ampoules is used as short-term treatment to relieve certain symptoms during episodes of rheumatoid arthritis and ankylosing spondyloarthritis (rheumatic conditions of the spine), such as swelling, stiffness and joint pain.

This medicine is used by injection when the oral and rectal routes cannot be used.

2. BEFORE YOU TAKE FELDENE 20 MG/1 ML SOLUTION FOR INJECTION IN AMPOULE (IM)

Never take FELDENE 20 mg/1 mL, solution for injection in ampoule (IM)

- if you are allergic to the active substance or to any of the other ingredients of this medicine, listed in section 6,
- if you are pregnant, from the start of the 6th month of pregnancy (beyond 24 weeks of amenorrhoea),
- history of allergy or asthma triggered by taking this medicine or another similar medicine, particularly other non-steroidal anti-inflammatories, aspirin,
- history of severe skin reactions such as exfoliative dermatitis (intense reddening of the skin with peeling of the skin in scales or layers), vesiculobullous reactions (Stevens-Johnson syndrome, a condition where the skin is bloody with red blisters, erosion and scabs) and Lyell's syndrome (serious skin condition characterised by blisters and the detachment of the upper layer of the skin),
- history of ulcers, bleeding or perforation of the stomach or intestines,
- current or past digestive disorders (inflammation of the stomach or intestines) that predispose you to bleeding disorders such as haemorrhagic rectocolitis, Crohn's disease, gastrointestinal cancers or diverticulitis (inflammation or infection of the vesicles of the colon),
- intake of acitretin,

- active duodenal or stomach ulcer,
- serious heart disease,
- serious liver disease,
- serious kidney disease,
- children under 15 years of age,
- aorto-coronary bypass (cardiac surgery to bypass a constricted artery),
- in premature infants and full-term newborns, as this medicine contains benzyl alcohol and propylene glycol (see "Warnings and precautions"),
- intake of mifamurtide.

If any of the situations above applies to you, you should not take piroxicam. Inform you doctor immediately if any of these situations applies to you.

IF YOU ARE UNSURE OF ANYTHING, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Warnings and precautions

Talk to your doctor or pharmacist before taking FELDENE 20 mg/1 mL, solution for injection in ampoule (IM).

Warnings

THIS MEDICINE SHOULD ONLY BE TAKEN UNDER MEDICAL SUPERVISION.

Be careful with FELDENE 20 mg/1 mL, solution for injection in ampoule (IM) and make sure you always inform your doctor before using it. As with all non-steroidal anti-inflammatories (NSAIDs), FELDENE 20 mg/1 mL, solution for injection in ampoule (IM) can cause serious gastrointestinal reactions, such as pain, bleeding, ulcer or perforation. The administration of doses greater than 20 mg per day increases the risk of gastrointestinal side effects.

Medicines such as FELDENE 20 mg/1 mL, solution for injection in ampoule (IM) could increase the risk of heart attack ("myocardial infarction") or stroke. The risk increases when the doses used are higher and the duration of treatment longer. Do not exceed the recommended doses nor the treatment duration.

If you have heart problems, if you have had a stroke or if you think you have risk factors for this type of disease (for example, if you have high blood pressure, diabetes, high cholesterol levels or if you are a smoker), inform you doctor or pharmacist.

INFORM YOUR DOCTOR:

- if you have a history of asthma associated with chronic rhinitis, chronic sinusitis or polyps in the nose. Administration of this medicine can cause an asthma attack, particularly in certain patients who are allergic to aspirin or a non-steroidal anti-inflammatory (see section "Never take FELDENE 20 mg/1 mL, solution for injection in ampoule (IM)"),

STOP TREATMENT IMMEDIATELY AND INFORM YOUR DOCTOR if you have:

- stomach pain, or any sign of gastrointestinal bleeding (blood coming up to the mouth, presence of blood in the stool or black coloured stool),
- allergic reaction as seen by a skin eruption, swelling of the face, wheezing or difficulty breathing,
- in the event of abnormalities or an aggravation of liver function.

Precautions

This medicine is available in other dosage forms that can be more suitable.

It is important to inform the doctor preparing your prescription if you have any of the following, as this will require dose adjustment:

- if you have a history of digestive events (digestive bleeding, hiatal hernia, history of stomach or duodenal ulcer),
- if you have heart, liver or kidney disease.

If you are over 70 years of age, your doctor may need to reduce the treatment duration and see you more frequently during the period of piroxicam administration.

If you are over 70 years of age or if you are taking medicines such as corticosteroids or other medicines against depression called selective serotonin reuptake inhibitors (SSRIs) or acetylsalicylic acid to prevent the formation of blood clots, or if you consume alcohol, your doctor may prescribe you a medicine to protect your gastric mucosa at the same time as FELDENE 20 mg/1 mL solution for injection in ampoule (IM).

You must not take this medicine if you are over 80 years of age.

If you have current or past medical problems or allergies, or if you are not sure if you should use piroxicam, please inform your doctor before using this medicine.

Make sure that you have told your doctor all the other medicines that you may be taking, including those that you purchased without a prescription.

IF YOU ARE UNSURE OF ANYTHING, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Children and adolescents

Not applicable.

Other medicines and FELDENE 20 mg/1 mL solution for injection in ampoule (IM)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please inform your doctor of the other medicines that you are taking or have recently taken (during the last week), including medicines that you purchased yourself without a prescription.

Some medicines can sometimes interfere with the activity of other medicines. Your doctor may limit your use of piroxicam or other medicines or give you a different medicine. It is particularly important to inform him or her:

- if you are taking mifamurtide,
- if you are taking acitretin,
- if you are taking acetylsalicylic acid or another non-steroidal anti-inflammatory for pain relief,
- if you are taking oral corticosteroids, which are medicines that are given to treat various conditions such as allergies and hormonal imbalances,
- if you are taking anticoagulants such as coumarin-type derivatives (warfarin) and direct oral anticoagulants (for example apixaban, dabigatran, rivaroxaban) to prevent blood clots from forming,
- if you are taking certain medicines intended to treat depression called selective serotonin reuptake inhibitors (SSRIs), lithium,
- if you are taking medicines such as acetylsalicylic acid to prevent platelet aggregation,
- if you are taking methotrexate,
- if you are taking heparins,
- if you are taking other potassium-sparing agents,
- if you are taking pemetrexed (used to treat lung cancer),
- if you are taking cyclosporin, tacrolimus (used to decrease the body's defences in the case of transplants or certain skin diseases),
- if you are taking medicines for hypertension,
- if you are taking diuretics,
- if you are taking deferasirox,
- if you are taking tenofovir disoproxil,
- if you are taking nicotinic acid,
- if you are taking medicines causing a withdrawal reaction,
- if you are taking vitamin K antagonists,
- if you are taking irreversible MAOIs,
- if you are taking insulin,

- if you are taking sedatives,
- if you are taking metformin,
- if you are taking hypoglycaemic sulfamides,
- if you are taking pentoxifylline,
- if you are taking platelet anti-aggregants,
- if you are taking cobimetinib,
- if you are taking mixed adrenergic-serotonergic drugs,
- if you are taking nicorandil.

FELDENE 20 mg/1 mL, solution for injection in ampoule (IM) with food and drink

Not applicable.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Before the beginning of the 6th month of pregnancy (up to the 24th week of amenorrhoea), you should not take this medication except in case of absolute necessity determined by your doctor, due to the potential risk of miscarriages or deformities. In this case, the dose should be as low as possible and the duration of treatment as short as possible.

From the start of the 6th month until the end of pregnancy (beyond 24th week of amenorrhoea), this medicine is **contraindicated**, which means that you MUST NOT take this medicine, because the effects on your baby, especially on his/her heart, lungs and/or kidneys, can be serious or even fatal, even with a single dose.

Benzyl alcohol may cross the placental barrier (see below).

If you have taken this medicine while pregnant, talk to your obstetrician-gynaecologist immediately, to make sure that you are offered suitable monitoring if necessary.

Breast-feeding

As this medicine passes into breast milk, it is not recommended to use it while breast-feeding.

Fertility

Like all non-steroidal anti-inflammatories (NSAIDs), this medicinal product can alter fertility in women and cause difficulties in becoming pregnant, being reversible when the treatment is discontinued. Tell your doctor if you are planning to become pregnant or having difficulties conceiving.

Driving vehicles and using machines

In rare cases, use of this medicine can cause dizziness and drowsiness.

FELDENE 20 MG/1 ML, SOLUTION FOR INJECTION IN ampoule (IM) contains benzyl alcohol, ethanol, propylene glycol and sodium.

This medicine contains 20 mg of benzyl alcohol per ampoule.

Benzyl alcohol can lead to allergic reactions.

Benzyl alcohol, a preservative, is associated with a risk of serious adverse events, including breathing problems (called “gasping syndrome”) and death in young children. While at the usual therapeutic doses, the quantities of benzyl alcohol delivered are considerably less than doses at the origin of “gasping syndrome”, the minimum quantity of benzyl alcohol for which toxicity may occur is not known. Premature infants and infants with a low birth weight have a greater risk of presenting with toxicity. It may also cause toxic reactions and allergic reactions in infants and children up to 3 years old (see “Never use FELDENE 20 mg/1 mL, solution for injection in ampoule (IM) in following cases”).

Inform your doctor or pharmacist if you are pregnant or if you are breast-feeding. Large quantities of benzyl alcohol can accumulate in your body and cause side effects (called “metabolic acidosis”).

Inform your doctor or pharmacist if you have a liver or kidney disease. Large quantities of benzyl alcohol can accumulate in your body and cause side effects (called “metabolic acidosis”).

WARNING THE ALCOHOL CONTENT OF THE SOLUTION IS 12.6% (V/V) OR 100 mg OF ALCOHOL PER ampoule.

This medicine contains 12.6% volume of ethanol (alcohol), i.e. 100 mg per ampoule, *which is the equivalent of 2.47 mL of beer or 1.03 mL of wine per* ampoule.

The use of this medicine is dangerous in alcoholic subjects and should be taken into consideration in women who are pregnant or breast-feeding, children and high-risk groups, such as those with hepatic insufficiency or epilepsy.

This medicine contains 400 mg of propylene glycol per ampoule *and may cause similar symptoms to those caused by alcohol.*

If you are pregnant or breastfeeding, do not use this medicine except on your doctor's advice. Your doctor might proceed to additional examinations while you are taking this medicine.

If you have a liver or kidney disease, use this medicine only if advised by your doctor. Your doctor might proceed to complementary examinations while you are taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially "sodium-free”.

3. HOW TO USE FELDENE 20 mg/1 mL solution for injection in AMPOULE (IM)?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Posology

Adults and elderly patients:

The maximum daily dose is 20 milligrams (1 ampoule) of piroxicam in a single daily dose.

Your doctor may prescribe you another medicine intended to protect your stomach and intestines against possible side effects in combination with piroxicam.

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

Method of administration

Intramuscular route.

This medicine can be injected either with a glass syringe or with a single-use syringe.

Inject the medicine as soon as you fill up the syringe.

The injections must be administered deeply and slowly under strictly aseptic conditions in the upper-outer quadrant of the buttock. If repeated injections are given, change sides for each injection.

It is important to pull back slightly on the plunger before injecting the medicinal product to make sure that the tip of the needle is not in a blood vessel.

If the injection is very painful, stop the injection immediately.

If you have a hip prosthesis, administer the injection contralaterally.

Frequency of administration

One single injection per day.

IN ALL CASES, STRICTLY FOLLOW YOUR DOCTOR’S INSTRUCTIONS.

Duration of treatment

It is on the order of 2 or 3 days. Beyond that, continue oral or rectal treatment.

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

If you have used more FELDENE 20 mg/1 mL, solution for injection in ampoule (IM) than you should have

Immediately consult your doctor or pharmacist.

If you forget to use FELDENE 20 mg/1 mL, solution for injection in ampoule (IM):

Not applicable.

If you stop using FELDENE 20 mg/1 mL, solution for injection in ampoule (IM):

Not applicable.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, but not everyone gets them.

Medicines such as FELDENE 20 mg/1 mL solution for injection in ampoule could increase the risk of heart attack ("myocardial infarction") or stroke.

The following may occur:

- allergic reactions:
  - skin reactions such as skin rash, itching, a strong reaction when skin is exposed to the sun or UV rays, worsening of chronic hives,
  - respiratory reactions such as an asthma attack,
  - general reactions such as anaphylaxis, acute inflammation of blood vessels (vasculitis), hives on the face with difficulty breathing (angio-oedema), severe allergic reactions related to the appearance of antibodies (serum sickness).
- in rare cases, blister-type bullous skin lesions all over the body and sometimes on the mucosa,
- in exceptional cases, jaundice.

In certain rare cases, digestive bleeding may occur (blood coming up to the mouth or in the stool, black coloured stool). This type of bleeding becomes more frequent with higher doses.

In all cases, you must stop treatment immediately and inform your doctor.

During treatment, the following may occur:

- digestive disorders: loss of appetite, heavy feeling in the abdomen, nausea, vomiting, constipation, diarrhoea, flatulence, abdominal pain, bloating,
- headache, drowsiness, dizziness, meningitis (stiffness of the neck with fever and sometimes coma), sight disorders or buzzing in the ears, swelling of certain parts of the body due to liquid infiltrating into the tissues (oedema, particularly in the legs) and in exceptional cases, decreased hearing,
- effects related to the route of administration:
  - in rare cases: pain at the injection site,
  - occasionally: local burning sensations.

You must inform your doctor if you experience these effects.

Other side effects may occur:

- ulcers or gastrointestinal perforations, inflammation of the mouth and exceptionally severe inflammation of the liver and pancreas have been observed,
- some biological changes may potentially require blood tests, a liver and kidney panel,
  - reversible kidney function disorders,
  - abnormally low levels of certain cells in the blood that can be seen as paleness or intense fatigue (red blood cells), signs of infection or unexplained fever (white blood cells), bleeding from the nose or gums (platelets) or abnormally high levels of other cells in the blood,
  - liver function disorders that are usually temporary or reversible,
  - fluid retention,

- hypertension,
- decreased fertility in women.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FELDENE 20 mg/1 mL solution for injection in AMPOULE (IM)

Do not store above 25°C

Keep out of the reach and sight of children.

Do not use FELDENE 20 mg/1ml solution for injection in ampoule (IM) after the expiry date which is stated on the outer packaging.

Once opened the product should be used immediately.

The expiry date refers to the last day of that month.

Keep this medicine away from light.

Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What FELDENE 20mg/1 mL solution for injection in *ampoule* (IM) contains

- The active substance is:

Piroxicam ..... 20.00 mg

For one ampoule

- The other ingredients are:

Sodium dihydrate dihydrogen sulphate, nicotinamide, propylene glycol (E1520), ethanol, benzyl alcohol, sodium hydroxide, hydrochloric acid, water for injection (see section 2).

What FELDENE 20 mg/1 mL solution for injection in *ampoule* (IM) *look* like and contents of the pack

This medicine is in the form of solution for injection in a ampoule of 1 mL. Carton of 1 or 2 or 3 ampoules.

Not all pack sizes may be marketed.

Marketing authorisation holder

PFIZER HOLDING FRANCE
23-25, AVENUE DU DOCTEUR LANNELONGUE
75014 PARIS, FRANCE

Manufacturer

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37530 POCE-SUR-CISSE, FRANCE

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

Council of Arab Health Ministers

Union of Arabic Pharmacists