Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed without a doctor's prescription

Feldene Gel®
Piroxicam 0.5% (5 mg/g)

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use the medicine according to the instructions in the dosing section of this leaflet. Consult your pharmacist if you need further information. Contact your doctor if your symptoms of illness get worse or do not improve after 4 weeks.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For application on the skin, to relieve conditions characterized by pain and inflammation, e.g., relieving pain and reducing swelling affecting joints and muscles.

Therapeutic group:
Nonsteroidal anti-inflammatory drugs (NSAIDs)

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (see section 6).
- you are sensitive (allergic) to aspirin preparations or to other anti-inflammatory preparations or if these preparations caused side effects such as difficulty breathing, nasal polyps, skin irritation and inflammation.

Do not use the medicine without consulting a doctor before starting treatment:
- If you suffer, or have suffered in the past, from impaired liver or kidney function.

Special warnings regarding use of the medicine
- Use of piroxicam has been reported to be associated with skin reactions that may be life-threatening, e.g., DRESS syndrome, Stevens-Johnson syndrome and toxic epidermal necrolysis. The skin rash on the body may first appear as red, focal spots or round patches with blisters in the middle. Additional signs to examine include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These life-threatening skin reactions are usually accompanied by flue-like symptoms. The rash may spread as blisters or skin peeling. The highest risk of the occurrence of skin reactions is in the first week of treatment.
- If you developed a serious skin reaction after using piroxicam in the past, do not use it again.
- Treatment should be discontinued immediately at the first appearance of skin rash, blistering, peeling of the skin, mucosal lesions, or any other symptom of hypersensitivity. In such case, contact your doctor immediately and inform your doctor that you are using Feldene Gel®. These reactions have not been associated with topical piroxicam use, but the possibility of occurring with topical piroxicam cannot be ruled out. Reported cases of DRESS syndrome following piroxicam use have been present only after systemic treatment, and the likelihood of DRESS syndrome following topical treatment with piroxicam is currently unknown.
- Nonsteroidal anti-inflammatory preparations, including Feldene Gel®, may cause kidney damage or kidney failure.

Children and adolescents
Feldene Gel® is not intended for treating children below the age of 12 years.

Drug interactions
No drug interactions between Feldene Gel® and other medicines are known.
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Pregnancy, breastfeeding, and fertility

If you are trying to become pregnant or are undergoing fertility tests, cessation of treatment with this preparation should be considered. Feldene Gel® may increase the risk of miscarriages in the early stages of pregnancy.
If you are pregnant, are planning to become pregnant, or if you are breastfeeding, consult a doctor before starting treatment.

Driving and using machines
Use of Feldene Gel® is not expected to affect your ability to drive or use machines.

Important information about some of this medicine's ingredients
Feldene Gel® contains propylene glycol, benzyl alcohol and ethanol
Feldene Gel® contains 200 mg/g propylene glycol. Propylene glycol may cause skin irritation. Do not use this medicine on open wounds or large areas of broken or damaged skin (such as burns) without consulting with your doctor or pharmacist.

Feldene Gel® contains 10 mg/g benzyl alcohol. Benzyl alcohol may cause mild local irritation and may also cause allergic reactions.
Feldene Gel® contains 250 mg/g alcohol (ethanol 96%). The alcohol may cause a burning sensation on damaged skin.

The alcohol from this medicine may be absorbed through the skin in babies and may cause systemic toxicity. In babies less than 4 weeks old, including babies that are prematurely born, high concentrations of ethanol may cause severe local reactions and also general toxic side effects as it would be absorbed through the baby's skin (especially if skin is covered).

3. HOW TO USE THIS MEDICINE?
Always use this preparation according to your doctor's or pharmacist's instructions.
Check with the doctor or pharmacist if you are uncertain and need further information.

Attention: Do not swallow!
Feldene Gel® is intended for external use only, for application on the skin.

Pierce the tube by reversing the cap and screwing down to break the seal on the tube.
The usual dosage, unless instructed otherwise by the doctor:
Apply 1 gram (approximately 3 cm) of the gel on the affected area 3-4 times a day.
If there is no improvement in the symptoms, inform the doctor.

Instructions for use:
Apply the gel and rub it in until absorbed into the skin. If the gel is not fully absorbed, mild temporary staining of the skin and staining of the clothing may occur. Do not use this preparation for a period exceeding four weeks without informing the pharmacist or doctor.
Do not apply near the eyes, nose, mouth, genitals or rectum, on mucous tissues or in places where the skin is damaged, for example: wounds, scratches, infections or dermatitis. If the preparation comes into contact with these areas, wash the area thoroughly with water.
Do not cover/bandage the area treated with Feldene Gel®.
After using the preparation: Recap the tube and wash your hands.

Do not exceed the recommended dose.

If you used an excessive amount (too high a dosage) or if the medicine was accidentally swallowed
It is unlikely that use of an excessive amount of the preparation will cause side effects.
If someone accidentally swallowed some of the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to use the medicine at the scheduled time, use it as soon as you remember, unless it is time for the next application. Never use a double amount!

If you stop using this medicine, the pain may return.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Feldene Gel® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking this medicine and contact a doctor immediately if you experience any of the following effects:

Sudden wheezing, breathing difficulties, fever, swelling of the eyelids, face or lips, widespread rash or itching on the entire body.

These effects are rare, but they may be serious.

Severe skin reaction that may be life-threatening and is characterized by a skin rash, sometimes accompanied by blisters and sores (e.g., Stevens-Johnson syndrome and toxic epidermal necrolysis) – very rare.

Additional side effects:

Redness, rash and/or local itching at the application site (e.g., eczema, contact dermatitis), fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching. The frequency of this reaction is unknown.

Skin reaction upon exposure to sunlight.

Additional side effects that occur infrequently:

Nausea, digestive system discomfort and disturbances.

These effects should resolve upon discontinuing use of the preparation. If the digestive system disturbances continue after discontinuing use of the preparation, consult your doctor or pharmacist.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- The preparation should be used within 6 months after first opening, and in any event no later than the expiry date.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Purified water, ethanol 96%, propylene glycol, diisopropanol amine, benzyl alcohol, carbopol 980, hydroxyethyl cellulose.

What the medicine looks like and contents of the pack:

A clear, slightly yellowish gel with a characteristic alcohol scent.

Each Feldene Gel® tube contains 25, 50 or 100 gram of gel.

Not all pack sizes may be marketed.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725.

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

Feldene Gel®: 113.55.26646

Revised in 10/2021 according to the Ministry of Health guidelines.