

**PATIENT PACKAGE INSERT  
IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

**EXIPAN®  
Gel 0.5% W/W  
Roll-on bottle, Tube**

**The active ingredient and its quantity:**  
Piroxicam 0.5% W/W

Inactive ingredients and allergens in the product – see section 2 "Important information regarding some of the ingredients of the medicine" and section 6 in the leaflet.

**Read this leaflet carefully in its entirety before using this medicine.** This leaflet contains concise information about the medicine.

If you have further questions, refer to the doctor or pharmacist.

Use this product according to the dosing instructions in section 3 of this leaflet. Consult the pharmacist if you require further information.

Contact your doctor if your symptoms of illness get worse or do not improve after four weeks.

**1. What is the medicine intended for?**

Exipan Gel is intended for local treatment of inflammatory conditions accompanied by pain.

**Therapeutic group** – Nonsteroidal anti-inflammatory drugs (NSAIDs).

**2. Before using the medicine**

**Do not use the medicine if:**

- you are sensitive (allergic) to the active ingredient piroxicam or to any of the other ingredients contained in the medicine (see section 6).
- you are sensitive (allergic) to aspirin or to other anti-inflammatory products or if these products have caused side effects of asthma, nasal polyps, allergic rhinitis, skin irritation and inflammation.

**Do not use the product 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 this product**

- Use of Exipan Gel has been reported to be associated with skin reactions that may be life-threatening such as DRESS syndrome, Stevens-Johnson syndrome and toxic epidermal necrolysis. The skin rash on the body may first appear as clustered red spots or round patched with blisters in the middle. Additional symptoms that should be checked include: ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These life-threatening skin reactions are generally accompanied by flu-like symptoms. The rash may spread as blisters or peeling skin. The highest risk of occurrence of these 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, blisters, peeling of the skin, mucosal lesions, or any other symptom of hypersensitivity. In such a case refer to a doctor immediately and inform them that you are using Exipan Gel.
- Nonsteroidal anti-inflammatory products, including Exipan Gel, may cause kidney damage or kidney failure.

**Warning! Flammable, keep away from fire. Do not light a cigarette or be exposed to an open flame until the product has dried completely.**

**Children and adolescents**

Exipan Gel is not intended for treating children below the age of 12 years.

**Drug interactions**

**No drug interactions between Exipan Gel and other medicines are known. If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.**

**Pregnancy, breastfeeding and fertility**

If you are trying to become pregnant or undergoing fertility tests, consider cessation of treatment with the product.

Exipan Gel may increase the risk of miscarriages in the early stages of pregnancy.

Consult a doctor before starting treatment if you are pregnant, planning to become pregnant or are breastfeeding.

This product has a possible side effect of kidney damage in the fetus and reduced amniotic fluid starting from the 20<sup>th</sup> week of pregnancy. It is recommended to avoid using products from the NSAIDs group from the 20<sup>th</sup> week of pregnancy and to consult a medical staff member if necessary.

**Driving and using machines**

The use of Exipan Gel is not expected to affect your ability to drive or use machines.

**Important information regarding some of the ingredients of the medicine**

Exipan Gel contains:

- Parabens which may cause allergic reactions (delayed reactions may occur).
- About 18.1 grams of ethanol 95% in each 100 grams, which may cause a burning sensation on damaged skin.

The alcohol in this product 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, a high concentration of ethanol may cause severe local reactions and also general toxic side effects, as it will be absorbed through the baby's skin (especially if the skin is covered).

**3. How to use this medicine**

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the product.

The usual dosage is:

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:**

**Roll-on bottle:**

Massage the painful area using the roll-on ball at the top of the bottle for about half a minute.

Afterwards, you can massage the area by hand until the gel has been fully absorbed into the skin (until the gel "disappears").

Wash your hands after use.

**Note:** If the medicine is not used regularly, a thin and yellowish layer with a typical smell may form on the roll-on ball. This layer does not affect the quality and

activity of the medicine. Wipe the roll-on ball until the layer disappears and the odor disappears with it.

**Tube:**

Apply the gel and rub it in until it is absorbed into the skin. If the gel is not entirely absorbed, mild temporary staining of the skin and staining of the clothing may occur.

Do not use this medicine for a period exceeding four weeks without informing the pharmacist or doctor.

Do not apply near the eyes, nose, mouth, genital or anal area, on mucous tissues or on places where the skin is injured, or on any other skin condition that affects the treated area. If the gel comes into contact with these areas, wash the area thoroughly with water.

Do not cover/bandage the area treated with Exipan Gel.

**After using the medicine:** Close the tube or the roll-on bottle tightly and wash your hands.

**Do not exceed the recommended dose! Attention: Do not swallow! Exipan Gel is intended for external use only, for application to the skin.**

**If you used an excess amount (too high a dosage) or if the medicine was accidentally swallowed**

Use of an excess amount of the medicine is unlikely to cause side effects.

If someone accidentally swallowed the medicine, immediately refer to 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 use. **Under no circumstances should you use a double amount!**

**If you stop using the medicine,** your pain may return

**Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

**4. Side effects**

As with any medicine, use of Exipan Gel may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Discontinue use and refer to a doctor immediately if you experience the following effects:**

Sudden wheezing, breathing difficulties, fever, swelling of the eyelids, face or lips, rash or itching all over the body. The frequency of these effects is rare, but they can be serious.

A severe skin reaction that can 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 itching in the area of application (e.g., eczema, skin inflammation), fixed drug eruption (may look like round or oval patches of skin redness and swelling), blistering (hives), itching. The frequency of this reaction is unknown. A skin reaction upon exposure to sunlight.

**Additional side effects that occur infrequently:**

Nausea, digestive system discomfort and disturbances. These side effects should pass upon discontinuing use of the medicine.

If the digestive system disturbances continue after discontinuing use of the product, consult your doctor or the pharmacist.

**If a side effect appears, if one of the side effects worsens, or if you experience a side effect not mentioned in this leaflet, consult the doctor.**

**Reporting of side effects:**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) which directs to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

Additionally, you can report to Padagis via the following address: [padagis.co.il](mailto:padagis.co.il)

**5. How to store the medicine**

- Avoid poisoning! This medicine and any other medicine must be stored in a safe 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 the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Can be used for 6 months after first opening, and in any case not later than the expiry date.

**6. Additional information**

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

Purified Water, Alcohol 95%, Diethylene Glycol Monoethylether (Transcutol), Cetiol HE, Hydroxyethyl Cellulose (Natrosol), Poloxyl-(23)-Lauryl Ether (BRIJ 35), Trolamine, Arfacel 186, Methyl Parahydroxybenzoate (Methyl Paraben), Propyl Parahydroxybenzoate (Propyl Paraben)

**What the medicine looks like and what the package contains:** Exipan Gel is a clear-yellowish gel in a tube containing 50 grams, or in a roll-on bottle containing 90 ml. Not all package sizes may be marketed.

• Manufacturer, Registration holder and its address: Padagis Israel Pharmaceuticals Ltd., 1 Rakefet St., Shoham.

• Registration number of the medicine in the National Drug Registry of the Ministry of Health: 065-11-27132-00

• Revised in March 2022 according to MOH guidelines.

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