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 per dosage unit:
Piroxicam 0.5% W/W
Inactive and allergenic ingredients in the product – see section 2 'Important information about some of the ingredients of the medicine' and section 6 'Further information' in the leaflet.
Read the leaflet carefully in its entirety before using the product. This leaflet contains concise information about the product.
If you have further questions, refer to the doctor or pharmacist.
Use the product according to the dosage instructions in section 3 in this leaflet. Consult the pharmacist if you need further information.
Refer to a doctor if the symptoms of the disease worsen or do not improve after four weeks.

1. WHAT IS THE MEDICINE INTENDED FOR?

Exipan Gel is intended for topical 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 additional ingredients contained in the medicine (see section 6 'Further information').
- you are sensitive (allergic) to aspirin products or to other anti-inflammatory products or if these products caused side effects such as difficulty in breathing, itching, skin irritation and redness.

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 the medicine
- Use of piroxicam has been reported to be associated with onset of 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 on the trunk. 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 skin peeling. The highest risk for occurrence of skin reactions is within the first week of treatment.
- If you developed a serious skin reaction after using piroxicam in the past, do not use it again.
- Stop the treatment immediately at the onset of a skin rash, blisters, skin peeling, mucosal sores or any other symptom of hypersensitivity. Similarly, in case of development of sores on the mucosal tissue, such as the lips or inside of the cheek, refer to a doctor immediately and inform him that you are using Exipan Gel.
  These reactions have not been linked to topical use of piroxicam, but their occurrence after topical use of piroxicam cannot be ruled out.
  DRESS syndrome after use of piroxicam has only been reported after systemic treatment, and the likelihood of DRESS syndrome after topical treatment with piroxicam is currently unknown.
- Nonsteroidal anti-inflammatory products, including Exipan Gel, may cause kidney damage or kidney failure.

Caution! Inflammable material, keep away from fire! Do not light a cigarette or be exposed to fire before the product has completely dried.

Children and adolescents
Exipan Gel is not intended for the treatment of children under 12 years of age.

Drug interactions
There are no known drug interactions between Exipan Gel and other medicines. **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 are undergoing fertility tests, cessation of treatment with this product should be considered.
Exipan Gel may increase the risk of miscarriages in the early stages of pregnancy.
If you are pregnant, are planning to become pregnant, or are breastfeeding, consult a doctor before starting treatment.
From week 20 of pregnancy, kidney damage in the fetus and low amniotic fluid are possible side effects of this product. It is recommended to avoid using NSAIDs starting from week 20 of pregnancy and to consult a healthcare professional, if needed.

Driving and operating machinery
Use of Exipan Gel is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of the medicine
Exipan Gel contains:
- parabens which can cause allergic reactions (late reactions can occur).
- about 181 mg/g of ethanol 95%, 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 under 4 weeks of age, including premature babies, a high concentration of ethanol may cause severe localized reactions and generalized toxic side effects, as it is absorbed through the baby's skin (especially if the skin is covered).

3. HOW SHOULD THE MEDICINE BE USED?

Check with the doctor or pharmacist if you are uncertain about the product dosage and treatment regimen.
The usual dosage is generally:
Apply 1 gram (approximately 3 cm) of gel on the affected area 3-4 times a day.
If there is no improvement in the symptoms after 4 weeks, inform the doctor.

Method of use:
Roll-on bottle:
Rub the painful area with the ball at the top of the bottle for approximately half a minute.
Then, the area can be rubbed with your hand until the gel is fully absorbed into the skin (until the gel "disappears").
Note: If the product is not used continuously, a thin, yellowish layer with a characteristic smell may form on the ball. This layer does not affect the quality and activity of the medicine. Wipe the ball until the layer along with the smell disappear.
Tube:
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 clothing may occur.
Do not apply near the eyes, nose, mouth, genitals or rectum, on mucosal tissues or in places where the skin is damaged, inflamed or in 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 product: Close the tube or roll-on bottle tightly and wash your hands.
Do not exceed the recommended dosage!
Attention: Do not swallow! Exipan Gel is intended for external use only, for application on the skin.

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

If you forgot to use this product at the required time, use it as soon as you remember, unless it is time for the next application. Do not use a double amount under any circumstances!

If you stop using the product, your 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 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 by the list of side effects. You may not suffer from any of them.

Stop using the product and refer to a doctor immediately if you experience the following effects:
- Sudden wheezing, breathing difficulties, fever, swelling of the eyelids, face or lips, widespread rash or itching on the entire body.
- Severe skin reaction that can be life-threatening and is characterized by a skin rash, which is 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 at the application site (e.g., eczema, skin inflammation), skin reaction upon exposure to sunlight.

Additional side effects that occur infrequently:
Nausea, digestive system discomfort and disturbances. These side effects should resolve upon discontinuing use of the medicine.
If the digestive system disturbances persist after discontinuing use of the product, consult your doctor or pharmacist.
If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting 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) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il
In addition, they can be reported to Padagis via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order 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 no later than the expiry date.
- Caution! Inflammable material; keep away from fire.

6. FURTHER 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, Arlacel 186, Methyl Parahydroxybenzoate (Methyl Paraben), Propyl Parahydroxybenzoate (Propyl Paraben)
- What the product looks like and the contents of the package: Exipan Gel is a clear-yellowish gel packaged in a tube containing 50 grams or in a roll-on bottle containing 90 mL. Not all package sizes may be marketed.
- Registration holder and manufacturer: 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 December 2023 in accordance with the Ministry of Health guidelines.