PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Ketospray 10%

Dermal spray

Composition:

Active ingredient:
1 ml of solution contains:
Ketoprofen 100 mg

Each spray dose (0.2 ml) contains:
Ketoprofen 20 mg

For a list of inactive ingredients and allergens in the medicine – please see section 2 under "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

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

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

Ketospray is intended for use in adults and adolescents over 12 years of age.

1. What is the medicine intended for?

Ketospray is given for local treatment of pain caused by trauma (e.g. sport injuries), such as bruising, strains, sprains, local hematomas, joint and muscle pain, and lower back pain.

Therapeutic class:
Ketospray is a medicine of the non-steroidal anti-inflammatory drugs (NSAIDs) class.
Ketospray is a spray for local use on the skin. **Ketospray** contains an active ingredient known as **ketoprofen**. This active ingredient belongs to a class of medicines called NSAID. This active ingredient has anti-inflammatory and analgesic properties.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient ketoprofen or to any of the other ingredients this medicine contains (please see section 6 – "Additional information").
- You have experienced in the past an allergic reaction, such as symptoms of asthma or allergic rhinitis (hay fever), to ketoprofen, aspirin (acetylsalicylic acid), fenofibrate, tiaprofenic acid, and to other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen.
- You experience any skin reaction, including skin reactions following concomitant use with products that contain octocrylene, an ingredient found in cosmetic and hygiene products such as: shampoos, aftershaves, shower gels, creams, lipsticks, make-up removers or hair sprays that delay photodegradation. In these cases, stop using the medicine **Ketospray** immediately.
- You have a history of sensitivity reactions to sunlight/UV light.
- You have a history of allergic skin reactions to ketoprofen, fenofibrate, tiaprofenic acid, UV blockers (sunscreen) or perfumes.
- You are under 12 years of age.
- You are in the last trimester of pregnancy.
- You suffer from skin conditions such as: eczema or acne, infected skin or open wounds. Do not use **Ketospray** on these areas.

Special warnings regarding the use of the medicine:
Talk to your doctor or pharmacist before starting treatment with **Ketospray**.

- Before treatment with the medicine, you should inform your doctor or pharmacist if you suffer from impaired function of the kidney/urinary system, heart or liver. In some cases, general side effects such as renal function impairment have been reported.
- Do not cover the treated area with an occlusive dressing.
- Do not use **Ketospray** in such a way that the medicine comes into contact with the eyes, ears or mucosal tissues (such as the mouth, genitals and anus).
- Exposure of the areas treated with **Ketospray** to sunlight (including on a cloudy/wintry day) or to UV light may cause severe skin reactions (photosensitisation). Therefore:
  - During the treatment and for two weeks after discontinuing the treatment, you should avoid sun exposure and ensure appropriate protection such as: long-sleeve clothes, hat, sunscreen etc. (do not use sunbeds).
  - Wash your hands thoroughly after using the medicine, except when treating your hands.
  - Stop the treatment immediately if a skin reaction appears after using **Ketospray**.
- Do not exceed the recommended duration of treatment, 7 days (see section 3 "How should you use the medicine?"), since the longer the treatment, the greater the risk of developing side effects such as dermatitis or sensitivity to light (photosensitisation).
- Patients who suffer from asthma, chronic respiratory disorders (such as bronchitis), hay fever, sinusitis and allergic rhinitis have a higher risk of developing asthma attacks, painful swelling of the skin and the mucosal tissues, especially in the face (Quincke's edema) or hives (urticaria – skin rash) as a result of using aspirin and/or other non-steroidal anti-inflammatory drugs (NSAIDs).

Children and adolescents:
This medicine should not be used in children under 12 years of age.

Drug interactions:
If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist.
Especially if you are taking:

- Anticoagulants (such as: coumadin derivatives)

Pregnancy, breastfeeding and fertility:
If you are pregnant, think you are pregnant, are planning to become pregnant or breastfeeding, do not use this medicine before consulting your doctor or pharmacist.
Pregnancy
Do not use **Ketospray** if you are in the last trimester of pregnancy.
Do not use **Ketospray** during the first 6 months of pregnancy, unless it is necessary and has been recommended by your doctor. If you need treatment during this period, use the lowest dosage for the shortest time possible.
Oral forms of administration of ketoprofen (such as tablets) may cause side effects in your unborn baby. It is not known whether the same risk applies when using ketoprofen on the skin.
Breastfeeding
Do not use **Ketospray** while breastfeeding, since there is not enough information on whether ketoprofen passes into breastmilk.

Driving and operating machinery:
No effect on driving or operating machinery is expected.

Important information about some of the ingredients of the medicine:
Ketospray contains propylene glycol.
Propylene glycol may irritate the skin.

3. How should you use the medicine?

Use according to your doctor's instructions. Check with your doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.
The dosage and treatment regimen will be determined only by your doctor.
The accepted dosage for adults and adolescents over 12 years of age is:
The number of sprays of the medicine depends on the treated area of the body, three times a day:

- For a small area such as a finger or a toe – two sprays
- For a medium area such as an ankle or wrist – four sprays
- For a large area such as a shoulder, knee or back – up to six sprays

- Do not cover the treated area with an occlusive dressing.
- Do not spray more than 18 sprays per day.

- After every 1-2 sprays, massage the medicine gently into the skin of the treated area and allow it to dry.
- Wash your hands thoroughly after use, except when treating your hands.
- Stop the treatment when your symptoms (such as: pain and swelling) subside, usually after about seven days of treatment.
- If there is no improvement in your condition within seven days, contact your doctor again.

Do not exceed the recommended dose.

If you accidentally use a higher dosage no toxicity effects are expected following an overdose of **Ketospray** on the skin.
If the amount of spray sprayed is higher than recommended, remove the remaining medicine using a cloth and/or wash the skin area which was sprayed with the medicine.

If you accidentally swallow the medicine, side effects may appear, depending on the amount swallowed.
In such a case, refer to a doctor or to a hospital emergency room immediately and bring the package of the medicine with you.

If you forget to use the medicine at the required time, do not spray a double dose of the medicine.

Follow the treatment as recommended by your doctor.

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

If you have any other questions regarding the use of the medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using **Ketospray** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

The most commonly reported side effects are local skin reactions.
Stop using the medicine immediately and refer to your doctor or pharmacist if you experience a skin reaction/irritation.

Uncommon side effects, effects that occur in 1-10 users out of 1,000:
- Itching
- Eczema
- Redness
- Burning sensation in the skin

Rare side effects, effects that occur in 1-10 users out of 10,000:
- Severe skin reactions due to sunlight exposure.
- Urticaria (hives).
- Cases of severe skin reactions, such as bullous eczema or phlytenular eczema (a skin disease with blisters and pustules) which may spread.

Very rare side effects, effects that occur in less than one user out of 10,000:
- Cases of worsening of existing renal insufficiency have been reported
- When using the medicine on extensive areas of the skin and for a prolonged period, it is impossible to rule out side effects (mainly of the digestive system) such as stomach ulcer, bleeding in the gastrointestinal tract or diarrhea.

Side effects with unknown frequency (effects whose frequency has not yet been determined):
- Anaphylactic shock (an allergic reaction, often accompanied by a decrease in blood pressure, dizziness, nausea and possibly breathing difficulties).
- Angioedema (an allergic painful swelling of the skin and the mucous membrane, especially in the face).
- Hypersensitivity reactions.

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

Reporting side effects:
Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il) which will direct you to the online form for reporting side effects, or by clicking on the following link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package.
- The expiry date refers to the last day of that month.

Storage conditions
- Store at a temperature lower than 25°C.
- Do not freeze, store in the original package and protect from light.
- Use this medicine within 12 months from opening the package (but do not continue using it beyond the expiry date appearing on the outer package).
- Do not discard medicines in wastewater or domestic trash. Ask the pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. Additional information

- In addition to the active ingredient ketoprofen, the medicine also contains:
  Isopropyl Alcohol, propylene glycol, macrogol 15 hydroxystearate, sodium hydroxide, disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, peppermint oil, purified Water
- What does the medicine look like and what are the contents of the package?
  Ketospray is a transparent to slightly yellowish solution, in a brown glass bottle with a spraying button and a cap.
- **Ketospray** contains spray for local use on the skin only
- Available in packages of 12.5 ml and 25 ml.
- Not all package sizes may be marketed.
- Marketing authorization holder and address: MegaPharm Ltd., 15 Hatidhar Raanana, Israel.
- Name and address of the manufacturer:
  Pharbil Waltrop GmbH, Waltrop, Germany
  For:
  CYATHUS Exquirere PharmaforschungsGmbH Korneuburg, Austria
- Revised in November 2024 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the national drug registry of the Ministry of Health: 144 45 33067.