



PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
This medicine can be sold with a doctor's prescription only

KETOSPRAY 10%

Dermal Spray

Composition:

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

Each spray dose (0.2 ml) contains: Ketoprofen 20 mg
The product contains 2.5% alcohol.

Read this entire leaflet carefully before you start taking this medicine. This leaflet contains concise information about the medicine. If you have any further 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.

Therapeutic group: Ketospray is a medicine of the non-steroidal anti-inflammatory drugs (NSAIDs) class.

What is the medicine used for?

Ketospray is a spray for local use on the skin. Ketospray contains an active ingredient named ketoprofen. This active ingredient belongs to the group of medicines named NSAID. This active ingredient has anti-inflammatory and pain relieving attributes. Ketospray is given for local treatment of pains caused by trauma (e.g. sport injuries), such as injuries, strains, sprains, local hematomas, joint and muscle pains and lower back pains.

Before using this medicine

Do not use this medicine if:

- Do not use this medicine if you have a known sensitivity to any of the medicines ingredients.
- Do not use this medicine if you have ever experienced an allergic reaction to aspirin, to other anti-inflammatory products (e.g. NSAIDs such as ketoprofen and ibuprofen), to fenofibrate, to tiaprofenic acid, to UV blockers, to different perfumes, to products containing octocrylene (an ingredient present in cosmetic and hygiene products such as: shampoo, aftershave, creams, lipstick etc.) or when these products caused symptoms of asthma, nasal polyps, allergic rhinitis or irritation and inflammations of the skin.
- A sensitivity reaction to sun or UV light appears.
- Do not use this medicine in children under 12 years.
- Do not use this medicine if you are in the last trimester of pregnancy.

Special warnings regarding the use of this medicine:

- Before treatment with this medicine inform your doctor if you suffer or have suffered in the past from impaired function of the respiratory tract (e.g. asthma); the gastrointestinal

tract (e.g. ulcer); the kidney/urinary tract; the heart and/or vascular system; the blood system (e.g. coagulation etc.) and the liver.

- Do not cover the treated area with a sealed dressing.
- Do not use Ketospray on sensitive skin such as mucous membranes (as the mouth, genitals and anus) or the eyes.
- Do not use Ketospray on damaged skin such as: eczema (an itching rash with scales) or acne, infectious skin or open wounds.
- This medicine may cause acute sensitivity upon exposure to the sun:** therefore, avoid exposure to the sun during the treatment and for two weeks after discontinuation of the treatment (including solarium treatments and exposure to UV rays) and take care to use appropriate protection such as: long clothes, a hat, sunscreen etc.
- Wash your hands thoroughly after use, unless your hands were the treated area.
- Do not exceed the recommended treatment duration, because the danger of developing side effects such as dermatitis or sensitivity to light increases **as the duration of the treatment gets longer.**

- Patients suffering from asthma, chronic diseases of the respiratory system (such as bronchitis), hay fever and allergic rhinitis are more likely to develop asthma attacks, swelling of the face or urticaria following use of aspirin and/or other anti-inflammatory non-steroidal medicines (NSAIDs).
- Stop the treatment immediately if you have a skin reaction following the use of Ketospray.

Children

Safety and efficacy in children have not been proved, therefore do not use this medicine in children under the age of 12 years.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements.

Especially inform your doctor or pharmacist if you are taking: anticoagulants (such as: coumarin derivatives)

Pregnancy and breastfeeding

If you are pregnant, think you are pregnant, planning to become pregnant or breastfeeding, do not use this medicine before consulting a doctor.

Do not use Ketospray if you are in the last trimester of pregnancy. It is not recommended to use Ketospray if you are in the first or second trimester of pregnancy. It is not recommended to use Ketospray during breastfeeding because small amounts might be transferred into the milk.

Driving and operating machinery

There is no expected effect on driving or operating machinery.

Ketospray contains Propylene glycol

Propylene glycol may cause skin irritation.

How to use this medicine

Always use according to doctors's instructions. Check with your doctor or pharmacist if you are not sure.

The dosage and administration will be determined by the doctor only. Do not exceed the recommended dose.

Recommended dosage for adults and adolescents above 12 years of age is:

- The number of sprays of the medicine is according to the treated area, three times within 24 hours:
- For a small organ such as a finger or toe – two sprays
 - For a medium size organ such as an ankle or wrist – four sprays
 - For a large organ such as a shoulder, knee or back – up to six sprays
 - Do not cover the treated area with a sealed dressing.
 - Do not spray more than 18 sprays within 24 hours.
 - After each 1-2 sprays, absorb the medicine into the skin by spreading it on the required area and wait for the skin to dry.
 - Wash your hands after use, unless your hands are the treated area.
 - Discontinue treatment once symptoms disappear (e.g.: pain and swelling), this usually occurs after approximately seven days of treatment.
 - If there is no improvement in your condition within seven days refer to your doctor again.

If you have accidentally taken an higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or hospital emergency room and bring the package of the medicine with you. Because Ketospray is given as local treatment, absorption into the blood circulation is low and signs of poisoning due to an overdose are unlikely.

If you forget to take this medicine at the specified time, do not take a double dose next time. Continue with the treatment as recommended by your doctor.

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

Side effects:

Like all medicines, Ketospray can cause side effects, although not everybody gets them. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Appear commonly:

- Local skin irritation (such as: redness, itching, eczema that can spread over the body and a burning sensation of the skin)

Appear rarely:

- Sensitivity to the sun and to light (photosensitivity), hives-like rash.
- More severe reactions of skin irritations such as: skin rash with blisters or fistulas which may spread.

Appear very rarely:

- Worsening of an existing renal insufficiency.

Appear at unknown frequency:

- Allergic reactions that may lead to breathing difficulties and/or may be severe (anaphylactic shock), angioedema, symptoms of hypersensitivity.

When used on large areas for a prolonged period of time, absorption into the blood system may occur. In this case, side effects which are typical to oral administration may appear, mainly in the digestive system (rare). If any of the side effects appears or worsens or if you experience

side effects not mentioned in this leaflet, consult your doctor.

How to store the medicine

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Store in a cool place, below 25°C.
- Store in the original package and protect from light.
- Use this medicine within 12 months from first opening the package.

إذا نسيت تناول الدواء في الوقت المطلوب، لا تتناول جرعة مضاعفة في المرة التالية. يجب المداومة على العلاج كما أوصى الطبيب.
إذا كانت لديك أسئلة إضافية حول استعمال الدواء، إستشر الطبيب أو الصيدلي.

الأعراض الجانبية

كل اي دواء قد يسبب اسخدام كيتوكسبرى اعراض جانبية لدى جزء من المستخدمين. لا تفرغ من قراءة قائمة الاعراض الجانبية من الممكن ان لا تصاب بأي واحدة منها.

ظهور في أوقات متقاربة:
• تهيج وحشسوي في الجلد (مثل: احمرار، حكة، اكزيما التي قد تنتشر في الجسم وشحور الارتفاع على الجلد)

ظهور في أوقات متباينة:
• حساسية للشمس والضوء، طفح يشبه الشرى
• ردود فعل أثرة حادة لنبيجات الجلد مثل: طفح جلدي مع بنور أو دوارتها قادر جداً

ظهور بتأثير غير معروف:
• ردود فعل حساسية، التي قد تؤدي لصعوبات في التنفس / أو قد تكون وخيمة (صدمة فاقية-anaphylactic shock)، وذمة وعائية، اعراض حساسية مفرطة.

عند الاستعمال على مساحات واسعة ولفترات مستمرة، قد يحدث امتصاص للجهاز الدموي في هذه الحالة قد تظهر اعراض جانبية المبنية على تناول الدواء عن طريق الفم، خاصة بالجهاز الهضمي (نادراً).
إذا ظافتت إحدى الأعراض الجانبية أو سنتها تماق من عرض جانبى لم يذكر في هذه النشرة، عليك استشارة الطبيب.

كيفية تخزين المستحضر

• يجب التسليم! يجب حفظ هذا الدواء وكل دواء آخر في مكان مغلق بعيداً عن متناول أيدي الأطفال و/أو الرضع وبذلك تمنع التسمم. لا تسبب التسمم دون تلفيات صريحة من الطبيب.

• لا جوز تناول أدوية في الطعام! تحقق من الملصق والجرعة الدوائية في كل مرة تتناول فيها دوا. ضع النظارات الطبية إذا لزم الأمر ذلك.

• لا يجوز استعمال الدواء بعد تاريح انتهاء الصلاحية (exp. date) الذي يظهر على العبوة اخراج الماء. تاريخ انتهاء الصلاحية يرجع إلى اليوم الأخير من نفس الشهر.

• يجب التخزين في مكان بارد، دون الـ 25 درجة مئوية.
• يجب التخزين في العبوة الأصلية والحماية من الضوء.
• يجب استعمال هذا الدواء خلال 12 شهر من لحظة فتح العبوة.

معلومات إضافية

• بالإضافة للبيانات المعلنة كيتوكسبرى وفين، يحتوى الدواء أيضاً على:
Propylene Glycol, Isopropyl Alcohol, Soy bean Lecithin, ethanol anhydrous, Sodium dihydrogen phosphate dihydrate, Disodium Phosphate dodecahydrate, Sodium Hydroxide, Peppermint Oil, Purified Water

• كيف يبدو الدواء وما هو محتوى كيتوكسبرى وفين: يحتوى كيتوكسبرى وفين على بخاخ للاستعمال الموضعي للجلد فقط الموجود في زجاجة بنية مع مكبس لإخراج الماء وقطعة، يأتى بعوائض من 12.0 غرام وـ 25 غرام.

• صاحب التسجيل وعنوانه: ميجافارم.م.ض، ص.ب. ٥١٩، هود هشaron ٤٠١٥١

• اسم المنتج وعنوانه: CYATHUS Exquirere Pharmaforschungs GmbH Rudolfsplatz 2/1/8, AT – 1010 Wien, AUSTRIA

• فحصت هذه النشرة رقم المصادقة عليها من قبل وزارة الصحة في ٢٠١٣ شباط.

• رقم تسجيل الدواء في سجل الأدوية الحكومي في وزارة الصحة: ٤٢٦٧٤٥٤٤٦٤.
• للتيسير وتسهيل القراءة، تحت صياغة هذه النشرة بصيغة المذكر.
• لكن الدواء مخصوص لكلا الجنسين.