SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Ketospray 10%

2. Qualitative and quantitative composition

Dermal spray.
Active substance: Ketoprofen 10%
1 ml of the solution contains 100 mg of ketoprofen.
1 spray puff (0.2 ml) contains 20 mg ketoprofen.

Excipient with known effect: propylene glycol (100mg/ml).
For excipients see section 6.1.

3. Pharmaceutical form

Cutaneous spray, colourless to slightly yellowish, transparent solution.

4. Clinical particulars

4.1 Therapeutic indications

Topical treatment for the symptomatic relief of soft tissue pain and inflammation due to strains, sprains, distortions, and contusions.

4.2 Posology and method of administration

Posology

Paediatric population: Ketospray 10% – Spray should not be used in children below 12 years of age because of safety and efficacy concerns.

Adults and children over 12 years:
A sufficient amount of solution should be applied on the skin in order to cover the affected area with Ketospray 10% - Spray. The number of spray puffs depends on the size of the area to be treated: 2 spray puffs for small joints (fingers, toes), 4 spray puffs for medium-sized joints (wrist, ankle) and up to 6 spray puffs for large joints (shoulder, knee) or larger areas (f.i. on the back). Therefore 0.4 – 1.2 ml spray are applied per application, which equals 40 – 120 mg ketoprofen. Treatment should be carried out 3 times per day. The maximum daily dose should not exceed 18 spray puffs (equals 3.6 ml spray, or 360 mg ketoprofen).
The solution is gently spread over the affected area after 1 – 2 spray puffs each and let dry.

Elderly:
The same dosage as for adults may be applied.

Method of administration
Adults and children over 12 years of age:
Do not apply occlusive dressing to the treated area.
Hands should be washed subsequently, unless they are also included in the treatment. The treatment may be stopped after the symptoms (pain and swellings) have eased. 7 days duration of treatment is sufficient in most cases.

4.3 Contraindications

Ketospray 10% – Spray must not be used in the following cases:

- Hypersensitivity to the active substance ketoprofen, or any of the excipients listed in section 6.1;
- Children under 12 years of age.
- History of hypersensitivity reactions, such as symptoms of asthma, or allergic rhinitis due to ketoprofen, fenofibrate, tiaprofenic acid, acetylsalicylic acid, or any other NSAIDs;
- History of any photosensitivity reactions.
- History of skin reactions to ketoprofen, tiaprofenic acid, fenofibrate, UV blockers or perfumes;
- Sun exposure, even in case of hazy sunlight, including UV light from solarium, during the treatment and for 2 weeks after its discontinuation;
- On pathological skin changes such as eczema or acne; or in infected skin or open wounds;
- Third trimester of pregnancy (see section 4.6);

4.4 Special warning and precautions for use

- Ketospray 10% – Spray should be used with caution in patients with reduced heart, liver or renal function: isolated cases of systemic adverse reactions consisting of renal affections have been reported.
- Ketospray 10% – Spray must not be used with occlusive dressings.
- Ketospray 10% – Spray must not come into contact with mucous membranes (in the oral, genital, or anal area) or the eyes.
- Treatment should be discontinued immediately upon development of any skin reaction including cutaneous reactions after co-application of products containing octocrylene .
- It is recommended to protect treated areas by wearing clothing during all the application of the product and two weeks following its discontinuation to avoid the risk of photosensitization.
- Hands should be washed thoroughly after each application of Ketospray 10% – Spray.
- The recommended length of treatment of up to 7 days should not be exceeded because the risk of developing contact dermatitis and photosensitivity reactions increases over time.
- Patients with asthma, chronic obstructive respiratory disorders, hay fever or swelling of the nasal mucous membrane are more likely to react to acetylsalicylic acid and/or NSAID’s with asthma attacks, Quincke's edema or urticaria than other patients.
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Propylene glycol

Ketospray contains propylene glycol. This ingredient may cause irritations of the skin.

4.5Interactions with other medicinal products

Interactions are unlikely as serum concentrations following topical administration are low. Serious interactions have been recorded after use of high dose methotrexate with non-steroidal anti-inflammatory agents, including ketoprofen, when administered by the systemic route. It is advisable to monitor patients under treatment with anticoagulants such as coumarinic substances.

4.6 Fertility, Pregnancy and lactation

In absence of clinical experience with the cutaneous form and by reference to the systemic forms:

Pregnancy

There are no clinical data from the use of topical forms of ketoprofen during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic ketoprofen exposure reached after topical administration can be harmful to an embryo/fetus. During the first and second trimester of pregnancy, Ketospray should not be used unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors including ketoprofen may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy, prolonged bleeding time in both mother and child may occur, and labour can be delayed. Therefore, Ketospray 10% is contraindicated during the third trimester of pregnancy (see section 4.3).

Breastfeeding
There is only insufficient information on whether ketoprofen/metabolites pass(es) into mothers' milk. Risk for the newborn/child cannot be excluded. Therefore, Ketospray should not be used by breast-feeding mothers.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Frequencies of undesirable effects are given as follows:
Very common (>1/10); common (>1/100, <1/10); uncommon (>1/1,000, <1/100); rare (>1/10,000, <1/1,000); very rare (<1/10,000) and not known (frequency cannot be estimated from the data available).

The most commonly reported side effects are local skin reactions.

System organ class	Frequency	
Immune System disorders	*Not known*	Anaphylactic shock, angioedema (Quincke-edema), hypersensitivity reactions.
Skin and subcutaneous tissue disorders	*Uncommon*	Local skin reactions such as erythema, eczema, pruritus and burning sensations.
	Rare	Dermatological: Photosensitisation, urticaria. Cases of more severe reactions such as bullous or phlyctenular eczema which may spread or become generalized.
Renal and urinary disorders	*Very rare*	Cases of aggravation of previous renal insufficiency.
Gastrointestinal disorders	*Very rare*	Stomach ulcer, gastrointestinal bleeding, diarrhea

Reporting of suspected adverse reactions***:***
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

If too much spray is applied, it should be wiped off with a cloth and/or the affected skin areas should be rinsed.
No toxic effects are to be expected after a topical overdose of Ketospray 10%.
If accidentally ingested, the spray may cause systemic adverse effects depending on the amount ingested, such as gastrointestinal disorders.
In that case treatment should be supportive and symptomatic in accordance with overdose of oral NSAID's(antiphlogistics).

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Topical products for joint and muscular pain. Nonsteroidal antiphlogistics for topical use.
ATC Code: M02AA10
Ketospray 10% - contains ketoprofen, a non-steroidal antiphlogistic. As such it possesses analgesic, anti-inflammatory and anti-rheumatic properties. These effects are mainly due to the inhibition of prostaglandine synthesis.

5.2 Pharmacokinetic Properties

The percutaneous resorption of ketoprofen is slow. Bioavailability of ketoprofen after topical administration has been estimated to be approximately 5% of the level obtained after a similar dose administered orally. Due to the low rate of resorption a local antiphlogistic and analgetic effect is achieved.
After metabolism of ketoprofen in the liver the pharmacologically inactive metabolites are mainly excreted through the kidneys as glucuronide conjugate.

5.3 Preclinical Safety Data

After chronic oral administration of ketoprofen in animals, gastrointestinal lesions and renal changes typical of non-steroidal antiphlogistic drugs have been observed. Animal experiments have not indicated any mutagenic or carcinogenic effects of ketoprofen.
Based on conventional pharmacologic studies concerning safety, toxicity at repeated administration, genotoxicity and cancerogenic potential the pre-clinical data did not reveal any special risks for humans.

6. Pharmaceutical Particulars

6.1 List of Excipients

Propylene Glycol, Isopropyl Alcohol, Macrogol 15 hydroxystearate, Sodium Hydroxide (to adjust the pH), Disodium hydrogen phosphate dodecahydrate, Sodium dihydrogen phosphate dehydrate, Peppermint Oil, Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Can be used for 1 year after first opening, and no later than the expiry date of the product.

6.4 Special precautions for storage

Do not freeze. Store below 25°C. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of the container

Amber glass bottle with spray pump and protective cap; cardboard carton; bottles of 12.5 ml or 25 ml solution.

6.6 Instructions for use and handling

No special requirements.

7. Manufacturer:
Pharbil Waltrop GmbH, Waltrop, Germany
For
CYATHUS Exquirere Pharmafoschungs GmbH
Korneuburg, AUSTRIA

8. License Holder:
MegaPharm 15 Hatidhar street, Israel

9. Marketing Authorization Number(s)

144-45-33067

10. Revised in September 2024 according to MOH's guidelines.

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