

PATIENT INFORMATION LEAFLET

ELEKTRA 1.25 % Gel

It is applied externally.

- **Active ingredient:** 1 g of gel contains 18.45 mg of dexketoprofen trometamol, which corresponds to 12.5 mg of dexketoprofen as an active ingredient.
- **Excipients:** Carbomer, lavender essence, ethyl alcohol, deionized water, potassium hydroxide solution.

Please read this INSTRUCTIONS FOR USE carefully before you start using this medicine, because it contains important information for you.

- *Keep these instructions for use. You may need to read it again later.*
- *If you have any additional questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital.*
- *Follow exactly what is written in this instruction. Do not use **high or low** doses other than the dose recommended to you about the drug.*

In This Leaflet:

1. *What ELEKTRA is and what it is used for?*
2. *What you need to know before you use ELEKTRA?*
3. *How to use ELEKTRA?*
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1. What ELEKTRA is and what it is used for?

ELEKTRA is a painkiller from a group of drugs called nonsteroidal anti-inflammatory drugs (NSAIDs).

ELEKTRA is used in the treatment of painful and inflammatory conditions of traumatic or degenerative origin in [®]

ELEKTRA acts by preventing or reducing the formation of substances that cause pain and inflammation in damaged areas of [®] When applied locally, the gel reduces pain and swelling in the applied area.

ELEKTRA gel contains dexketoprofen (as trometamol) as an active ingredient and is presented in an aluminium tube containing 60 g of gel.

2. What you need to know before you use ELEKTRA?

DO NOT use ELEKTRA if:

If

- If you are allergic (hypersensitivity) to dexketoprofen tromethamol or any of the excipients in ELEKTRA,
- If you are allergic to acetylsalicylic acid (aspirin) or other nonsteroidal anti-inflammatory drugs,
- If you have asthma or have had an asthma attack, acute allergic rhinitis (short-term inflammation in the nose due to allergies), nasal polyps (masses in the nose due to allergies), urticaria (skin rash), swelling of the face and throat (swelling of the face, eyes, lips or tongue, or difficulty breathing) or wheezing in the chest (wheezing) as a result of allergies after using acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs in the past,
- Do not use if you are in the third trimester of your pregnancy or breastfeeding.
- It should not be applied to open wounds or permanently present skin lesions.
- It should not be applied to the mucous membranes, eyes and anal or genital area.
- ELEKTRA should not be administered with an [®]

Take special care with ELEKTRA with caution in the following situations

- Topically, products that are used for a long time, especially for a long time, can cause sensitivity and regional irritation.
- In order to prevent possible light sensitivity or hypersensitivity, direct sunlight, UVA and solarium should be avoided during the treatment and until two weeks have passed since the treatment.
- Although it has little systemic effect, it should be used with caution in those with severe renal impairment or liver disease.
- Treatment should be discontinued immediately if a skin reaction occurs after administration of ELEKTRA.

If these warnings apply to you, even at any time in the past, please consult your doctor

Use of ELEKTRA with food and beverage

Since it is applied by rubbing on the skin, it is not expected to interact with food and drink.

Pregnancy

Consult your doctor or pharmacist before using the medicine.

It is not recommended to [®] during the third trimester of your pregnancy.

Use ELEKTRA with caution during the first or second trimester of your pregnancy.

If you are pregnant or planning to become pregnant, consult your doctor before using ELEKTRA.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Lactation

Consult your doctor or pharmacist before using the medicine.

If you are breastfeeding your baby, consult your doctor before using ELEKTRA.

The use of ELEKTRA during breastfeeding is not recommended.

Driving and using machines

There is no known effect on the use of vehicles and machines.

Concomitant use with other drugs

Since dexketoprofen passes into the systemic circulation in very small amounts as a result of topical application, drug and other interactions are almost never seen.

Concomitant use with other non-steroidal anti-inflammatory drugs (NSAIDs) may lead to an increased risk of side effects.

If you are currently using or have recently used any prescription or over-the-counter medication, please tell your doctor or pharmacist about them.

3. How to use ELEKTRA?**Instructions for proper use and dose/frequency of administration:**

It can be rubbed into the painful area 2-3 times a day.

The course of treatment should be no more than 7 days.

Unless otherwise recommended by the doctor, use in the specified doses.

Route and method of administration:

ELEKTRA is administered[®] externally.

By rubbing gently, it should be ensured that the gel is completely absorbed.

Hands should be washed thoroughly after[®].

Different age groups:**Use in children:**

Since there is no indication or dose in children under 6 years of age, it is not recommended for use in this age group.

Use in the elderly:

No dose adjustment is required in elderly patients.

Specific use cases:**Renal/Hepatic impairment:**

Although it has little systemic effect, it should be used with caution in patients with severe renal impairment or severe hepatic impairment.

If you have an impression that the effect of ELEKTRA is too strong or weak, talk to your doctor or pharmacist.

If you[®] than you should:

Do not use more than 7.5 g (about 14 cm gel) of ELEKTRA gel per day.

If it is accidentally taken by mouth, notify your doctor immediately or go to the emergency department of the nearest hospital.

If you have used more of ELEKTRA than you should, talk to a doctor or pharmacist.

If you forget to use ELEKTRA:

Do not take double doses to compensate for forgotten doses.

Effects that may occur when treatment[®] is terminated:

None.

4. Possible side effects

Like all medicines, people who are sensitive to the ingredients in ELEKTRA[®] may have side effects.

Rare side effects (seen in at least 1 in 10,000 patients; in up to 1 in 1000 patients)

- Dermatitis (Redness of the skin, severe itching, swelling, watering, crusting, dandruff)

Very rare side effects (seen in at least 1 in 10,000 patients)

- Hypersensitivity reactions (hives, swelling of the face, eyes, lips, or tongue, or difficulty breathing)

Side effects of unknown frequency

- Photosensitivity reactions (fluid-filled blisters on the skin, redness)

If you experience any side effects that are not mentioned in this instructions for use, inform your doctor or pharmacist.

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

5. How to store ELEKTRA?

Keep ELEKTRA out of sight and reach of children and in its packaging.

Store below 30°C.

Use in accordance with the expiry date.

Do not use ELEKTRA after the expiry date on the packaging.

If you notice defects in the product and/or its packaging, do not use ELEKTRA.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization

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This leaflet has been approved <{DD month YYYY}>.

[To be completed nationally]