Package leaflet: Information for the user

Kenacort-T 40 mg/ml, suspension for injection

triamcinolone acetonide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kenacort-T is and what it is used for

Kenacort-T contains the active ingredient triamcinolone acetonide, a synthetic adrenocortical hormone (a glucocorticoid), which suppresses the immune system.

Kenacort-T is used to suppress the immune system in the following conditions:
- Rheumatoid arthritis;
- Certain skin diseases;
- Allergic rhinitis;
- Allergic asthma.

Kenacort-T is injected into the gluteal muscle (intramuscularly) or into a joint (intra-articularly). The effect of Kenacort-T often lasts approximately 2 to 4 weeks.

Triamcinolon acetonide found in Kenacort-T may also be approved to treat other diseases not mentioned in this product information. Ask your doctor, pharmacist or other health professional if you have any further questions and always follow their instructions.

2. What you need to know before you use Kenacort-T

Do not use Kenacort-T:
- If you are allergic to triamcinolone acetonide or any of the other ingredients of this medicine (listed in section 6)
- If you have certain infections (e.g. tuberculosis or gonorrhoea).

Warnings and precautions
Talk to your doctor before using Kenacort-T:
- If you suffer from osteoporosis;
- If you have a recently performed anastomosis (operation to connect blood vessels or intestines);
- If you suffer or have suffered from psychosis;
- If you have a gastric ulcer or a duodenal ulcer;

- If you have tuberculosis;
- If you have diabetes;
- If you have high blood pressure;
- If you have heart failure;
- If you have an infection;
- If you are planning to get vaccinated.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents
Caution should be exercised when giving Kenacort-T to growing individuals.
Kenacort-T should not be given to children under 6 years of age because they may experience severe allergy-like reactions.
This medicine should not be given to premature or newborn infants.

Other medicines and Kenacort-T
If you are planning to get vaccinated you should mention that you have been given Kenacort-T because it may affect the efficacy of the vaccine.

Kenacort-T may affect the way the certain medicines which contain the following active ingredients work, or they may affect the way Kenacort-T works:
- *Rifampicin* (an antibiotic);
- *Phenytoin, phenobarbital and carbamazepine* (used to treat e.g. epilepsy).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is a risk of teratogenic effects.

Driving and using machines
Kenacort-T may cause vertigo, which may affect your ability to drive and operate machinery.

Kenacort-T contains benzyl alcohol and sodium
Benzyl alcohol
Kenacort-T contains benzyl alcohol as a preservative. Benzyl alcohol can cause allergic reactions. This medicine contains 9.9 mg of benzyl alcohol per one millilitre (ml). Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3 years old. Benzyl alcohol is associated with the risk of serious side effects such as difficulty breathing in young children.

If you are pregnant or breast-feeding, consult your doctor or pharmacist before using this medicine. Large amounts of benzyl alcohol can be stored in the body and cause side effects (metabolic acidosis).

If you have impaired liver function or kidney function, consult your doctor or pharmacist before using this medicine. Large amounts of benzyl alcohol can be stored in the body and cause side effects (metabolic acidosis).

Sodium
Kenacort-T contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium-free’.

3. How to use Kenacort-T

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Kenacort-T is administered by your doctor or nurse as an injection either into the gluteal muscle or into a joint, depending on what you are being treated for. The dose is determined by your doctor, who will adjust it individually for you.

Use in children
Kenacort-T should not be given to children under 6 years of age because they may experience severe allergy-like reactions.
This medicine must not be given to premature or newborn infants.

If you use more Kenacort-T than you should
If you have taken more medicine than you should, or if children have taken the medicine by accident, please contact your doctor or hospital.

The probability of an acute overdose is small. Treatment is usually not required.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Method of administration
STRICT ASEPTIC TECHNIQUE IS MANDATORY. The vial should be shaken before use to ensure a uniform suspension. Prior to withdrawal, the suspension should be inspected for clumping or granular appearance (agglomeration). Agglomeration occurs when the drug substance separates from the solution and appears as a white precipitate in the vial. An agglomerated product should be discarded and should not be used. After withdrawal, inject without delay to prevent settling in the syringe.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur during treatment with Kenacort-T:

Possible serious side effects include serious allergic reactions, which may cause shortness of breath (also included in the list below).

Common (may affect more than 1 in 100 people):
- Local atrophy of the skin and soft tissue (when injected under the skin)
- Atrophy of subcutaneous tissue (when injected into a joint)
- Local irritation and pain (when injected into and around a joint).

Uncommon (may affect up to 1 in 100 people):
- Allergic reactions, sometimes severe allergic reactions which may cause shortness of breath
- Vertigo
- Transient flushing of the face

The following side effects may occur in long-term treatment (repeated injections) with Kenacort-T:
Side effects affecting the whole body are uncommon in local treatment, but they may occur in long-term treatment with repeated injections given locally into the skin or into the joints.

Common (may affect more than 1 in 100 people):
- Cataracts

Uncommon (may affect up to 1 in 100 people):
- Blood clot
- High blood pressure in the head
- High blood pressure
- Cushingoid symptoms (e.g. weight increase with accumulation of fat, muscular weakness, tendency to bruise easily, pimples, osteoporosis, mood effects)
- Impaired adrenal function
- High sodium levels
- Low potassium levels
- Elevated blood sugar
- Accumulation of fluid (oedema)
- Death of bone tissue
- Muscle atrophy
- Psychological problems (e.g. emotional disturbances)
- Glaucoma
- Osteoporosis
- Muscle weakness
- Menstrual disturbances
- Bleeding after the menopause
- Impaired wound healing
- Nitrogen deficiency

Not known (frequency cannot be estimated from the available data):
- Activation of a pre-existing infection (e.g. tuberculosis)
- Weakened immune system
- Activation of latent diabetes
- Blurred vision
- Visual impairment

Additional side effects in children
In long-term treatment (which may affect the whole body), growth of the child may be slower.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kenacort-T

Keep this medicine out of the sight and reach of children.

Store between 15 °C-25 °C.
Do not refrigerate or freeze. Store in the original package in order to protect from light. Store in an upright position. Shake before use. See section 3.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kenacort-T contains
- The active substance is triamcinolone acetonide.
- The other ingredients are carmellose sodium, sodium chloride, polysorbate 80, benzyl alcohol, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), water for injections.

What Kenacort-T looks like and contents of the pack
Kenacort-T is a suspension.
Each pack of Kenacort-T contains 1 vial containing 1 ml suspension.

Marketing Authorisation Holder
To be completed nationally

Manufacturer
To be completed nationally

This leaflet was last revised in 2024-08-06