SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Kenacort-T 40 mg/ml, suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 40 mg triamcinolone acetonide.

Excipients with known effect: benzyl alcohol 9.9 mg.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Conditions where an anti-inflammatory and immunosuppressive effect is desired, such as rheumatoid arthritis and dermatoses. Parenteral glucocorticoid therapy. Allergic rhinitis, allergic asthma.

4.2 Posology and method of administration

Kenacort-T 40 mg/ml suspension for injection is for intramuscular or intra-articular injection only.

Kenacort-T 40 mg/ml suspension for injection is not for intravenous, intraocular, epidural or intrathecal injection (see section 4.4).

Posology

Intramuscular use
Adults and children aged over 12 years
Hay fever and pollen asthma: 40-100 mg. If symptoms return, one or more additional injections should be given. Rheumatoid arthritis, dermatoses and other conditions: Initially: approximately 60 mg. The dosage range is 40-80 mg depending on response and duration. In continued treatment, a dose of 20 mg or lower may be sufficient.

Children aged 6 to 12 year
All indications: 40 mg. The dosage should nevertheless be adjusted according to the severity of symptoms rather than according to body weight or age.

In *maintenance therapy* for all age groups: The product should be given when symptoms return and not according to a predefined schedule. Usually, the effect of 1 ml Kenacort-T 40 mg/ml lasts from 2 to 4 weeks. Single doses exceeding 2.5 ml (100 mg) are not recommended.

When switching from oral therapy, the first injection should be given at the same time as the last oral dose. If high oral doses have been given previously, injections every 14 days may be necessary initially to maintain a comparable steroid effect.

Intra-articular use
Standard doses: Small joints, 0.25 ml; medium-sized joints (elbow, wrist) 0.5 ml; large joints (shoulder, knee, hip) 1 ml.

Method of administration

Intramuscular use
Injections are given deep into the gluteal musculature and the site of injection should be varied. Subcutaneous or intradermal administration should be avoided, as atrophy of fatty tissue may develop.

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.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Local therapy: Local viral and bacterial infections, e.g. tuberculosis and gonorrhoea.

4.4 Special warnings and precautions for use

In systemic treatment, corticosteroids should be given with caution in the presence of: Osteoporosis, recent anastomosis, psychosis, ulcus ventriculi et duodeni, tuberculosis, diabetes, hypertension, cardiac insufficiency.

In infections, corticosteroids should be given with extreme caution, initiating causal therapy at the same time.

Kenacort-T must not be administered epidurally or intrathecally. Serious undesirable effects have been reported with epidural and intrathecal administration.

Corticosteroids given in high doses may interfere with active immunisation. Vaccination with live vaccines should be performed under close supervision.

Adequate studies to demonstrate the safety of Kenacort-T use by intraocular (intravitreal) injections have not been performed.

In addition to serious injection-related complications such as endophthalmitis, eye inflammation, increased intraocular pressure, chorioretinopathy, including crystalline maculopathy and viral retinitis (mainly by cytomegalovirus), cataracts and visual disturbances have been reported after intraocular (intravitreal) administration of triamcinolone.

The preservative (benzyl alcohol) in Kenacort-T has also been associated with retinotoxic effects in animal studies.
Kenacort-T 40 mg/ml suspension for injection is not for intravenous, intraocular, epidural or intrathecal injection (see section 4.2).

Cases of serious anaphylactic reactions and anaphylactic shock, including death, have been reported in individuals receiving triamcinolone acetonide, regardless of the route of administration.

Menstrual irregularities may occur and in postmenopausal women vaginal bleeding has been observed. This possibility should be mentioned to female patients but should not deter appropriate investigations as indicated.

Kenacort-T contains benzyl alcohol as a preservative.

Due to the potential risk of accumulation and toxicity (metabolic acidosis) with exposure to excessive amounts of benzyl alcohol, large doses should be used with caution and only if necessary, especially in patients with impaired liver or renal function. Benzyl alcohol may also cause allergic reactions.

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

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids including triamcinolone acetonide.

Paediatric population
The product should be given with caution to growing individuals, and it should not be given to children aged less than 6 years.
This medicinal product contains benzyl alcohol which has been associated with the risk of serious side effects such as breathing difficulties ("gasping syndrome") in young children.
Benzyl alcohol may cause toxic reactions and/or anaphylactoid reactions in infants and children up to 3 years old. This medicine must not be given to premature or newborn infants.

4.5 Interaction with other medicinal products and other forms of interaction

Glucocorticoids interact with the following substances and may require dosage adjustment:

Rifampicin
Rifampicin induces the microsomal oxidation of glucocorticoids (hydrocortisone, prednisolone, methylprednisolone). This results in increased need for steroids during treatment with rifampicin and reduced need for steroids after such treatment.

Phenytoin, phenobarbital and carbamazepine
Phenobarbital (which is a metabolite of primidone), phenytoin and carbamazepine, administered separately or in combination, induce the metabolism of hydrocortisone, prednisolone and methylprednisolone (demonstrated in children with asthma) and fludrocortisone resulting in the need of increased dose. It is likely that this interaction is applicable to the entire group of glucocorticoids.

4.6 Fertility, pregnancy and lactation

Pregnancy
Animal studies have shown reproductive toxicity (see section 5.3). The relevance to humans is unknown. Reduced placental and birth weights have been observed in humans after long-term treatment. Long-term treatment is also associated with a risk of adrenal suppression in the newborn child. Therefore, corticosteroids should only be given during pregnancy after careful consideration. Please see also section 4.4 concerning the risk of benzyl alcohol build-up, which can lead to toxicity (metabolic acidosis).

Breastfeeding
Triamcinolone passes into breast milk; at therapeutic doses, however, the risk to the child appears to be unlikely. Please see also section 4.4 concerning the risk of benzyl alcohol build-up, which can lead to toxicity (metabolic acidosis).

4.7 Effects on ability to drive and use machines

Vertigo may occur as an undesirable effect. In these circumstances judgment and the ability to react may be impaired; therefore, caution should be observed when driving or performing work requiring precision.

4.8 Undesirable effects

Systemic undesirable effects are uncommon in *local therapy*; however, they cannot be excluded in long-term therapy with repeated injections given into the skin and joints.

Undesirable effects are presented in the table below. Undesirable effects are presented by system organ class and frequency. Frequencies have been defined as follows: common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), not known (cannot be estimated from the available data).

System Organ Class	Frequency	Local therapy	Systemic undesirable effects*
Immune system disorders	Uncommon	Hypersensitivity, anaphylactic/anaphylactoid reaction with or without bronchospasm, anaphylactic shock	
	Not known		Decreased resistance to infections and activation of latent infections, e.g. tuberculosis
Endocrine disorders	Uncommon	Systemic effects	Cushingoid symptoms, adrenal suppression
Metabolism and nutrition disorders	Uncommon		Sodium retention, fluid retention, high blood sugar
	Not known		Activation of latent diabetes mellitus
Psychiatric disorders	Uncommon		Psychological symptoms, including affective symptoms
Nervous system disorders	Uncommon		Benign intracranial hypertension.
Eye disorders	Common		Cataracts
	Uncommon		Glaucoma
	Not known		Central serous chorioretinopathy (see also section 4.4), blurred vision, visual impairment (see also section 4.4)
Ear and labyrinth disorders	Uncommon	Vertigo	
Vascular disorders	Uncommon		Hypertension, embolism
Skin and subcutaneous tissue disorders	Common	Local atrophy of the skin and soft tissue (subcutaneous injections), subcutaneous atrophy (intra-articular injections.)	
	Uncommon	Transient flushing of the face	
Musculoskeletal and connective tissue disorders	Uncommon		Osteoporosis, osteonecrosis, muscular weakness, muscle atrophy, growth retardation in children
Reproductive system and breast disorders	Uncommon		Menstrual irregularities, amenorrhoea, postmenopausal vaginal bleeding

General disorders and administration site conditions	Common	Local irritation and pain (injection into and around joints)	
	Uncommon		Impaired wound healing
Investigations	Uncommon		Hypokalaemia, nitrogen balance negative

* The following undesirable effects are signs of systemic effects and may occur in long-term treatment with repeated injections into the skin and joints.

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V:

4.9 Overdose

Toxicity and symptoms: Acute toxicity with even massive doses not usually constitute a clinical problem. Acute overdosage may possibly aggravate pre-existing conditions such as ulcers, electrolyte disturbances, infections, oedema.

Treatment: Usually not required. Symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Glucocorticoids, suspension for intramuscular and intra-articular injection, ATC code: H02AB08.

Triamcinolone acetonide is a derivative of prednisolone. The mechanism of action is not yet fully known. Triamcinolone is a glucocorticoid with marked anti-inflammatory, anti-allergic and immunosuppressive effect, but without a mineralcorticoid effect, and the risk of sodium retention and associated oedema is very small. The anti-inflammatory effect is 5 times greater compared with hydrocortisone. The low solubility and slow metabolism of the active substance provide a markedly prolonged effect. The effects of an injection of 1 ml Kenacort-T 40 mg/ml usually last from 2 to 4 weeks or even longer; in pollen allergies, this may provide freedom from symptoms throughout the pollen season.

5.2 Pharmacokinetic properties

Triamcinolone binds to plasma proteins less extensively than hydrocortisone. It is metabolised mainly in the liver, but also in the kidneys, and excreted in urine.

5.3 Preclinical safety data

Animal studies have shown that corticosteroids can induce malformations (cleft palate, skeletal malformations). Reduced placental and birth weight have been observed in animals after long-term treatment.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium

Sodium chloride
Polysorbate 80
Benzyl alcohol
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.
When administered via intra-articular injection, the product must be used within 24 hours of opening the package.

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

1 ml vial.

6.6 Special precautions for disposal and other handling

Shake before use. See section 4.2

7. MARKETING AUTHORISATION HOLDER

To be completed nationally

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1968-04-19 / 2006-07-01

10. DATE OF REVISION OF THE TEXT

2024-08-06