Package leaflet: Information for the user

ALUTARD SQ Bee 100 000 SQ-U/ml
ALUTARD SQ Bee Initial Pack
(100 SQ-U/ml, 1 000 SQ-U/ml, 10 000 SQ-U/ml and 100 000 SQ-U/ml)
Suspension for injection

Allergen from honey bee venom (*Apis mellifera*)

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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ALUTARD SQ Bee is and what it is used for

ALUTARD SQ Bee contains allergen (the substance that cause the allergic reaction) from honey bee venom and is used as preventive treatment for allergy against honey bee stings.

This treatment is used for patients who are known to have serious allergic reactions to honey bee stings. The aim of the treatment is to address the underlying cause of the allergy. It works by gradually increasing the immune system's tolerance to honey bee venom.

2. What you need to know before you use ALUTARD SQ Bee

Do not use ALUTARD SQ Bee
- if you are allergic to any of the other ingredients of this medicine (listed in section 6)
- if you have a disease which affects the immune system
- if you have recently had an asthma attack and/or have recently experienced worsening of your asthma symptoms e.g. increase in daytime symptoms, nightly wakening, increased need for medication and/or activity limitations
- if you suffer from severe heart or blood vessel disease

Warnings and precautions
Talk to your doctor before using ALUTARD SQ Bee if:
- you experienced any side effects after the last treatment with ALUTARD SQ Bee.
- you have a chronic heart disease
- you know that you suffer from reduced kidney function, as there may be a risk of aluminium accumulation in your body
- you have an autoimmune disease
- you have cancer
- you have a fever or show any other signs of an infection

- you have suffered from allergic symptoms such as hay fever in the last 3 to 4 days
- you have eczema which has worsened
- you know that you have an increased level of the protein tryptase in your blood
- you know that you are suffering from mastocytosis or any other condition that causes you to have an increased number of mast cells in your body
- you have asthma

If any of the above applies to you it is important that you speak to your doctor about it. This is to minimise the risk of allergic reactions in connection with the treatment with ALUTARD SQ Bee (see section 4 "Possible side effects")

Children and adolescents
Children from 5 years: information on the effect of treatment in children is limited. Safety data have not shown any increase in risk for children compared to adults. It is recommended that the doctor evaluates the risks and benefit of the individual child.
Children under 5 years: the doctor must carefully evaluate the risks and benefit of the treatment for the individual child.

Other medicines and ALUTARD SQ Bee
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Particularly tell your doctor or nurse if you

- are taking any other medicines for treatment of allergy such as antihistamines or corticosteroids, as they may increase your tolerance to this treatment. The doctor may need to adjust the dosage.

- are taking medicines containing large amounts of aluminium, such as some antacids (used for heartburn). Since ALUTARD SQ Bee also contains aluminium there may be a risk of aluminium accumulation in your body.

- recently had another vaccination, such as Tetanus vaccination. There should be at least one week between injection with ALUTARD SQ Bee and another vaccination

- are taking beta blockers or ACE inhibitors to treat high blood pressure or heart disease, tricyclic antidepressants or mono amino oxidase inhibitors (MAOIs) for depression or COMT inhibitors for Parkinson´s disease. These medicinal products may increase the risk for/or influence the treatment of any allergic reactions when you use ALUTARD SQ Bee

ALUTARD SQ Bee with alcohol
Alcohol should be avoided on the day of injection as this might increase the risk of a severe allergic reaction (anaphylaxis).

Pregnancy and breast-feeding
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 having this treatment.

Up-dosing treatment with ALUTARD SQ Bee should not be started during pregnancy. If you become pregnant during maintenance treatment you should speak to your doctor about the risks of continuing the maintenance treatment.

It is not known whether ALUTARD SQ Bee passes into breast milk. You should consult your doctor before starting treatment, if you are breast feeding.

Driving and using machines
ALUTARD SQ Bee may in some cases have an effect on driving or using machines, as you can feel dizzy after the treatment.

ALUTARD SQ Bee contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use ALUTARD SQ Bee

Treatment with ALUTARD SQ Bee is given by injection. The injections are usually given in your arm, just under the skin. The injections are always given by a doctor or a nurse.

You will need to stay at the clinic for at least 30 minutes following the injection in order to detect and treat any potential allergic reaction.

On the day of your injection you should avoid: strenuous physical exercise, hot baths and alcohol.

The treatment is divided into two phases: the up-dosing phase and the maintenance phase.

Up-dosing Phase:
Treatment is started according to a schedule that has been worked out by your doctor. During the up-dosing phase, the injections are usually given once a week. The up-dosing phase takes between 7 and 25 weeks.
The aim is to gradually increase the dose until reaching the highest dose that you can tolerate or the highest recommended maintenance dose. If an injection site reaction occurs and it persists for more than 6 hours after the injection, the doctor may adapt the dose depending on the size of your skin reaction. Your doctor may provide you with an antihistamine before your injection.

Maintenance Phase:
When the maintenance dose is reached, the period between injections will be gradually increased. Thereafter injections are given every 6 - 8 weeks for 3 - 5 years.

Treatment with more than one allergen at the same:
If you receive treatment with multiple allergens at the same time the injections should be given 30 minutes apart.

If you are given more ALUTARD SQ Bee than you should
Treatment with ALUTARD SQ Bee is administered by a doctor. In the event of an overdose, you will be monitored and treated by a doctor.

If you have missed a dose of ALUTARD SQ Bee
Ask your doctor if you think you have not been given a dose. If the interval between 2 injections is too long, the doctor will reduce the dose in order to prevent an allergic reaction.

If you stop having ALUTARD SQ Bee
To achieve the best outcome from your treatment you will need to have the injections for 3 to 5 years.

Talk to your doctor if you have any questions about your treatment

4. Possible side effects

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

The side effects may be an allergic reaction to the allergen you are being treated with. Local reactions such as itching, redness and swelling may occur at the site of injection after each injection. The side effects usually occur within 30 minutes after the injection. However, late reactions can occur up to 24 hours after the injection.

Get medical help immediately if your asthma suddenly becomes worse or if you experience the following symptoms which may be signs of an anaphylactic reaction (frequency cannot be estimated from the available data):

- Rapid swelling of face or throat
- Difficulties in swallowing
- Difficulties in breathing
- Hives
- Flushing
- Worsening of existing asthma
- Nausea, stomach pain, vomiting and diarrhoea
- Severe discomfort

Other possible side effects (frequency cannot be estimated from the available data):

- Reactions at the injection site: swelling, nodules, pain, itching, redness, hair growth
- Headache
- Dizziness
- Prickling sensation of the skin
- Swollen eyelids
- Inflammation or itching of the eyes
- Fast heart rate
- Sensation of rapid forceful or irregular beating of the heart
- Low blood pressure
- Paleness
- Stuffy nose
- Tightness or irritating sensation in the throat
- Wheezing breathing
- Asthma symptoms, shortness of breath or cough
- Rash
- Joint pain or joint swelling
- Feeling hot
- Sensation of something stuck in the throat
- Swelling of tissue (usually in the lower limbs)
- Chest discomfort
- Tiredness
- Feeling of discomfort

In the event of any allergic reactions, you should contact a doctor immediately in order to receive adequate treatment.

Reporting of side effects
In UK: If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for "MHRA Yellow Card" in the Google Play or Apple App Store. By reporting side affects you can help provide more information on the safety of this medicine.

In Ireland: If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the HPRA via the HPRA Pharmacovigilance Website www.hpra.ie. By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store ALUTARD SQ Bee

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

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. The vial should be used within 6 months after opening when used for one individual patient and when stored in a refrigerator (2°C - 8°C).

Store in a refrigerator (2ºC - 8ºC). Do not freeze. Store in the original package, in order to protect from light.

Do not throw away any medicines via wastewater or household waste. 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 ALUTARD SQ Bee contains

The active substance is allergen from honey bee venom (*Apis mellifera*).

Other ingredients are aluminium hydroxide (hydrated), sodium chloride, sodium hydrogen carbonate, phenol, sodium hydroxide, human albumin solution and water for injection.

What the medicine looks like and contents of the pack

ALUTARD SQ Bee is a suspension for injection. The suspension is white to faintly brown or green.

The product is available in two different packs. An up-dosing pack with four strengths for up-dosing and a maintenance pack with the strength 100 000 SQ-U/ml. The vial numbers are colour coded to distinguish between the different strengths. Not all pack sizes may be marketed.

Activity is expressed in the unit SQ-U/ml.

The activity in 1 ml of suspension for injection is:

Vial/colour code	Vial 1 Grey	Vial 2 Green	Vial 3 Orange	Vial 4 Red
Strength	100 SQ-U	1000 SQ-U	10 000 SQ-U	100 000 SQ-U
Aluminium content in adjuvant	0.00113 mg/ml	0.0113 mg/ml	0.113 mg/ml	1.13 mg/ml

Marketing Authorisation Holder
ALK-Abelló A/S
Bøge Allé 6-8
2970 Hørsholm
Denmark

Manufacturer
ALK-Abelló S.A.
Miguel Fleta 19
E-28037 Madrid
Spain

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium, Ireland, Luxemburg, United Kingdom	ALUTARD SQ® Bee

(Northern Ireland)	
Norway, Sweden	Alutard SQ® Bigift
Portugal, Spain	ALUTARD SQ® Apis mellifera
Austria	ALUTARD SQ® Bienengift
France	ALUTARD® VENIN D'ABEILLE *APIS MELLIFERA*
Hungary	ALUTARD SQ® Méh
Italy	ALUTARD® Apis mellifera
Romania	ALUTARD SQ® venin de albină
Slovenia	Čebelji strup ALUTARD SQ®

This leaflet was last revised in June 2025

The following information is intended for healthcare professionals only:

Treatment with ALUTARD SQ Bee should be carried out under the supervision of a doctor experienced in specific immunotherapy. After each injection, the patient must be observed for at least 30 minutes.

During storage, a precipitate and a clear liquid can be observed. This is normal for a suspension and does not constitute a sign of deterioration of the quality of the product. The precipitate might be white to faintly brown or green. The vials must be turned slowly upside down 10 - 20 times to make a homogeneous suspension prior to use. Inspect the suspension visually for particulate matter prior to administration. Discard the product if visible particles are present.
ALUTARD SQ Bee is administered subcutaneously. The injection is given either laterally in the distal part of the upper arm or dorsally in the proximal part of the forearm.

Avoid intravascular injection by careful aspiration before injection. Aspiration must be repeated for every 0.2 ml during the injection and the injection must be given slowly. An anaphylactic emergency kit must be available while using ALUTARD SQ Bee.

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