

Summary Public Assessment Report

Alutard SQ Timotej (*Phleum pratense* pollen)

SE/H/2145/01-03/MR

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Alutard SQ Timotej

Allergen extract from timothy grass pollen (*Phleum pratense*)

Suspension for injection, 10 000 SQ-E/ml, 100 000 SQ-E/ml, Up-dosing pack

This is a summary of the public assessment report (PAR) for Alutard SQ Timotej. It explains how Alutard SQ Timotej was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Alutard SQ Timotej.

For practical information about using Alutard SQ Timotej, patients should read the package leaflet or contact their doctor or pharmacist.

What is Alutard SQ Timotej and what is it used for?

Alutard SQ Timotej is used in the treatment of grass pollen allergy caused by *Phleum pratense*. The aim of the treatment is to address the underlying cause of the allergy.

How does Alutard SQ Timotej work?

It works by gradually increasing the immune tolerance to *Phleum pratense* allergens.

How is Alutard SQ Timotej used?

The pharmaceutical form of Alutard SQ Timotej is suspension for injection for subcutaneous use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Alutard SQ Timotej have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Alutard SQ Timotej is effective in treating grass pollen allergy caused by *Phleum pratense*.

What are the possible side effects from Alutard SQ Timotej?

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Alutard SQ Timotej approved?

The Swedish Medical Products Agency decided that Alutard SQ Timotej's benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Alutard SQ Timotej?

A risk management plan has been developed to ensure that Alutard SQ Timotej is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Alutard SQ Timotej, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Alutard SQ Timotej

The full PAR for Alutard SQ Timotej can be found on the following website:

<http://mri.medagencies.org/Human/> for more information about treatment with Alutard SQ Timotej.

This summary was last updated in 2021-11.