LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Triglyva
(liraglutide (synthetic))

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Summary Public Assessment Report

Triglyva
liraglutide (synthetic)

Solution for injection in pre-filled pen, 6 mg/ml

This is a summary of the public assessment report (PAR) for Triglyva. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Triglyva and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for the product is Saxenda.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

The product is used for weight loss in addition to diet and exercise in adults aged 18 and above who have a BMI of 30 kg/m² or greater (obesity), or a BMI of 27 kg/m² and less than 30 kg/m² (overweight) and weight-related health problems. The product can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescents from the age of 12 years and above who have obesity (diagnosed by your doctor) and a body weight above 60 kg.

How does Triglyva work?

This product is a weight loss medicine that contains the active substance liraglutide. It is similar to a naturally occurring hormone called glucagon-like peptide-1 (GLP-1) that is released from the intestine after a meal. This product works by acting on receptors in the brain that control your appetite, causing you to feel fuller and less hungry. This may help you eat less food and reduce your body weight.

How is Triglyva used?
The pharmaceutical form is a solution for injection.

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 Triglyva have been shown in studies?

Because the product is a hybrid application of Saxenda, additional studies and data have been provided to show efficacy for the difference of Triglyva from the reference product Saxenda.

What are the possible side effects from Triglyva?

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 Triglyva approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Saxenda, the 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 Triglyva?
A risk management plan has been developed to ensure that the product 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, 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 Triglyva
The full PAR for Triglyva can be found on the following website: MRI - Home. For more information about treatment with Triglyva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-02.