LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Glanux,
(liraglutide (synthetic))

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Summary Public Assessment Report

Glanux
liraglutide (synthetic)

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

This is a summary of the public assessment report (PAR) for Glanux. 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 Glanux?
The product is a 'hybrid medicine'. This means that it is similar to a reference medicine already authorised in the European Union (EU) containing the same active substance, but manufactured synthetically whereas the active substance for the reference product is derived from Saccharomyces cerevisiae.

The reference medicine for the product is Victoza.

The product *is indicated for the treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.*

It is used on its own if your blood sugar is not properly controlled by diet and exercise alone, and you cannot use metformin (another diabetes medicine).

It is also used with other medicines for diabetes when they are not enough to control your blood sugar levels. These may include:
• oral antidiabetics (such as metformin, pioglitazone, sulfonylurea, sodium-glucose cotransporter 2 inhibitor (SGLT2i)) and/or insulin.

How does Glanux work?
The product contains the active substance liraglutide. It helps your body reduce your blood sugar level only when blood sugar is too high. It also slows food passage through your stomach and can help prevent heart disease.

How is Glanux used?
The pharmaceutical form is solution for injection in pre-filled pen for injection under the skin (subcutaneous 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 Glanux have been shown in studies?
Because the product is a hybrid application containing the same active substance, same strength and same pharmaceutical form, but manufactured synthetically compared to the reference medicine that is of biological origin, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Victoza. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Glanux?

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 Glanux approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Victoza, 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 Glanux?
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 Glanux
The full PAR for Glanux can be found on the following website: MRI - Home.

For more information about treatment with Glanux, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-07.