

# Summary Public Assessment Report

**Siluxir,<sup>1</sup>  
(liraglutide (synthetic))**

**SE/H/2731/001/DC**

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Siluxir  
liraglutide (synthetic)

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

This is a summary of the public assessment report (PAR) for Siluxir. 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 Siluxir and what is it used for?**

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 Saxenda.

The product is a weight loss medicine that contains the active substance liraglutide. It is similar to a natural occurring hormone called glucagon-like peptide-1 (GLP-1) that is released from the intestine after a meal.

## **How does Siluxir work?**

The 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 Siluxir 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 Siluxir 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, Saxenda. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

## **What are the possible side effects from Siluxir?**

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 Siluxir 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 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 Siluxir?**

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 Siluxir**

The full PAR for Siluxir can be found on the following website: [MRI - Home](#). For more information about treatment with Siluxir, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-06.