LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Striroxin
(levothyroxine sodium, anhydrous)

SE/H/2493/01-08/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Striroxin
levothyroxine sodium, anhydrous

Tablet, 25 microgram, 50 microgram, 75 microgram, 100 microgram, 125 microgram, 150 microgram, 175 microgram, 200 microgram

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

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Euthyrox.

The product is used:
- to treat benign goitre in patients with normal thyroid function,
- to prevent recurrence of goitre after surgery,
- to replace natural thyroid hormones, when your thyroid gland does not produce enough,
- to suppress tumour growth in patients with thyroid cancer.

Striroxin 25 microgram, 50 microgram, 75 microgram and 100 microgram are also used to balance thyroid hormone levels, when overproduction of hormones is treated with antithyroid medicines.

Striroxin 100 microgram, 150 microgram, and 200 microgram may also be used in the testing of your thyroid function.

How does Striroxin work?

Levothyroxine, the active substance in Striroxin, is a synthetic thyroid hormone for the treatment of diseases and dysfunctions of the thyroid gland. It has the same effect as the naturally occurring thyroid hormones.

How is Striroxin used?

The pharmaceutical form is tablet for oral 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 Striroxin have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Euthyrox. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Striroxin?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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 Striroxin 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 Euthyrox, 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 Striroxin?

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.

For more details, please see the full PAR for Striroxin on the following website: MRI - Home.

Other information about Striroxin

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

This summary was last updated in 2025-01.