



נובמבר 2025

רופא/ה, רוקח/ת נכבד/ה,

חברת רז רוקחות מבקשת להודיעכם על עדכון העלון לרופא של התכשיר:

L-THYROXINE SERB
אל-טירוקסין סרב
SOLUTION FOR INJECTION /
CONCENTRATE FOR SOLUTION FOR INFUSION

המרכיב הפעיל:

LEVOTHYROXINE SODIUM 0.2 MG/1 ML

התוויה מאושרת:

- Myxedema coma
- Replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא. שינויים בעלון המהווים החמרה מודגשים ברקע צהוב, תוספות מסומנות בצבע אדום והשמטות מסומנות בקו אפור. למידע נוסף יש לעיין בעלון לרופא המאושר.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות (www.health.gov.il), וניתן גם לקבלו מודפס ע"י פניה לבעל הרישום:

רז רוקחות בע"מ, רחוב גשר העץ 31, פארק תעשיות, עמק חפר, ובטלפון 04-9079710.

בברכה,

רז רוקחות בע"מ



העדכונים המהותיים שבוצעו בעלון לרופא:

[...]

4.4. Special warnings and precautions for use

[...]

Patients with adrenal insufficiency

In case of adrenocortical dysfunction, ~~patients this~~ should be treated ~~before starting the therapy with levothyroxine~~ by adequate ~~replacement treatment~~ glucocorticoid treatment to prevent acute adrenal insufficiency prior to starting the therapy with levothyroxine (See section 4.3).

As an adrenal insufficiency linked with myxedema coma can occur, an empiric intravenous glucocorticoid treatment should be administered in association to levothyroxine until confirmation or exclusion of adrenal insufficiency.

[...]

Levothyroxine and other treatments:

Monitoring is required in patients receiving concomitant administration of levothyroxine and medicinal products (such as amiodarone, tyrosine kinase inhibitors, salicylates and furosemide at high doses, selpercatinib, ...) which may affect the thyroid function. See also section 4.5.

For diabetic patients and patients under anticoagulant therapy, see section 4.5.

For patients receiving selpercatinib, hypothyroidism has been reported. Baseline laboratory measurement of thyroid function is recommended in all patients. Patients with pre-existing hypothyroidism should be treated as per standard medical practice prior to the start of selpercatinib treatment. All patients should be observed closely for signs and symptoms of thyroid dysfunction during selpercatinib treatment. Thyroid function should be monitored periodically throughout treatment with selpercatinib. Patients who develop thyroid dysfunction should be treated as per standard medical practice, however patients could have an insufficient response to substitution with levothyroxine (T4) as selpercatinib may inhibit the conversion of levothyroxine to liothyronine (T3) and supplementation with liothyronine may be needed (see section 4.5).

Important information about some of the ingredients:

Sodium:

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

4.5. Interaction with other medicinal products and other forms of interaction

[...]

Selpercatinib

Levothyroxine may be less effective when given with selpercatinib.

Selpercatinib could inhibit D2 deiodinase and thereby decrease the conversion of levothyroxine (T4) to liothyronine (T3). Patients could therefore have an insufficient response to substitution with levothyroxine and supplementation with liothyronine may be needed (see section 4.4).

[...]