יוני 2023

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

L-THYROXINE SERB

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא.

התוספות סומנו בצבע כחול, ההחמרות סומנו בצהוב והמחיקות סומנו בצבע אדום עם קו מחיקה.

העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:

www.health.gov.il וניתן לקבלו מודפס על ידי פנייה לבעל הרישום: רז רוקחות בע"מ, גשר בעץ 31, פארק תעשיות עמק חפר, ישראל.

בברכה,

אריאל מימון

מנהלת מחלקת רישום

מרכיב פעיל וחוזק:

LEVOTHYROXINE SODIUM 0.2 MG / 1 ML

התוויה מאושרת:

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

להלן העדכונים המהותיים שבוצעו בעלון לרופא:

4.4. Special warnings and precautions for use

Interferences with laboratory test:
Biotin may interfere with thyroid immunoassays that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results. The risk of interference increases with higher doses of biotin.
When interpreting results of laboratory tests, possible biotin interference has to be taken into consideration, especially if a lack of coherence with the clinical presentation is observed.
For patients taking biotin-containing products, laboratory personnel should be informed when a thyroid function test is requested. Alternative tests not susceptible to biotin interference should be used, if available. (see section 4.5)

Levothyroxine and other treatments:
Monitoring is required in patients receiving concomitant administration of levothyroxine and medicinal products (such

as amiodarone, tyrosine kinase inhibitors, doses) which may affect the thyroid
For diabetic patients and patients under 4.5.

salicylates and furosemide at high function. See also section 4.5.
anticoagulant therapy, see section

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

Combinations not recommended

ST. JOHN'S WORT (HYPERICUM PERFORATUM L.)

Risk of increased hepatic clearance of levothyroxine resulting in reduced serum concentrations of thyroid hormone and risk of decreased clinical effects~~ of thyroid hormones~~. Therefore, patients on thyroid replacement therapy may require an increase in their dose of thyroid hormone if these products are given concurrently.

Combinations requiring precautions for use

Anti-diabetic agents

Levothyroxine can reduce the blood sugar-lowering effect of antidiabetics (e.g. metformin, glimepiride, glibenclamide and insulin). Therefore, blood sugar levels in diabetic patients must be regularly checked, particularly at the start and at the end of thyroid hormone treatment. The dose of the blood sugar-lowering drug should also be adapted.

Coumarin derivatives

Levothyroxine can intensify the effect of coumarin-derivatives through plasma protein binding displacement. Therefore, regular blood coagulation checks are necessary in the case of simultaneous treatment; the dose of the anticoagulant must be adapted, if necessary (dose reduction).

Propylthiouracil, glucocorticoids and beta-receptor blockers (especially propranolol)

These substances inhibit the conversion of T4 into T3 and can result in a lowered T3 serum concentration.

Amiodarone and contrast media containing iodine

Due to their iodine content, these agents can trigger hyperthyroidism as well as hypothyroidism. Special care should be taken in the case of nodular goiter with possibly undetected functioning autonomies. Amiodarone inhibits the conversion of T4 into T3, resulting in a lowered T3 serum concentration and an increased TSH serum level.

Salicylate, dicumarol, furosemide, clofibrate

Levothyroxine can be displaced from the plasma protein binding through salicylate (particularly in doses greater than 2.0 grams per day), dicumarol, high doses (250 milligrams) of furosemide, clofibrate and other substances. This can lead to an initial, temporary increase of free thyroid hormones, jointly followed by a decrease of the total thyroid hormone level.

Contraceptives containing oestrogen, drugs for post-menopausal hormone substitution

The levothyroxine demand can increase during the intake of contraceptives containing oestrogen or during post-menopausal hormone replacement treatment. There may be increased binding of levothyroxine, which may lead to diagnostic and therapeutic errors.

Sertraline, chloroquine/proguanil

These substances reduce the efficacy of levothyroxine and increase the TSH serum level.

Enzyme inducing drugs

Barbiturates, rifampicin, carbamazepine, phenytoin and other drugs with liver enzyme-inducing characteristics can increase the hepatic clearance of levothyroxine and result in a decreased plasma level.

Protease inhibitors

There are reports stating that protease inhibitors can result in a loss of the therapeutic effect of levothyroxine if simultaneously administered with lopinavir/ritonavir. Therefore, careful monitoring of clinical symptoms and thyroid function should be carried out in patients who use levothyroxine and protease inhibitors simultaneously.

Tyrosine kinase inhibitors (e.g. Imatinib, sunitinib, sorafenib, motesanib)

These agents can reduce the efficacy of levothyroxine. Therefore, careful monitoring of clinical symptoms and thyroid function should be carried out in patients who use levothyroxine and tyrosine kinase inhibitors simultaneously.

Interferences with laboratory test:

Biotin may interfere with thyroid immunoassays that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results (see section 4.4).