

Dear Patient,

Compliant with Ministry of Health instructions, we would like to inform you of a change in the composition of the inactive ingredients of **Euthyrox (levothyroxine)** 50 mcg and 100 mcg tablets: Lactose has been replaced with mannitol, and citric acid has been added. This change will improve the stability of the active substance, levothyroxine, and will maintain a consistent dose over the course of the recommended period of use.

There is no change in the active substance (levothyroxine sodium) in the product.

The new formulation has been marketed in many countries around the world for several years, with no known safety issues. However, in hormonal products, a change in the absorption of the active substance is possible. Therefore, when switching to the new formulation close monitoring is necessary, until balance is reached.

The Ministry of Health has informed the health funds of this and instructions have been sent to the health fund doctors. Please contact your doctor (family doctor/endocrinologist, whichever is more available) to arrange monitoring during the month after starting treatment with this product. Until you see or talk to your doctor, continue taking the new formulation in exactly the same way as you took the previous formulation.

In addition, the doctor should be informed of symptoms that could indicate thyroid imbalance (such as fatigue and/or constipation, which can indicate low thyroid hormone levels, or symptoms of sweating, increased heart rate, and agitation, which can indicate high thyroid hormone levels).

Please note that during the transition phase both products may still be available in pharmacies throughout the country. However, if you start taking the product with the new formulation, do not switch back to the previous product; you must continue taking only the product with the new formulation.

In addition to the 50 and 100 mcg strengths, a strength of 25 mcg has been approved in order to enable optimal transition to the new formulation (a wider dose range in order to reach balance).

If you have further questions about the new formulation, you may contact Merck at the following phone number: 09-9510737, Sunday–Thursday, 8:00 am–4:00 pm.

Read the patient information leaflet attached to the package before using the medicine.

Sincerely,
Merck Serono Ltd.