

Dear patient,

You have probably read on the pack of your drug that it has a change in the composition. As well, you have noticed that the pack design is different from your old medicine. Because of the changed formulation, we made a change in the box design, so that you are visually alerted and motivated to read more about the changes and hence take the newly formulated drug with confidence.

The changes are related to improvements in the composition of your drug by changing few of the excipients. Those changes contribute to better stability of the product, which is important for you. However, the active ingredient levothyroxine sodium remains unchanged. The change of excipients does not affect the quality, safety and efficacy of the product.

L-Thyroxin Berlin-Chemie (levothyroxine): changes in the formulation

1. What is levothyroxine used for?
2. What are exactly the changes to the formulation?
3. Are the instructions for taking this new formulation different?
4. What should I do if my pharmacist gave me the new formulation for the first time? Do I need to go see my doctor?
5. What are the risks related to the changes of the formulation?
6. What are the thyroid imbalance symptoms that I should be aware of?
7. What are the changes to the box and blister of the medicine?

1. What is levothyroxine used for?

Levothyroxine is a thyroid replacement hormone used in cases of hypothyroidism (insufficient or lack of secretion of the thyroid gland), or in situations where it is necessary to slow down the secretion of a thyroid stimulating hormone, known as TSH.

2. What are exactly the changes to the formulation of the medicine?

The changes made are:

- Optimisation of the formulation intended to ensure that the content of active substance, meaning the levothyroxine, is more constant during the entire shelf life of the product.

3. Are the instructions for taking this new formulation different?

No, the way you take your medicine has not changed. Always follow your doctor's instructions regarding doses, how to take your medicine, and follow-up.

4. What should I do if my pharmacist gave me the new formulation for the first time? Do I need to go see my doctor?

Check the name and strength of the medicine you have been given as the box and blister of your medicine may have changed colours (see Annex).

Take the new formulation in exactly the same way that you took the old formulation.

Contact your doctor to clarify if your TSH is needed to be checked after starting the new formulation.

Once you have started to take the new formulation, you have to stay on that formulation.

5. What are the risks related to the changes of the formulation of the medicine?

No change in the safety profile is expected. The active ingredient is still levothyroxine sodium, from the same source. Only the excipients have been changed.

It has been shown that the new excipients do not change the quantity of active substance that enters the blood or how quickly it reaches the target organ. This ensures that the efficacy and safety are the same as in the old formulation.

However, the uptake of the active substance may still differ between the formulations in some patients, this may lead to thyroid imbalance (see Question 6 “What are the thyroid imbalance symptoms that I should be aware of?”). If you think you have symptoms that indicate a thyroid imbalance, you should contact your doctor as soon as possible.

6. What are the thyroid imbalance symptoms that I should be aware of?

The clinical symptoms of a thyroid imbalance are not very specific and they can vary from patient to patient.

Hypothyroidism: unusual tiredness, constipation, and a general feeling of slowing down are the most common symptoms related to an insufficient level of thyroid hormone.

Hyperthyroidism: sweating, tachycardia (fast heart rate), palpitations and agitation are symptoms that may indicate too high a level of thyroid hormone.

7. What are the changes to the box and blister of the medicine?

L-Thyroxin 50 Berlin-Chemie 50 mcg old formulation tablets	L-Thyroxin 50 Berlin-Chemie 50 mcg new formulation tablets
 <p>The image shows the old packaging for L-Thyroxin 50 Berlin-Chemie. The box is white with black and purple text. The main text reads "L-Thyroxin Berlin-Chemie 50 mikrogramu tabletae". Below this, it says "Levothyroxinum natrium". At the bottom, it indicates "100 tabletae" and the Berlin-Chemie logo.</p>	 <p>The image shows the new packaging for L-Thyroxin 50 Berlin-Chemie. The box is white with purple and black text. The main text reads "L-Тироксин 50 Берлин-Хеми". Below this, it says "Левотироксин-натрий 50 мкг". At the bottom, it indicates "100 таблеток" and the Berlin-Chemie logo. A large "Example" watermark is overlaid on the image.</p>