

L-Thyroxin Berlin-Chemie (levothyroxine) new formulation tablets: monitoring of patients switching between tablets

Dear Healthcare Professional,

Berlin-Chemie Menarini in agreement with the Scientific Centre of Drug and Medical Technology Expertise would like to inform of the following:

Summary

- A new formulation of L-Thyroxin Berlin-Chemie tablets was registered in Armenia in 13.07.2022 and will be available on the market as of January 2023.
- The re-formulated tablets offer improved stability of the active substance throughout the medicinal product's shelf life.
- How L-Thyroxin Berlin-Chemie is taken and monitored remains unchanged.
- Close monitoring of patients switching between tablets is recommended as thyroid imbalances can be triggered by the switch. This includes a clinical and laboratory assessment to ensure that the patient's individual dose remains appropriate.**
- Particular attention should be paid to vulnerable groups (e.g. patients with thyroid cancer, cardiovascular disease, pregnant women, children, and the elderly).

For prescribing physicians:

- Confirm that the patient's individual daily dose remains appropriate using clinical and laboratory assessments.
- If necessary, adjust the dosage following the patient's clinical response and laboratory test.
- Ensure that patients are sufficiently informed.

For pharmacists:

- Advise patients to take L-Thyroxin Berlin-Chemie new formulation tablets exactly the same way as L-Thyroxin Berlin-Chemie old formulation tablets.
- Advise patients to seek medical advice on the need of close monitoring when switching between tablets.
- Advise patients not to change back to L-Thyroxin Berlin-Chemie old formulation tablets once they have moved to L-Thyroxin Berlin-Chemie new formulation tablets.
- Provide patients with the patient information sheet supplied by your representative together with L-Thyroxin Berlin-Chemie new formulation tablets.
- Please bear in mind that the package layout is changed (see Annex).

Background on the safety concern

L-Thyroxin Berlin-Chemie is prescribed for the treatment of hypothyroidism (deficient secretion by the thyroid gland) and for conditions, whether or not associated with hypothyroidism, in which it is necessary to suppress the secretion of thyroid-stimulating hormone (TSH).

A new formulation of levothyroxine tablets will be available as of January 2023. It is characterised by an improvement in the stability of the active substance throughout the medicinal product's shelf life.

The bioequivalence between the old and new formulations has been demonstrated by bioavailability studies. However, the uptake of the active substance may still differ between the formulations in some patients.

It should be confirmed by clinical and laboratory assessments that the patient’s individual daily dose remains appropriate after the transition to L-Thyroxin Berlin-Chemie new formulation tablets. A TSH test <time point for TSH check in accordance with national guidance> provides a reliable basis for such confirmation. Circulating T4 tests are justified under certain specific conditions. If necessary, the dosage should be adjusted following the patient's clinical response and laboratory test.

Contact details for reporting adverse events:

Scientific Center of drugs and Medical Technologies named after academician E. Gabrielyan MoH, Republic of Armenia, by the following link: www.pharm.am, contact via email: vigilance@pharm.am or call the hotline: Phone: (+374 10) 20 05 05; (+374 96) 22 05 05

Berlin-Chemie AG Armenian representation contact details

Address: Armenia, 0070, Yerevan, Kajaznunu St.,4/1 Building, 4th Floor

Tel.: (374 10) 500-773



Fax: (374 10) 500-772

e-mail: office-armenia@berlin-chemie.com

am.pv@berlin-chemie.com

Annex

The package layouts were modified as indicated below:

L-Thyroxin 50 Berlin-Chemie 50 mcg old formulation tablets	L-Thyroxin 50 Berlin-Chemie 50 mcg new formulation tablets
	

Patient information sheet to be handed over by pharmacist together with the new formulated medicinal product.