Statement from the National Agency for the Safety of Medicines and Health Products in France

Sanofi Winthrop Industrie has informed the ANSM (French National Agency for the Safety and Health) that it will discontinue the marketing of Cynomel (liothyronine sodium) as of October 31, 2025. To ensure continuity of patient treatment, the laboratory is organizing imports of Thybon 20 Henning (liothyronine hydrochloride). Cynomel 0.025 mg, scored tablet, is used in adults and children over 6 years of age to treat hypothyroidism, certain goiters, and nodules.

An alternative identified in the short and longer term

In anticipation, we have identified an alternative to Cynomel: Thybon 20 Henning (liothyronine hydrochloride), which has had a marketing authorization (MA) in Germany for over 25 years. Sanofi has committed to importing this medication into France.

These imports will take effect upon the discontinuation of Cynomel and will be followed by a marketing authorization application for Thybon in France to ensure continued access to this medication and avoid patients having to repeatedly change treatment.

There will therefore be no disruption in supply between the end of Cynomel distribution and the start of Thybon availability.

Points of attention

Scoring
Thybon 20 Henning has a score line, allowing the tablet to be cut in half, unlike Cynomel, which is quarter-scored.

If a more precise dosage adjustment is necessary, medical advice, along with appropriate hormonal dosages, may lead to the tablet being cut into quarters. A tablet cutter should be used, although perfectly even cuts are not guaranteed.

Pregnancy
Liothyronine is contraindicated during pregnancy, in accordance with international recommendations for replacement therapy in pregnant women. Levothyroxine should be used in this case.

Excipient with known effect
Thybon 20 Henning contains castor oil, which may cause an allergic reaction in some patients. Recommendations

In agreement with the French Society of Endocrinology (SFE), the Thyroid Research Group (GRT), and following advice from the National Professional Council (CNP) for Endocrinology, Diabetology, and Nutrition and patient associations, we have established the recommendations below.

If you are currently being treated with Cynomel, your doctor may prescribe Thybon 20 Henning as an alternative to Cynomel. A new prescription from your doctor will be required.

You must take this medication according to the dosage specified on the prescription. Follow it strictly. Your doctor will also prescribe thyroid hormone tests (TSH, T4, T3):

- Systematically 6 to 8 weeks after starting treatment
- 6 to 8 weeks after any dose change during treatment
- In the event of a significant change in your weight;
- In the event of clinical signs or symptoms suggesting a thyroid imbalance or if you have any other unusual symptoms or feelings
- In the event of persistence and/or worsening of clinical signs.

Regular monitoring during treatment allows the dose to be adjusted to achieve the therapeutic goal, taking into account your feelings.

For patients currently receiving Cynomel, treatment may be continued with Thybon 20 Henning, referring to the information sheet for healthcare professionals. A new prescription will be required.

TSH, T4, and T3 levels should be monitored to determine the optimal effective dose:

- Systematically 6 to 8 weeks after starting treatment
- 6 to 8 weeks after any dose change during treatment
- In the event of a significant change in your body weight
- In the event of clinical signs or symptoms suggestive of thyroid imbalance or if you have any other unusual symptoms or feelings
- In the event of persistence and/or worsening of clinical signs.

Monitoring of clinical signs and the patient's experience should be considered in conjunction with TSH laboratory results. It is not recommended to use clinical signs as the sole parameters.

Regular monitoring during treatment allows the dose to be adjusted to achieve the therapeutic objective, taking into account the patient's feelings, according to the updated HAS recommendations in the management of hypothyroidism.

The boxes of the imported drug Thybon 20 Henning (liothyronine) and the drug L-Thyroxin Henning (levothyroxine), both from Sanofi, look very similar in France.

We encourage pharmacists to raise awareness among patients about this risk of confusion, particularly among patients taking these two treatments simultaneously.

The packaging of Thybon 20 Henning is written in German, not French.

To reduce the risk of medication errors and avoid confusion, particularly among patients taking these two treatments simultaneously, we have asked the laboratory to:

- Add a label in French to the sachets of Thybon given to patients by pharmacists;
- Include in each sachet of Thybon an information letter in French, as well as a patient information leaflet informing them of the precautions for use.

At the same time, the laboratory will send all relevant healthcare professionals a letter and an information leaflet about Thybon.