Medicine Shortage Communication

10 November 2026

Lenzetto (estradiol hemihydrate solution) 1.53 mg/spray: supply shortage

Dear Healthcare Professional,

Gedeon Richter Plc. is notifying healthcare professionals about a shortage of Lenzetto.

This shortage affects all EU/ EEA countries where the product is marketed.

Overview of situation

- **The demand for Lenzetto has grown much faster than anticipated, significantly exceeding forecasted volumes and available supply capacity. As manufacturing capacity could not immediately keep pace with this increase, this resulted in temporary supply challenges. The shortage affects all EU/ EEA countries where the product is marketed.**
- **In response to the increased demand, Gedeon Richter is taking measures to progressively improve available manufacturing capacity and efficiency.**
- **Based on current forecasts, supply constraints are expected to continue in certain markets throughout 2027. Supply is expected to recover progressively as additional manufacturing capacity becomes available. A return to normal supply levels is currently anticipated following implementation of the planned capacity increase activities.**
- **These timelines remain subject to manufacturing performance, market demand, and the successful completion of the capacity expansion projects.**
- **The shortage is not due to any safety, efficacy or quality concerns with Lenzetto.**

Mitigation measures

In order to manage the shortage, Gedeon Richter Plc. is engaging with the European Medicines Agency and the National Competent Authorities on mitigation measures.

Doctors and health care providers are informed so that patients can be safely switched to alternative therapies, ensuring continuity of care.

During the shortage, healthcare professionals should:

- **Consider reserving available supplies of Lenzetto to women who are already using the product.**

- **For women starting menopausal hormone therapy (MHT) consider alternative treatment approaches such as transdermal estradiol-based MHT products, based on national prescribing guidelines and local product availability.**
- **There is no universally established dose conversion between menopausal hormone therapy (MHT) products. Individual differences in absorption and metabolism may require dose adjustment and clinical follow-up after switching. Healthcare professionals should consult relevant guidance, such as those from the European Menopause and Andropause Society (EMAS) and the European Society of Endocrinology (ESE), to support clinical decision-making regarding product switching and approximate estradiol dose equivalence. Treatment should remain individualized based on the woman's clinical response and needs.**

Any treatment switch should be decided by the treating healthcare professional based on clinical judgement and the needs of the woman.

For additional information consult EMA's shortage catalogue, your country's shortage register or your national competent authority.

Background on the shortage

Lenzetto is an oestrogen-only hormone replacement therapy delivered via a transdermal spray. It is indicated for the treatment of oestrogen deficiency symptoms in postmenopausal women (in women at least 6 months since last menses or surgical menopause, with or without a uterus).

In response to increased demand, Gedeon Richter is taking all possible measures to ensure continuous supply. However, due to the exceptional surge in interest, we are facing capacity constraints.

We are maximizing the use of our existing manufacturing capabilities while also establishing additional supplier and manufacturing options. We are working to improve the availability of the device used for administering the medicine (applicator), while at the same time creating new manufacturing capacity and increasing production capacity at the current finished product manufacturing site. These developments require significant time and expertise, as expanding pharmaceutical manufacturing capacity can only be achieved while meeting all necessary quality and regulatory requirements.

There is no quality or safety issue behind the shortage.

If women are unable to obtain Lenzetto, healthcare professionals should consider clinically appropriate alternatives and maintain continuity of care.

Company contact point

Further information about the content of the letter is available at the following contact details:
Gedeon Richter Plc.
1103 Budapest
Gyömrői út 19–21.
Phone: +36 1 505 7032
E-mail: medinfo@richter.hu

Reporting of adverse events and side effects related to Richter products:
drugsafety@richter.hu

Annexes *(if applicable)*

<Link/reference to other available relevant information, such as information on the website of a competent authority>

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Lenzetto 1.53 mg/spray, (estradiol hemihydrate transdermal spray, solution)
Marketing authorisation holder(s)	Gedeon Richter Plc. 1103 Budapest Gyömrői út 19–21.
Purpose of the communication	Informing healthcare professionals about a shortage of Lenzetto.
MSC recipients	Prescribing physicians (gynaecologists), and pharmacists. Relevant national Medical Societies. The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the MSC will be distributed	Belgium, Croatia, Czechia, Estonia, Finland, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.

Timetable	**Date**
MSC and communication plan (in English) agreed by SPOC WP	3 November 2026
MSC and communication plan (in English) agreed by MSSG	11 November 2026
Submission of translated MSCs to the national competent authorities for review	25 November 2026
Agreement of translations by national competent authorities	According to the timelines set by NCAs
Dissemination of MSC	Within 10 business days after MSC COMMUNICATION PLAN respective national competent authorities approval