

IMPORTANT INFORMATION

Cham, 22. August 2024

Zemplar (paricalcitolum), solution for injection

Translation error in the French text of the package leaflet

Dear Sir or Madam

In consultation with Swissmedic, AbbVie would like to inform you on the following facts:

Summary

The package leaflets enclosed with all batches of Zemplar 5 µg/ml, solution for injection currently on the Swiss market contain a translation error in the French text under 'Dosage/Administration'. The German text is correct.

The following batches currently on the market and within shelf-life are affected:

Batch	Strength	Expiry Date
A000067728	5 µg/ml	28.02.2027
A000065996	5 µg/ml	31.01.2027
A000063736	5 µg/ml	31.10.2026
A000059936	5 µg/ml	30.04.2026
A000058155	5 µg/ml	28.02.2026
A000056593	5 µg/ml	31.01.2026
A000054747	5 µg/ml	30.10.2025
A000054545	5 µg/ml	31.10.2025
A000049817	5 µg/ml	30.04.2025
A000044174	5 µg/ml	31.10.2024
A000045101	5 µg/ml	30.09.2024

The current Information for healthcare professionals with the correct French translation is published at www.swissmedicinfo.ch.

AbbVie is working on correcting the package leaflet. Until the corrected version is available, this letter will be included with all shipments of Zemplar 5 µg/ml, solution for injection.

Background information

The French translation of the Information for healthcare professionals with 'Status of information' December 2020 contains the information in the section 'Dosage/Administration' that for the initial dosage 'the interval between 2 injections must not exceed 2 days'.

However, the **correct information** on the initial dosage is that 'the injection frequency must not exceed one injection every two days'.

Reporting adverse drug reactions

For reporting adverse drug reactions (ADR), Swissmedic recommends using the Electronic Vigilance System (EIViS) reporting portal developed for this purpose. All the necessary information can be found at www.swissmedic.ch.

Contact details

If you have any questions, please contact our Medical Department (Tel.: 041 399 16 89 or email: medinfo.ch@abbvie.com).

Kind regards,

AbbVie AG