**Teriparatide and Biosimilars**

**February 2023**

## **Switching from Forsteo® to Sondelbay®**

This leaflet contains information about your medicines for your osteoporosis condition and our plan to switch your treatment from Forsteo® to Sondelbay®. If you have any further questions after reading this leaflet, please speak to <insert name and contact details for relevant clinical team member>.

## **Why am I receiving this leaflet?**

You are currently undergoing treatment with teriparatide (Forsteo®). You may be aware that the patent for Forsteo® has expired and other versions of teriparatide, including biosimilar medicines, have now been approved and are available to patients. The HSE now recommends that patients receive Sondelbay® as the biosimilar version of Forsteo®.

## **What is a biosimilar?**

The European Medicines Agency (EMA) defines a biosimilar medicine as a biological medicine that is highly similar to another biological medicine that is already approved in the EU, in terms of quality, safety and effectiveness.

This means that biosimilar medicines (such as Sondelbay®) are allowed to have small structural differences from the original biological medicine (Forsteo®) but this must not alter how well the drug works, how safe it is, or how the drug reacts with the body’s immune system.

Biosimilar medicines are regulated in a similar way to the original biological medicine. The EMA has approved the use of Sondelbay® as it has been shown to be as safe and effective as Forsteo®.

We are confident that Sondelbay® is just as effective and has the same safety profile as Forsteo®. Sondelbay® costs less than Forsteo®. Switching patients to Sondelbay® will save the HSE money. This will help the HSE give new innovative medicines to even more patients.

## **What does this mean for me?**

Because Sondelbay® and Forsteo® contain the same active medicine (teriparatide), treatment for your osteoporosis remains unchanged.

Like Forsteo®, Sondelbay® is given by subcutaneous injection. With Forsteo®, you received a new pre-filled pen each month. The same will happen with Sondelbay®; you will receive a new pre-filled pen each month.

You will continue to inject Sondelbay® once a day, as you currently do with Forsteo®.

You will continue to get your repeat prescription from us, and you can collect Sondelbay® from the same pharmacy that provided you with Forsteo®.

Supports for patients prescribed Sondelbay® include:

* nurse home visit to provide training on administering the injection
* supply of sharps bins and waste collection service
* provision of product information

We will register you for these services.

## **Will any additional monitoring be required?**

We are not required to make any additional safety checks in patients who are switched to Sondelbay® but we still plan to monitor every patient who switches. You will be contacted by a member of our team four weeks after you switch so that we can check that Sondelbay® is working just as well as Forsteo® and to follow-up on any issues you may have encountered.

If you do have a problem with Sondelbay®, for example having trouble using the injection device or experiencing side-effects, we can help you to manage these.

## **What if I have further questions?**

If you have concerns about switching to Sondelbay®, we are here to help. Please ask <insert name of relevant clinical team member>. If necessary, they will arrange an appointment with one of the doctors to answer any further questions you may have.

## **Contact us**

If you have any further questions, please contact the <insert name of clinic/service> on <insert number + staff member name> (Monday to Friday, 9am to 5pm) or you can email insertemail@xxxx.ie.

## **Where can I get more information on biosimilar medicines?**

Further information for patients on biosimilar medicines is available on the following websites:

**HSE-Medicines Management Programme:** <https://www.hse.ie/yourmedicines> under Best-value medicines

**Health Products Regulatory Authority:** <http://www.hpra.ie/homepage/medicines/special-topics/biosimilar-medicines>

**European Medicines Agency:** <https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview#information-for-patients-and-healthcare-professionals-section>

Further information on osteoporosis, including the medicines that are used in its treatment, is available on the website of the **Irish Osteoporosis Society**: [www.irishosteoporosis.ie](http://www.irishosteoporosis.ie)