

Information for Patients about Medicines containing Ustekinumab

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Ustekinumab is a biological medicine used to treat inflammatory conditions such as plaque psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis. Biological medicines are medicines made or derived from living cells, and they are widely used in the treatment of many conditions.

Ustekinumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body. Ustekinumab works by blocking the chemical messengers interleukin-12 and interleukin-23, which can cause inflammation. Ustekinumab reduces inflammation and associated signs and symptoms of the condition.

When used in the treatment of plaque psoriasis and psoriatic arthritis, ustekinumab is usually administered by injection under the skin (subcutaneous injection) at week 0, week 4 and then every 12 weeks thereafter. When starting treatment for Crohn's disease or ulcerative colitis, the initial dose is given as an infusion via a drip in hospital, followed by subcutaneous injection every 8 to 12 weeks.

The subcutaneous injection of ustekinumab is supplied to patients by their Community Pharmacy.

What are the best-value biological medicines for ustekinumab?

The best-value biological (BVB) medicines identified by the HSE for ustekinumab are:

- **Imuldosa®**
- **Otulf®**
- **Pyzchiva®**
- **Wezenla®.**

Imuldosa®, Otulfi®, Pyzchiva® and Wezenla® are biosimilar medicines; what is a biosimilar medicine?

A biosimilar medicine is very similar to the original biological medicine. It works in the same way.

Stelara® was the original biological medicine for ustekinumab. Recently, biosimilar medicines containing ustekinumab became available. Imuldosa®, Otulfi®, Pyzchiva® and Wezenla® are biosimilar medicines of Stelara®.

Are biosimilar medicines safe?

Biosimilar medicines are tested to show they are just as safe and effective as the original biological medicine.

The original biological medicine (Stelara®) and the biosimilar medicines (e.g. Imuldosa®, Otulfi®, Pyzchiva® and Wezenla®) can cause similar side-effects.

Biosimilar medicines are also available for adalimumab, etanercept and infliximab. These biosimilar medicines are frequently prescribed by Dermatologists, Gastroenterologists, Rheumatologists, and their teams.

What's changing?

At present, no changes are being introduced in relation to the reimbursement of ustekinumab on the High Tech Arrangement.

The HSE has identified BVB medicines for ustekinumab; Imuldosa®, Otulfi®, Pyzchiva® and Wezenla®.

The HSE recommends that all new patients being initiated on ustekinumab for the treatment of plaque psoriasis, psoriatic arthritis or Crohn's disease should be prescribed a BVB medicine.

I am an existing patient prescribed ustekinumab, what does this mean for me?

If you are an existing patient, you will continue to receive your medicine from your community pharmacy.

If you are currently on a non-BVB medicine of ustekinumab (e.g. Stelara®) for the treatment of plaque psoriasis, psoriatic arthritis or Crohn's disease, your consultant or a member of their team may discuss the possibility of switching to a BVB medicine.

Has my consultant being informed about the best-value biological medicines?

Yes. Consultants in dermatology, gastroenterology and rheumatology are aware of the BVB medicines.

Biosimilar medicines are widely used by Dermatologists, Gastroenterologists Rheumatologists, and their teams.

Why is the HSE recommending a best-value biological medicine for ustekinumab?

The BVB medicines are provided to the HSE at a lower cost. Prescribing the BVB medicines will save the HSE money. This means we can give new innovative medicines to even more patients, including for the treatment of conditions in dermatology, gastroenterology and rheumatology.

What supports are available?

Supports for patients prescribed this medicine can include:

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

Your consultant or a member of their team will register you for these services.

Where can I get more information on biosimilar medicines?

Further information on biosimilar medicines and the BVB medicines is available on the following websites:

HSE-Medicines Management Programme: www.hse.ie/mmp under Best-value medicines

Health Products Regulatory Authority: www.hpra.ie/regulation/human-medicine/patients-and-healthcare-professionals/biosimilar-medicines/biological-and-biosimilar-medicines--what-patients-should-know

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