

UPTRAVI (selexipag) treatment initiation and titration

Dear Healthcare Professional,

In this package you will find information on the use of UPTRAVI as a long-term oral treatment for pulmonary arterial hypertension (PAH) in adult patients with World Health Organization (WHO) functional class (FC) II-III.

UPTRAVI may be used as combination therapy in patients insufficiently controlled on treatment with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type-5 inhibitor (PDE-5i), or as monotherapy in patients who are not candidates for these therapies.

Starting patients on UPTRAVI involves dose titration, according to tolerability, to reach the individually appropriate dose for each patient.

To aid you while going through the titration process with your patient, and to reduce the risk of medication error due to the need to take multiple tablets of up to 2 different dose strengths for up-titration, we have included the following resources in this prescriber kit (also available electronically on www.medicines.ie and www.hpra.ie):

An A4 laminated card (HCP titration guide) containing:

- A titration schedule and dosing explanation
- A guide to communicating with patients through initiation, titration and maintenance

Product information comprising:

- UPTRAVI Summary of Product Characteristics (SmPC)

A patient titration guide and patient leaflet:

- This guide and the patient leaflet are intended for demonstration and discussion with patients about the safe and effective use of UPTRAVI
- The titration guide should be given to the patient after the demonstration

Please note that the patients will receive a similar titration guide and patient leaflet in their titration pack.

Adverse event reporting details

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via HPRA Pharmacovigilance Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland on 1800 709 122 or at dsafety@its.jnj.com.

Thank you for your support. Please do not hesitate to contact us directly by calling 1800 709 122 if we can be of any further assistance or if you need to order additional patient titration guides.

Yours faithfully,



Dr Bríd Seoighe
Head of Medical Affairs