Important risk minimization information for health care professionals

UPTRAVI®
film-coated tablets
selexipag

Titration Guide

The goal of titration is to reach the individually appropriate dose for each patient. This usually happens within 8 weeks.


200 microgram tablet


800 microgram tablet

Titration Pack*

Start with 200 micrograms twice daily (BID) every 12 hours. To improve tolerability, take tablets with food. The first tablet should be taken in the evening

Reduce Tablet Burden‡

If a dose higher than 800 micrograms is needed, patients may be given:

- Another UPTRAVI 200 microgram titration pack
- A pack of UPTRAVI 800 microgram tablets

Titrate Up

Increase the dose by 200 micrograms BID. Each dosing step lasts about one week, but may take longer. The first dose of each step should be taken in the evening

Patient Follow-up

Increase the dose until side effects that cannot be tolerated or medically managed are experienced§

Step Down

If a patient reaches a dose that cannot be tolerated or medically managed, reduce the dose to the previous level

Maximum Dose

1,600 micrograms is the maximum dose a patient should be given

Maintenance Phase

The highest tolerated dose becomes the individualised maintenance dose and may be replaced with an equivalent single tablet BID.
This dose should never exceed 1,600 micrograms BID

Tablets are not actual size

*The titration pack contains 140 UPTRAVI 200 microgram film-coated tablets. This is enough tablets to titrate up to 800 micrograms.

‡The two packs have enough tablets to titrate up to 1,600 micrograms.

§The most common side effects your patients may experience while taking UPTRAVI are: headache, diarrhoea, nausea and vomiting, jaw pain, myalgia, pain in the extremity, arthralgia and flushing. For a full list of side effects see package leaflet for further information.

For dosing, dose adjustments and other information, please consult full Prescribing Information.

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Getting Patients Started

Treatment with UPTRAVI should only be initiated and monitored by a physician experienced in the treatment of pulmonary arterial hypertension (PAH).

Patient titration pack includes:

- UPTRAVI 200 microgram film-coated tablets for titration
- A patient titration guide that includes an explanation of the titration process and a diary to record the number of tablets taken daily
  - Upon initiation, be sure to review the titration guide with patients to ensure they fully understand the process and are prepared if they experience side effects

Note: to reduce tablet burden, if a dose higher than 800 micrograms is needed, patients may be given a second UPTRAVI 200 microgram titration pack and a pack of UPTRAVI 800 microgram tablets

Patient Communication

- Contact your patients weekly during the titration period to discuss their progress and to ensure that any pharmacological effects are treated effectively
- Side effects associated with the pharmacological action of UPTRAVI, such as headache, diarrhoea, jaw pain, nausea and vomiting, mylagia, pain in extremity, flushing and arthralgia, have been observed frequently, in particular during the individualised dose titration
- Expected pharmacological side effects are usually transient or manageable with symptomatic treatment
- In clinical practice, gastrointestinal (GI) events have been observed to respond to antidiarrhoeal, antiemetic and antinauseant medications and/or drugs for functional GI disorders. Pain-associated events have been frequently treated with analgesics (such as paracetamol)

Maintenance

- Once a maintenance dose is achieved, an equivalent single-tablet strength for the individualised maintenance dose can be prescribed (200–1,600 microgram tablets available)
- This allows the patient to take one tablet in the morning and one in the evening
- Every patient is different and not everyone will end up on the same maintenance dose. No dose should exceed 1,600 micrograms BID

The single maintenance dose tablets will differ in color and have numbers stamped onto the surface showing the dose (in hundreds of micrograms)

If you have any additional questions, please contact
Janssen Medical Information
*RA-MedInfoEmMarkets@ITS.JNJ.com
Adverse events reporting guidance:
*SFDA (National Pharmacovigilance center)
*Email: npc.drug@sfda.gov.sa
*Telephone: 19999 Fax: +966 11 2057662
*Online: http://ade.sfda.gov.sa

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PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

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To report Adverse Events/Product Complaint, please contact us at
Email:GCC-PV2@its.jnj.com Hotline: 00966540015811

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA).