Titration Guide

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

Titration Phase:

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 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

Patient Follow Up

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

Maximum Dose

1600 micrograms is the maximum dose a patient should be given

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

Step Down

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

Maintenance Phase

The highest tolerated dose becomes the individualized maintenance dose and may be replaced with an equivalent single tablet BID. This dose should never exceed 1600 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 2 packs have enough tablets to titrate up to 1600 micrograms.
‡The most common side effects your patients may experience while taking Uptravi are: headache, diarrhea, 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.

Uptravi▼
film-coated tablets
selexipag

Getting Patients Started

Treatment with Uptravi should only be initiated and monitored by a physician experienced in the treatment of 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

Uptravi
film-coated tablets
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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, diarrhea, jaw pain, nausea, myalgia, vomiting, pain in extremity, flushing, and arthralgia, have been observed frequently, in particular during the individualized 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 antidiarrheal, 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 individualized maintenance dose can be prescribed (200–1600 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 1600 micrograms BID

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

(Tablets are not actual size.)

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form available online at http://www.medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt

Alternatively, kindly contact directly Mr Nigel Cauchi at A.M. Mangion Ltd, Mangion Building, New Street Off Valletta Road, Luqa LQA 6000, Malta or on phone number 00356 23976333 or email at pv@ammangion.com.

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