Lexipia®

film-coated tablets
Selexipag 200 mcg, 400 mcg,
600 mcg, 800 mcg

Titration Guide

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

***800 microgram** tablet* ***200 microgram** tablet*

Titration Start

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

Titration Start

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

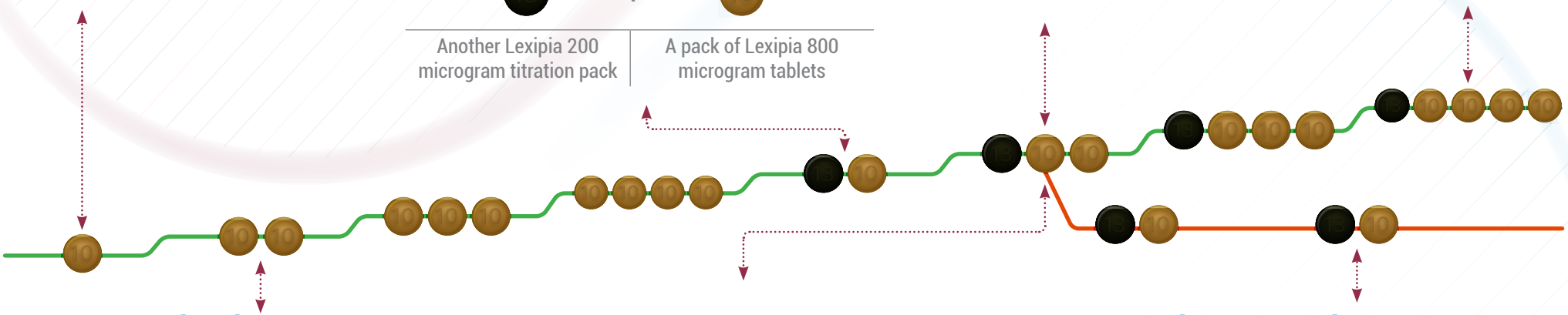
Another Lexipia 200 microgram titration pack	+	A pack of Lexipia 800 microgram tablets

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



Titration 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 individualised maintenance dose and may be replaced with an equivalent single tablet BID. This dose should never exceed 1600 micrograms BID

‡ The most common side effects your patients may experience while taking Lexipia are: headache, diarrhoea, nausea and vomiting, jaw pain, myalgia, pain in the extremity, arthralgia, flushing and nasopharyngitis (of non-infectious origin). For a full list of side effects see Summary of Product Characteristics for further information. The dosing of Lexipia should be reduced to once daily in patients with moderate hepatic impairment or if co-administered with moderate CYP2C8 inhibitors e.g. clopidogrel, deferasirox and teriflunomide. Dosing frequency of Lexipia should revert to twice daily when co-administration of CYP2C8 inhibitor is stopped.

For dosing, dose adjustments and other information, please consult full Summary of Product Characteristics (SmPC)

SPC سدير للأدوية

Version: 1.0
Date: June 2026

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

Getting Patients Started

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

Patient titration pack includes:

- Lexipia 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 Lexipia 200 microgram titration pack and a pack of Lexipia 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 Lexipia such as headache, diarrhoea, jaw pain, nausea, myalgia, vomiting, pain in extremity, flushing, arthralgia and nasopharyngitis (of non-infectious origin), 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 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 one or two tablet strength for the individualised maintenance dose can be prescribed (200–800 microgram tablets available)
- This allows the patient to take maximum one or two tablet in the morning and one or two 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

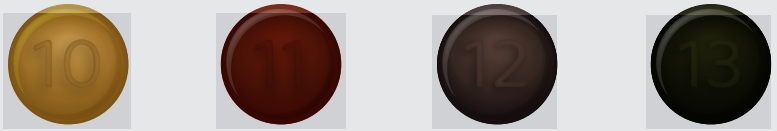
Dear Healthcare Professionals, please report any suspected adverse drug reaction experienced by your patient to the following contact :

Website: https://ade.sfda.gov.sa,
Email: npc.drug@sfda.gov.sa,
Call center: 19999

Also, you can report to Sudair Pharma Company via:
Phone: +966-920001432 Ext. 107,
Email: Pharmacovigilance@SudairPharma.com

** To acquire an additional copy of this booklet, please contact the provided information directly*

The single maintenance dose tablets will differ in colour



(Tablets are not actual size.)

SPC سدير للأدوية

Version: 1.0
Date: June 2026