

Lexipia®

film-coated tablets

Selexipag **200 mcg**, 400 mcg,
600 mcg, 800 mcg



Titration Guide

Starting Treatment With Lexipia

Please read the accompanying patient information leaflet before starting treatment. Tell your doctor if you experience side effects, take any other medicines or have any other health issues as they may need to make an adjustment to your Lexipia dose

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

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How should you take Lexipia?

Lexipia is a medicine taken every morning and evening for the treatment of pulmonary arterial hypertension, also called PAH .

The starting dose for Lexipia is 200 micrograms
once in the morning and once in the evening .

The first intake of Lexipia should be in the evening .

You should take each dose with a glass of water, preferably during a meal .

Talk to your doctor

Your doctor may recommend to take Lexipia only once daily in certain circumstances . Talk to your doctor before taking Lexipia if:

You are taking any other medicines, e .g .:

- Clopidogrel (medicine used to inhibit blood clots in coronary artery disease)
- Deferasirox (medicine used to remove iron from the blood stream)
- Teriflunomide (medicine used to treat relapsing-remitting multiple sclerosis)

You have or have had problems with your liver not working properly

There are 2 phases of treatment with Lexipia:

Titration

In the first several weeks, you will work with your doctor to find the dose of Lexipia that is right for you . Your doctor may have you step up from the starting dose to higher doses of Lexipia . Your doctor may step you down to a lower dose . This process is called titration . It lets your body gradually adjust to the medicine.

Maintenance

Once your doctor has found the dose that is right for you, this will be the dose you take on a regular basis . This is called the maintenance dose .

How should you step up your dose?

You will start at the 200 microgram dose in the morning and in the evening and after discussing with your doctor or nurse step up to the next dose.

The first intake of the increased dose should be in the evening. Each step usually lasts about 1 week . It could take several weeks to find the dose that is right for you.

***The goal is to reach the dose that is most appropriate to treat you.
This dose will be your maintenance dose.***

Every patient with PAH is different. **Not everyone will end up on the same maintenance dose.**

Some patients may have 200 micrograms in the morning and in the evening as their maintenance dose, while some will reach the highest dose of 1,600 micrograms in the morning and in the evening.

Others may reach a maintenance dose somewhere in between. What is important is that you reach the dose that is most appropriate to treat you.

What are the steps?

Each dosing step lasts about 1 week.

STARTING DOSE

10

STEP 1

Morning: One 200 microgram tablet
Evening: One 200 microgram tablet
(total daily dose: 400 microgram)

10 10

STEP 2

Morning: Two 200 microgram tablet
Evening: Two 200 microgram tablet
(total daily dose: 800 microgram)

10 10 10

STEP 3

Morning: Three 200 microgram tablet
Evening: Three 200 microgram tablet
(total daily dose: 1,200 microgram)

10 10 10 10

STEP 4

Morning: Three 200 microgram tablet
Evening: Three 200 microgram tablet
(total daily dose: 1,200 microgram)

(Tablets are not actual size.)

10

200 microgram tablet

13

800 microgram tablet (Use with steps 5 through 8 to reduce the number of tablets needed per dose.)

10

200 microgram tablet

13 10

STEP 5

Morning: One 800 and one 200 microgram tablet
 Evening: One 800 and one 200 microgram tablet
 (total daily dose: 2,000 microgram)

13 10 10

STEP 6

Morning: One 800 and two 200 microgram tablets
 Evening: One 800 and two 200 microgram tablets
 (total daily dose: 2,400 microgram)

13 10 10 10

STEP 7

Morning: One 800 and three 200 microgram tablets
 Evening: One 800 and three 200 microgram tablets
 (total daily dose: 2,800 microgram)

13 10 10 10 10

STEP 8

Morning: One 800 and four 200 microgram tablets
 Evening: One 800 and four 200 microgram tablets
 (total daily dose: 3,200 microgram)

(Tablets are not actual size.)



When should you step down?

As with all medicines, you may experience side effects with Lexipia as you step up to higher doses .

Talk to your doctor or nurse if you have side effects. There are treatments available that can help relieve them.

The most common side effects (may affect more than 1 in 10 people) you may experience while taking Lexipia are: • Headache • Diarrhoea • Nausea • Vomiting • Jaw pain • Muscle pain • Leg pain • Joint pain • Facial redness • Nasopharyngitis (stuffy nose) For a full list of side effects see patient information leaflet

If you cannot tolerate the side effects even after your doctor or nurse has tried to treat them, he or she may recommend you step down to a lower dose .

If your doctor or nurse tells you to step down to a lower dose, you should take one less 200 microgram tablet in the morning and one less in the evening.

You should only step down after speaking with your PAH doctor or nurse . This stepping-down process will help you find the dose that is right for you, also called your maintenance dose .

Stepping down

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200 microgram tablet

Each dosing step
lasts about 1 week.

START

STEP UP

STEP 1

10

Morning: One 200
microgram tablet
Evening: One 200
microgram tablet
(total daily dose: 400
microgram)

STEP 2

10 10

Increase your dose about every week by
adding a 200 microgram tablet to your
morning and evening dose

STEP 3

10 10 10

STEP UP

STEP DOWN

MAINTENANCE DOSE



13 800 microgram tablet (Use with steps 5 through 8 to reduce the number of tablets needed per dose.)

10 200 microgram tablet

When you move to your maintenance dose

The highest dose that you can tolerate during titration will become your maintenance dose . Your **maintenance dose** is the dose you should continue to take on a regular basis . Your doctor or nurse can prescribe an equivalent **one or two maximum tablet strength** for your maintenance dose .

This lets you take just one or two tablet in the morning and one or two in the evening, instead of multiple tablets for each dose.

For example, if your highest tolerated dose during titration was 1,200 micrograms two 600 mg in the morning and two 600 mg in the evening:



Over time, your doctor or nurse may adjust your maintenance dose as needed.

If you forget to take Lexipia

If you miss a dose, take the dose as soon as you remember, then continue to take your tablets at the usual times . If it is within 6 hours of when you would normally take your next dose, you should skip the missed dose and continue to take your medicine at the usual time .

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Lexipia

Do not stop taking Lexipia unless your doctor or nurse tells you to . If, for any reason, you stop taking Lexipia for more than 3 consecutive days (if you missed 6 doses in a row), **contact your PAH doctor or nurse immediately as your dose may need to be adjusted to avoid side effects.**

Your doctor or nurse may have you resume treatment at a lower dose, gradually increasing to your previous maintenance dose.

Titration diary

Please read the instructions in the package leaflet carefully.

The following diary pages help you keep track of the number of tablets you need to take in the morning and evening during titration.

Use them to write down the number of tablets you take in the morning and the evening.

Each step usually lasts about 1 week, unless your doctor or nurse instructs you otherwise. If your titration steps

last longer than 1 week there are additional diary pages to track this .

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Use pages 21 to 28 to track the first weeks of treatment, when you are using 200 microgram tablets only (steps 4–1)

10

13

If you have been prescribed both 200 and 800 microgram tablets, use pages 31 to 38 (steps 8–5) .

Remember to talk to your PAH doctor or nurse regularly:

Write down your doctor or nurse's instructions: _____

Doctor's office telephone and email: _____

Pharmacist's telephone: _____

Notes: _____

WEEK**1**

very day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
 Evening	 200 micrograms	#	#	#	#	#	#	#

The first intake of Lexipia should be in the evening

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
 Evening	 200 micrograms	#	#	#	#	#	#	#

The first intake of an increased dose of Lexipia should be in the evening

WEEK

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

#		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
 Evening	 200 micrograms	#	#	#	#	#	#	#

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
 Evening	 200 micrograms	#	#	#	#	#	#	#

Skip to page 29 if your doctor prescribes 800 microgram tablets

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
 Evening	 200 micrograms	#	#	#	#	#	#	#

Skip to page 29 if your doctor prescribes 800 microgram tablets

WEEK

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

#		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
 Evening	 200 micrograms	#	#	#	#	#	#	#

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
 Evening	 200 micrograms	#	#	#	#	#	#	#

Skip to page 29 if your doctor prescribes 800 microgram tablets

WEEK

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

#		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
 Evening	 200 micrograms	#	#	#	#	#	#	#

Skip to page 29 if your doctor prescribes 800 microgram tablets

10 200 microgram tablet

13 800 microgram tablet (Use with steps 5 through 8 to reduce the number of tablets needed per dose.)

Use the following diary pages if your doctor or nurse prescribes 800 microgram tablets in addition to your 200 microgram tablets .

On the diary pages, check off that you have taken **one** 800 microgram tablet every day in the morning and in the evening with your prescribed number of 200 microgram tablets.

Remember to talk to your PAH doctor or nurse regularly:

Write down your doctor or nurse's instructions: _____

Doctor's office telephone and email: _____

Pharmacist's telephone: _____

Notes: _____

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1
 Evening	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1
 Evening	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1
 Evening	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1
 Evening	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1
 Evening	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1
 Evening	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1
 Evening	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1

WEEK

#

Write down the number of the week of the treatment in the upper left hand corner. Every day write down in the boxes below how many tablets you take in the morning and evening. I spoke with my doctor or nurse on (DD/MM/YY)

		Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY	Date: DD/MM/YY
 Morning	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1
 Evening	 200 micrograms	#	#	#	#	#	#	#
	 800 micrograms	1	1	1	1	1	1	1

Notes:

You can help by reporting any side effects you may get . If you get any side effects, talk to your doctor, pharmacist or nurse . This includes any side effects not listed in the package leaflet . You can also report side effects directly to Saudi Food and Drug Authority (SFDA) via:



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*



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