

Uptravi

film-coated tablets
selexipag

Titration Guide

Starting Treatment With Uptravi

Please read the accompanying leaflet before starting treatment.

Tell the doctor if you experience side effects, because your doctor may advise you to change the dose of Uptravi.

Tell the doctor if you are taking other medicines because your doctor may advise you to take Uptravi only once a day.

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How should you take Uptravi?

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

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

The first intake of Uptravi should be in the evening.

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

There are 2 steps of treatment with Uptravi:

Titration

In the first weeks, you will work with your doctor to find the dose of Uptravi that is right for you. Your doctor may have you increase the dose to higher doses of Uptravi than the initial dose. Your doctor may have you reduce the dose to a lower dose. This process is called titration. It allows to 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 increase 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, increase 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 pulmonary arterial hypertension (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.

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

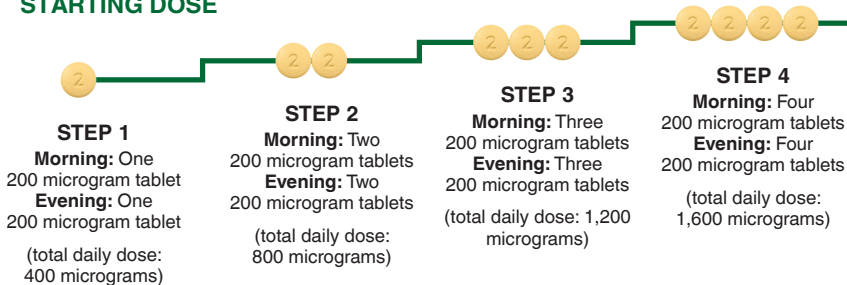


What are the steps?

2 200 microgram tablet

Each dosing step lasts about 1 week.

STARTING DOSE





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



200 microgram tablet

HIGHEST DOSE | 9



STEP 5

Morning: One 800 and one 200 microgram tablet
Evening: One 800 and one 200 microgram tablet

(total daily dose: 2,000 micrograms)



STEP 6

Morning: One 800 and two 200 microgram tablets
Evening: One 800 and two 200 microgram tablets

(total daily dose: 2,400 micrograms)



STEP 7

Morning: One 800 and three 200 microgram tablets
Evening: One 800 and three 200 microgram tablets

(total daily dose: 2,800 micrograms)



STEP 8

Morning: One 800 and four 200 microgram tablets
Evening: One 800 and four 200 microgram tablets

(total daily dose: 3,200 micrograms)

(The tablets are not shown in their actual size).



When should you reduce the dose?

As with any medicine, you may experience side effects while taking Uptravi as you increase the dose to higher doses.

Talk to your doctor if you experience side effects. There are treatments available that can help relieve the side effects.

The most common side effects (may affect more than 1 in 10 people) you may experience during treatment with Uptravi are:

- Headache • Diarrhea • Nausea • Vomiting • Jaw pain • Muscle pain
- Leg pain • Joint pain • Flushing

See the package leaflet for a full list of side effects and further information.

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

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

You should only reduce the dose after speaking with your PAH doctor. This dose reduction process will help you find the dose that is right for you, also called your maintenance dose.

Comment: PAH doctor = A doctor who treats pulmonary arterial hypertension

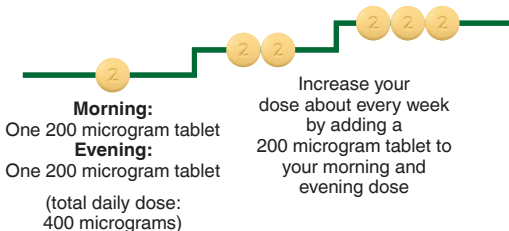
Reducing the dose

Each dosing step lasts about 1 week.

2

200 microgram tablet

(The tablets are not shown in their actual size).

START**STEP 1****STEP 2****STEP 3**

INCREASING THE DOSE

STEP 4

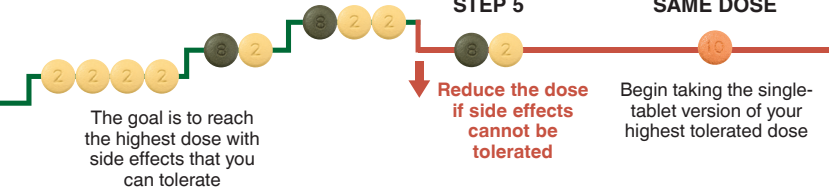
STEP 5

STEP 6

REDUCING THE DOSE

BACK TO
STEP 5

MAINTENANCE DOSE

SINGLE TABLET,
SAME DOSE

200 microgram tablet



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

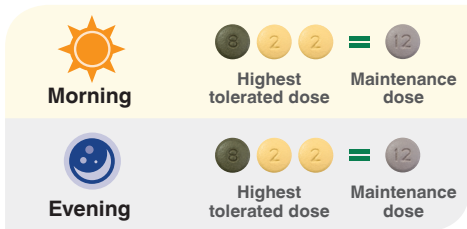
When you move to your maintenance dose

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 can prescribe an equivalent **single-tablet strength** for your maintenance dose.

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

When you move to your maintenance dose

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



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

If you forget to take Uptravi

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

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

If you stop taking Uptravi

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

Your doctor 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 instructs you otherwise.

If your titration steps last longer than 1 week, there are additional diary pages to track this.

- 2 Use pages 20 to 27 to track the first weeks of treatment, when you are using 200 microgram tablets only (steps 1-4).
- 2 3 If you have been prescribed both 200 and 800 microgram tablets, use pages 30 to 37 (steps 5-8).

Remember to talk to your PAH doctor regularly.

Write down your doctor's instructions: _____

Doctor's telephone and e-mail: _____

Pharmacist's telephone: _____

Notes: _____

WEEK

1

Every day write down in the boxes below how many tablets you take in the morning and evening.

20

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning



200
micrograms



Evening



200
micrograms



The first intake of Upravi should be in the evening

WEEK

Write down the number of the week of the treatment in the upper lefthand corner. Every day write down in the boxes below how many tablets you take in the morning and evening.

21

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms



Evening

2

200
micrograms



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

WEEK

Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

22

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms



Evening

2

200
micrograms



WEEK

Write down the number of the week of the treatment in the upper lefthand corner. Every day write down in the boxes below how many tablets you take in the morning and evening.

23

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms



Evening

2

200
micrograms



Skip to page 28 if your doctor prescribes 800 microgram tablets

WEEK

Write down the number of the week of the treatment in the upper lefthand corner. Every day write down in the boxes below how many tablets you take in the morning and evening.

24

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms



Evening

2

200
micrograms



Skip to page 28 if your doctor prescribes 800 microgram tablets

WEEK

Write down the number of the week of the treatment in the upper lefthand corner. Every day write down in the boxes below how many tablets you take in the morning and evening.

25

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning



200
micrograms



Evening



200
micrograms



Skip to page 28 if your doctor prescribes 800 microgram tablets

WEEK

Write down the number of the week of the treatment in the upper lefthand corner. Every day write down in the boxes below how many tablets you take in the morning and evening.

26

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms



Evening

2

200
micrograms



Skip to page 28 if your doctor prescribes 800 microgram tablets

WEEK

Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

27

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms



Evening

2

200
micrograms



Skip to page 28 if your doctor prescribes 800 microgram tablets

Use the following diary pages if your doctor prescribes 800 microgram tablets in addition to the 200 microgram tablets you are taking.

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.



200 microgram tablet



800 microgram tablet

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

Remember to talk to your PAH doctor regularly.

Write down your doctor's instructions: _____

Doctor's telephone and e-mail: _____

Pharmacist's telephone: _____

Notes: _____

WEEK

Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

30

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms

8

800
micrograms

Evening

2

200
micrograms

8

800
micrograms

Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms

3

800
micrograms



Evening

2

200
micrograms

3

800
micrograms



Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms

3

800
micrograms



Evening

2

200
micrograms

3

800
micrograms



Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms

3

800
micrograms



Evening

2

200
micrograms

3

800
micrograms



Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms

3

800
micrograms



Evening

2

200
micrograms

3

800
micrograms



Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms

3

800
micrograms



Evening

2

200
micrograms

3

800
micrograms



Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms

3

800
micrograms



Evening

2

200
micrograms

3

800
micrograms



Write down the number of the week of the treatment in the upper lefthand corner.
Every day write down in the boxes below how many tablets you take in the morning
and evening.

I spoke with the doctor on _____ (day/month/year).

Date: _____



Morning

2

200
micrograms

3

800
micrograms



Evening

2

200
micrograms

3

800
micrograms



Notes

The format of this card and its contents were updated and approved by the Ministry of Health in February 2022. For additional information, refer to the patient leaflet. Side effects can be reported to the Ministry of Health using the online form for reporting side effects found on the home page of the Ministry of Health website: www.health.gov.il, or by entering the link: <https://sideeffects.health.gov.il/> In addition, you can report directly to Jansen Israel 09-9591111.



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