

UPTRAVI FILM-COATED TABLETS

selexipag

Titration Guide - Starting Treatment With UPTRAVI

Please read the accompanying patient information leaflet before starting treatment. Tell your doctor if you experience side effects, as your doctor may recommend that you change your UPTRAVI dose. Tell your doctor if you are taking other medications as your doctor may recommend that you take UPTRAVI only once daily.

CONTENTS

- How should you take UPTRAVI?.....4
- How should you step up your dose?.....6
- What are the steps?8
- When should you step down?..... 10
- Stepping down12
- When you move to your maintenance dose 14
- If you forget to take UPTRAVI 16
- If you stop taking UPTRAVI 17
- Titration diary..... 18

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 two phases of treatment with UPTRAVI:

TITRATION

In the first several weeks, you will work with your doctor to find the dose of UPTRAVI that is right for you. Your doctor may have you step up from the starting dose to higher doses of UPTRAVI. 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?

 200 microgram tablet

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

STARTING DOSE



STEP 1

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



STEP 2

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



STEP 3

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



STEP 4

Morning:
Four 200 microgram tablets
Evening:
Four 200 microgram tablets
(total daily dose:
1,600 microgram)



STEP 5

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



STEP 6

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



STEP 7

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



STEP 8

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

Each dosing step lasts about 1 week.

HIGHEST DOSE

WHEN SHOULD YOU STEP DOWN?

As with all medicines, you may experience side effects with UPTRAVI 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 UPTRAVI are:

- Headache • Diarrhoea • Nausea • Vomiting • Jaw pain • Muscle pain
- Leg pain • Joint pain • Facial redness

For a full list of side effects see package leaflet for further information.

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.

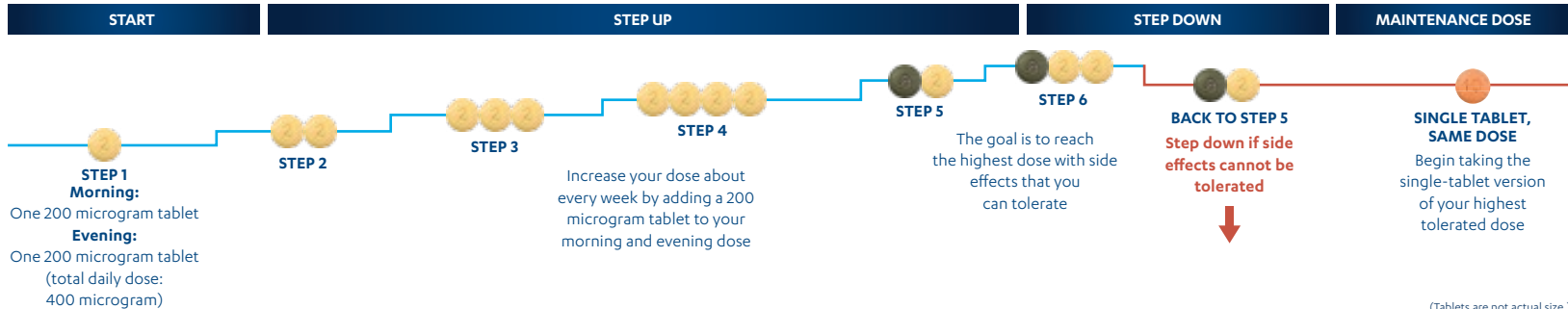
You should only step down after speaking with your PAH doctor or nurse. This stepping-down process will help you find the dose that is right for you, also called your maintenance dose.

STEPPING DOWN

Each dosing step lasts about 1 week.

 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 or nurse 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.

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 or nurse may adjust your maintenance dose as needed.

IF YOU FORGET TO TAKE UPTRAVI

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 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 six 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.



Use pages 20 to 27 to track the first weeks of treatment, when you are using 200 microgram tablets only (steps 1–4).



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 or nurse regularly.

Write down your doctor or nurse's instructions:

Doctor's office 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. I spoke with my doctor or nurse on DD/MM/YY

Date: Date: Date: Date: Date: Date: Date:

**MORNING**200
micrograms**MORNING**200
micrograms**EVENING**200
micrograms**EVENING**200
micrograms

Write down the number of the week of the treatment in the upper left hand corner.

WEEK



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: Date: Date: Date: Date: Date: Date:

Write down the number of the week of the treatment in the upper left hand corner.

WEEK 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: Date: Date: Date: Date: Date: Date:



 MORNING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>



 EVENING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Write down the number of the week of the treatment in the upper left hand corner.

WEEK 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

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 EVENING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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Date: Date: Date: Date: Date: Date: Date:

 MORNING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

 EVENING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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 EVENING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Write down the number of the week of the treatment in the upper left hand corner.

WEEK

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: Date: Date: Date: Date: Date: Date:



MORNING



200
micrograms



MORNING



200
micrograms



EVENING



200
micrograms



EVENING



200
micrograms



TITRATION DIARY

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.



200 microgram tablets



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 or nurse regularly.

Write down your doctor or nurse's instructions:

Doctor's office telephone and e-mail:

Pharmacist's telephone:



Notes:

Write down the number of the week of the treatment in the upper left hand corner.

WEEK

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: Date: Date: Date: Date: Date: Date:

 MORNING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	 800 micrograms	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>

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	 800 micrograms	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>

 EVENING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	 800 micrograms	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	<input type="text" value="1"/>




 EVENING	 200 micrograms	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Guidance for Adverse event Reporting:

Jordan Food and Drug Administration (JFDA)

- Email: jpc@jfda.jo
- Website: <https://primaryreporting.who-umc.org/JO>
- Phone No: +962-6-5632000

- QR code

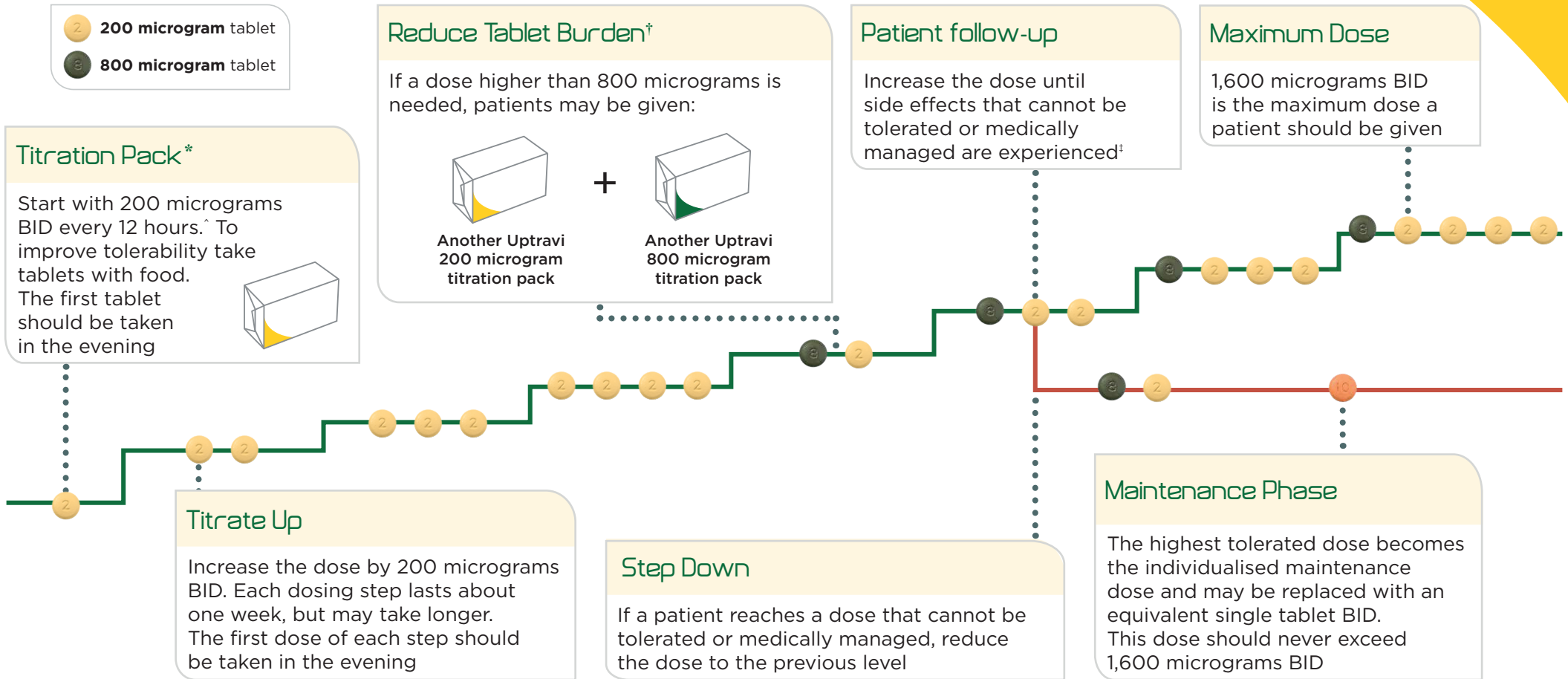


Janssen PV department

Email: JACEG-PV@its.jnj.com
mobile :+20100629760

Titration Phase:

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



(Tablets are not actual size.)

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

†The 2 packs have enough tablets to titrate up to 1,600 micrograms BID.

‡The most common side effects your patient may experience whilst taking Upravi are: headache, diarrhoea, nausea and vomiting, jaw pain, myalgia, pain in extremities, 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 Upravi 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 Upravi should revert to twice daily when co-administration of CYP2C8 inhibitor is stopped.

For dosing, dosing adjustment and other information, please consult full prescribing information.

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

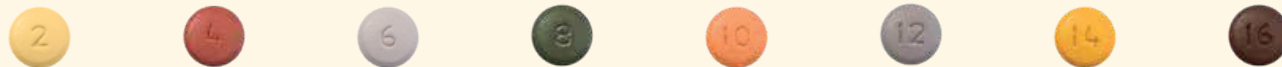
Patient Communication

- 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, myalgia, vomiting, pain in extremity, flushing, arthralgia and nasopharyngitis (of non-infectious origin), 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 colour and have numbers stamped into the surface showing the dose (in hundreds of micrograms)



(Tablets are not actual size)

Uptravi
film-coated tablets
selexipag

Janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

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EM-195814

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Janssen PV department

Email: JACEG-PV@its.jnj.com
mobile :+20100629760

Uptravi® (selexipag) treatment initiation and titration

Dear Healthcare Professional:

In this package you will find information on the use of Uptravi as a long-term oral treatment for pulmonary arterial hypertension in adult patients with WHO functional class (FC) II-III. Uptravi may be used as combination therapy in patients insufficiently controlled on treatment with an endothelin receptor antagonist (ERA) and/or a phosphodiesterase 5 inhibitor (PDE5i), or as monotherapy in patients who are not candidates for these therapies.

Starting patients on Uptravi involves dose titration, according to tolerability, to reach the individually appropriate dose for each patient.

To aid you while going through the titration process with your patient, and to reduce the risk of medication error due to the need to take multiple tablets of up to 2 different dose-strengths for up-titration, Janssen Pharmaceuticals Ltd has included the following resources in this prescriber kit according to the patient's starting dose:

An A4 laminated card (HCP Titration Guide) containing:

- A titration schedule and dosing explanation for selexipag starting doses of 200 micrograms twice daily
- A guide to communicating with patients through initiation, titration, and maintenance

Product information comprising:

- Uptravi Summary of Product Characteristics (SmPC)

A patient titration guide and patient leaflet:

- This guide and the patient leaflet are intended for demonstration and discussion with patients about the safe and effective use of Uptravi starting doses of 200 micrograms twice daily
- The titration guide corresponding to the patient's starting dose (200 micrograms) should be given to the patient after the demonstration

Please note that there is a titration pack available (200 micrograms) and the patient will receive a titration guide and patient leaflet in their titration pack.

Thank you for your support. Please do not hesitate to contact us directly through JACEG-PV@its.jnj.com if we can be of any further assistance or if you need to order additional patient titration guides.

Yours sincerely,
Janssen Team



Uptravi[®]
film-coated tablets
selexipag

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