UPTRAVI®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using UPTRAVI?

UPTRAVI contains the active ingredient selexipag. UPTRAVI is used to treat pulmonary arterial hypertension (PAH) in adults.

For more information, see Section 1. Why am I using UPTRAVI? in the full CMI.

2. What should I know before I use UPTRAVI?

Do not use if you have ever had an allergic reaction to selexipag or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use UPTRAVI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with UPTRAVI and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use UPTRAVI?

- At the start of treatment, you will take the lowest dose. This is one 200 micrograms tablet in the morning and another 200 micrograms tablet in the evening. As instructed by your doctor, you will gradually increase your dose. This is called titration. It lets your body adjust to the new medicine. The goal of titration is to reach the highest dose you can tolerate. This can be up to a maximum dose of 1600 micrograms twice a day.
- Swallow the tablets whole, do not split, crush or chew the UPTRAVI tablets.

More instructions can be found in Section 4. How do I use UPTRAVI? in the full CMI.

5. What should I know while using UPTRAVI?

Things you should do	• Remind any doctor or pharmacist you visit that you are taking UPTRAVI. • Tell your doctor if you become pregnant or are trying to become pregnant. • Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed. • Keep all of your doctor or clinic appointments.
Things you should not do	• Do not stop using this medicine unless you have agreed this with your doctor.
Driving or using machines	• Be careful driving or operating machinery until you know how UPTRAVI affects you. If you are affected, do not drive or operate machinery.
Looking after your medicine	• Store at or below 30°C. Protect from moisture.

For more information, see Section 5. What should I know while using UPTRAVI? in the full CMI.

6. Are there any side effects?

The most common side effects are headache, diarrhoea, feeling sick, being sick, jaw pain, muscle pain, pain in hands, arms, legs or feet, flushing, and joint pain. Serious side effects are allergic reaction or anaphylaxis and kidney failure.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

UPTRAVI (UP-tra-vee)

Active ingredient(s): Selexipag (se-le-xi-pag)

Consumer Medicine Information (CMI)

This leaflet provides important information about using UPTRAVI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using UPTRAVI.**

Where to find information in this leaflet:

1. Why am I using UPTRAVI?

UPTRAVI contains the active ingredient selexipag. UPTRAVI is a medicine that acts on a receptor that is the target of a natural substance called "prostacyclin".

UPTRAVI is used to treat pulmonary arterial hypertension (PAH) in adults.

It can be used on its own or with other medicines for PAH. PAH is high blood pressure in the blood vessels that carry blood from the heart to the lungs (the pulmonary arteries). In people with PAH, these arteries narrow, so the heart has to work harder to pump blood through them. This may cause people to feel tired, dizzy, short of breath, or experience other symptoms.

UPTRAVI widens the pulmonary arteries and reduces their hardening. This makes it easier for the heart to pump blood through the pulmonary arteries. It relieves the symptoms of PAH and improves the course of the disease.

2. What should I know before I use UPTRAVI?

Warnings

Do not use UPTRAVI if:

- you are allergic to selexipag, or any of the ingredients listed at the end of this leaflet.
- you have severe liver problems (Child-Pugh Class C)
- you have had a stroke within the last 3 months
- you have severe coronary heart disease or unstable angina
- you have had a myocardial infarction (heart attack) within the last 6 months
- you have a weak heart (decompensated cardiac failure) that is not under close medical observation
- you have severe arrhythmias (irregular heartbeat problem)
- you have defect of your heart valves (inborn or acquired) that causes the heart to work poorly (not related to pulmonary hypertension)
- you are taking medicines that are strong inhibitors of CYP2C8 (e.g. gemfibrozil).

Check with your doctor if you:

- have low blood pressure or experience dizziness or fainting
- have problems with your liver
- have severe problem with your kidneys or undergoing dialysis
- have problems with thyroid gland

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant or if you are breastfeeding or intend to breastfeed.

UPTRAVI is not recommended during pregnancy and breastfeeding. There is no experience with the use of this medicine during human pregnancy.

Women with PAH should avoid becoming pregnant as your condition may worsen. If you are a woman who can have children, you should use an effective contraceptive method while taking UPTRAVI.

Children and adolescents

Do not use UPTRAVI in children under 18 years of age. There is no experience with the use of this medicine in children or adolescents under 18 years old.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

You must tell your doctor if you are taking medicines for high blood pressure.

You must tell your doctor if you are taking:

- Rifampicin (antibiotic used to treat infections)
- Sodium valproate or valproic acid (used to treat epilepsy)
- Gemfibrozil (medicine used to lower the levels of fat in the blood)
- Lopinavir and ritonavir (antivirals used to treat HIV)
- Clopidogrel (used to treat heart disease/strokes)
- Deferasirox (used to treat some blood disorders)

- Teriflunomide (used to treat nervous system disorders)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect UPTRAVI.

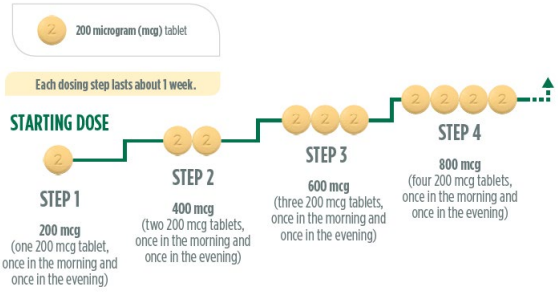
4. How do I use UPTRAVI?

How much to take

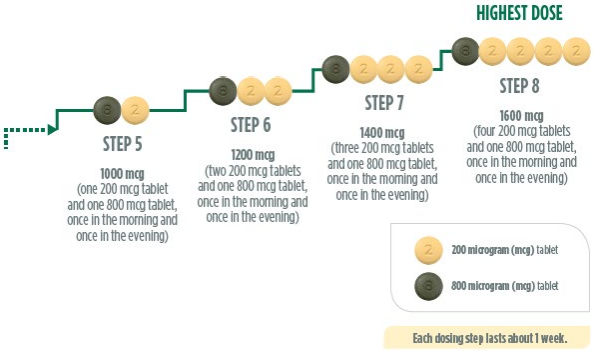
- Your doctor will decide what dose of UPTRAVI is suitable for you.
- Always take UPTRAVI exactly as your doctor has told you. Check with your doctor if you are not sure.
- Tell your doctor if you have problems with your liver or are taking other medications as your doctor may recommend different dose of UPTRAVI.

Finding the right dose for you

- At the start of treatment, you will take the lowest dose. This is one 200 micrograms tablet in the morning and another 200 micrograms tablet in the evening. It is recommended to take the first dose in the evening. As instructed by your doctor, you will gradually increase your dose. This is called titration. It lets your body adjust to the new medicine. The goal of titration is to reach the highest dose you can tolerate. This can be up to a maximum dose of 1600 micrograms twice a day.
- During titration, you will receive a titration pack containing light yellow UPTRAVI 200 micrograms tablets. These tablets have a "2" stamped on one side. Your doctor will tell you to increase your dose in steps, usually every week. With each step, you will add one 200 micrograms tablet to your morning and evening doses. The first intake of the increased dose should be in the evening. Below is a diagram to show the dose and the number of tablets at each step for the first 4 steps.



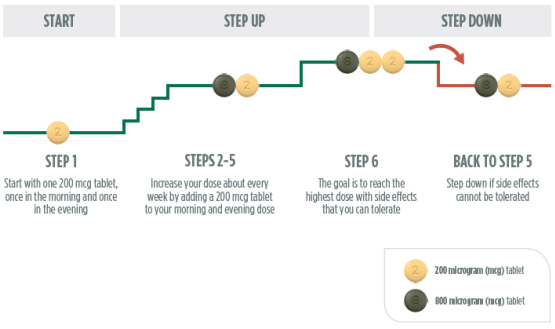
- If you reach a dose of 800 micrograms in the morning and 800 micrograms in the evening, your doctor may instruct you to increase your dose to 1000 micrograms in the morning and 1000 micrograms in the evening. This will be done by taking one green 800 micrograms tablet and adding one light-yellow 200 micrograms tablet. For this, you will receive a pack containing green UPTRAVI 800 micrograms tablets (with an "8" stamped on one side) and a titration pack containing light yellow UPTRAVI 200 micrograms tablets (with a "2" stamped on one side).
- Your doctor will tell you to increase your dose in steps, usually every week. As before, with each step, you will add a 200 micrograms tablet to your morning and evening doses. The first intake of the increased dose should be in the evening. The maximum dose of UPTRAVI is 1600 micrograms in the morning and in the evening. However, not every patient will reach this dose.
- Below is a diagram to show the dose and the number of tablets at each step starting with step 5.



- You will receive a titration guide providing information on how to increase your dose and allowing you to record the number of tablets you take every day. Remember to record the number of tablets you take every day. Remember to talk to your PAH doctor or nurse regularly during titration.

Stepping down to a lower dose due to side effects

- During titration, you may experience side effects such as headache, jaw pain, aching joints, muscle pain or a general feeling of being in pain, diarrhoea, feeling sick, being sick or reddening of the face. If these side effects are difficult for you to tolerate, talk to your doctor about how to manage or treat them. There are treatments available that can help relieve the side effects. Do not stop taking UPTRAVI unless your doctor tells you to.
- If the side effects cannot be treated or do not gradually get better on the dose you are taking, your doctor may adjust your dose by reducing by one the number of 200 micrograms yellow tablets you take in the morning and in the evening. The diagram below shows stepping down to a lower dose. Do this only if instructed to do so by your doctor.
- Do not stop taking UPTRAVI unless your doctor tells you to.

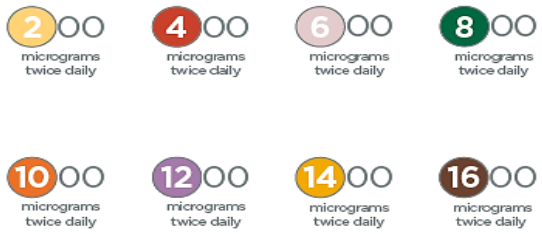


- If your side effects are manageable after stepping down your dose, your doctor may decide that you should continue to stay at that level. Please see

section "Maintenance dose" below for more information.

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, in the morning and in the evening with the minimum side effects.
- Every patient with PAH is different. Not everyone will end up on the same maintenance dose. Your maintenance dose will be between 200 micrograms and 1600 micrograms in the morning and in the evening. What is important is that you reach the dose that is most appropriate to treat you.
- Your doctor can prescribe an equivalent single-tablet strength for your maintenance dose.
- This allows you to take one tablet in the morning and one in the evening, instead of multiple tablets for each.
- The single tablet will be of a different colour depending on the dose. Each tablet will have a number on its surface showing the dose (in hundreds of micrograms). For a full description including colours and marking, please see Product details section of this leaflet.
- Over time, your doctor may adjust your maintenance dose as needed.



- If, at any time, after taking the same dose for a long time, you experience side effects that you cannot tolerate or side effects that have an impact on your normal daily activities, contact your doctor.
- Do not stop taking UPTRAVI unless your doctor tells you to.

When to take UPTRAVI

- Take UPTRAVI in the morning and in the evening, consistently either with or without meals. You might tolerate the medicine better when you take it with meals.

How to take UPTRAVI

- Swallow the tablets whole, do not split, crush or chew the UPTRAVI tablets.

If you forget to use UPTRAVI

UPTRAVI should be used regularly at the same time each day. If you miss your dose at the usual time, take a dose as soon as you remember, then continue to take your tablets at the usual times.

If it is almost time for your next dose (within six hours before you would normally take it), skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- Do not stop taking UPTRAVI unless your doctor tells you to. If, for any reason, you stop taking UPTRAVI for more than 3 consecutive days (if you missed 3 morning and 3 evening doses or 6 doses in a row or more), contact your doctor immediately as your dose may need to be adjusted to avoid side effects. Your doctor may decide to restart your treatment on a lower dose, gradually increasing to your previous maintenance dose.

If you use too much UPTRAVI

If you think that you have used too much UPTRAVI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (in Australia telephone **13 11 26** and in New Zealand telephone **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using UPTRAVI?

Things you should do

Tell your doctor or pharmacist that you are taking UPTRAVI if you are about to start on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

Keep all of your doctor or clinic appointments.

Your doctor may do certain tests, including blood tests, from time to time to make sure the medicine is working and to prevent unwanted side effects.

Remind any doctor or pharmacist you visit that you are taking UPTRAVI.

Things you should not do

- Do not stop using this medicine unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use UPTRAVI to treat any other complaints unless your doctor says to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how UPTRAVI affects you.

UPTRAVI can cause side effects such as headaches and low blood pressure and the symptoms of your condition can also make you less fit to drive. If you are affected, do not drive or operate machinery.

Looking after your medicine

- Store at or below 30°C. Protect from moisture.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

You may experience side effects not only during the titration period when your dose is being increased, but also later after taking the same dose for a long time.

If you experience any of these side effects: headache, jaw pain, aching joints, muscle pain or a general feeling of being in pain, diarrhoea, feeling sick, being sick or reddening of the face, that you cannot tolerate or that cannot be treated, you should contact your doctor as the dose you are taking may be too high for you and may need to be reduced.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Headache • Flushing (reddening of the face) • Nausea and vomiting (feeling sick and being sick) • Diarrhoea • Jaw pain, muscle pain, joint pain • Rash • Stuffy nose • Anaemia (low red blood cell levels) • Hyperthyroidism (overactive thyroid gland) • Decreased appetite • Weight loss • Hypotension (low blood pressure) • Stomach pain, including indigestion • Pain in hands, arms, legs or feet • Changes in some blood test results including those measuring blood cell counts or your thyroid function • Increased heart rate • Eye pain • Fever • Burning sensation • Feeling very tired • Flu like symptoms	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction such as: • wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest • swelling of the face, lips, tongue or other parts of the body • rash, itching, hives or flushed red skin • dizziness or light-headedness.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online in Australia at www.tga.gov.au/reporting-problems or in New Zealand at https://pophealth.my.site.com/carmreportnz/s/. By

reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What UPTRAVI contains

Active ingredient (main ingredient)	selexipag
Other ingredients (inactive ingredients)	**Tablet core:** mannitol, maize starch, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium stearate **Film coat:** **200 micrograms:** hypromellose, propylene glycol, titanium dioxide (E171), iron oxide yellow (E172), carnauba wax. **400 micrograms:** hypromellose, propylene glycol, titanium dioxide (E171), iron oxide red (E172), carnauba wax. **600 micrograms:** hypromellose, propylene glycol, titanium dioxide (E171), iron oxide red (E172), iron oxide black (E172), carnauba wax. **800 micrograms:** hypromellose, propylene glycol, titanium dioxide (E171), iron oxide yellow (E172), iron oxide black (E172), carnauba wax. **1000 micrograms:** hypromellose, propylene glycol, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172), carnauba wax. **1200 micrograms:** hypromellose, propylene glycol, titanium dioxide (E171), iron oxide black (E172), iron oxide red (E172), carnauba wax. **1400 micrograms:** hypromellose, propylene glycol, titanium dioxide (E171), iron oxide yellow (E172), carnauba wax. **1600 micrograms:** hypromellose, propylene glycol, titanium dioxide (E171), iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), carnauba wax.
Potential allergens	n/a

Do not take this medicine if you are allergic to any of these ingredients.

What UPTRAVI looks like

UPTRAVI 200 micrograms film-coated tablets are: Round, light yellow, film-coated tablets with “2” marked on one side. (AUST R 234161).

UPTRAVI 400 micrograms film-coated tablets are: Round, red, film-coated tablets with “4” marked on one side. (AUST R 234160)

UPTRAVI 600 micrograms film-coated tablets are: Round, light violet, film-coated tablets with “6” marked on one side. (AUST R 234159)

UPTRAVI 800 micrograms film-coated tablets are: Round, green, film-coated tablets with “8” marked on one side. (AUST R 234166)

UPTRAVI 1000 micrograms film-coated tablets are: Round, orange, film-coated tablets with “10” marked on one side. (AUST R 234162)

UPTRAVI 1200 micrograms film-coated tablets are: Round, dark violet, film-coated tablets with “12” marked on one side. (AUST R 234163)

UPTRAVI 1400 micrograms film-coated tablets are: Round, dark yellow, film-coated tablets with “14” marked on one side. (AUST R 234165)

UPTRAVI 1600 micrograms film-coated tablets are: Round, brown, film-coated tablets with “16” marked on one side. (AUST R 234164)

Who distributes UPTRAVI

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Road

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

This leaflet was prepared on 13 January 2025.