Patient Information Leaflet (PIL)

SCHEDULING STATUS
Schedule 4

UPTRAVI® 200 microgram film-coated tablets

UPTRAVI® 400 microgram film-coated tablets

UPTRAVI® 600 microgram film-coated tablets

UPTRAVI® 800 microgram film-coated tablets

UPTRAVI® 1 000 microgram film-coated tablets

UPTRAVI® 1 200 microgram film-coated tablets

UPTRAVI® 1 400 microgram film-coated tablets

UPTRAVI® 1 600 microgram film-coated tablets

Active substance: Selexipag

Contains sugar (mannitol).

UPTRAVI 200 microgram film coated tablets:

Each 7,3 mm diameter film-coated tablet contains 72,6 mg mannitol.

UPTRAVI 400 microgram film coated tablets:

Each 7,3 mm diameter film-coated tablet contains 72,4 mg mannitol.

UPTRAVI 600 microgram film coated tablets:

Each 7,3 mm diameter film-coated tablet contains 72,2 mg mannitol.

UPTRAVI 800 microgram film coated tablets:

Each 7,3 mm diameter film-coated tablet contains 72,0 mg mannitol.

UPTRAVI 1 000 microgram film coated tablets:

Each 7,3 mm diameter film-coated tablet contains 71,8 mg mannitol.

UPTRAVI 1 200 microgram film coated tablets:

Each 7,3 mm diameter film-coated tablet contains 71,6 mg mannitol.

UPTRAVI 1 400 microgram film coated tablets:

Each 7,3 mm diameter film-coated tablet contains 71,4 mg mannitol.

UPTRAVI 1 600 microgram film coated tablets:

Each 7,3 mm diameter film-coated tablet contains 71,2 mg mannitol.

Read all of this leaflet carefully before you start taking UPTRAVI film-coated tablets:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- UPTRAVI has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What UPTRAVI is and what it is used for

2. What you need to know before you take UPTRAVI

3. How to take UPTRAVI

4. Possible side effects

5. How to store UPTRAVI

6. Contents of the pack and other information

1. What UPTRAVI is and what it is used for

UPTRAVI is a medicine that contains the active substance selexipag. It acts on blood vessels in a similar way to the natural substance prostacyclin, making them relax and widen.

UPTRAVI is used for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients insufficiently controlled with other types of medicines for PAH known as endothelin receptor antagonists and phosphodiesterase type 5 inhibitors. UPTRAVI can be used on its own if the patient is not a candidate for these medicines.

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.

By mimicking the action of prostacyclin, 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 you need to know before you take UPTRAVI

Do not take UPTRAVI:

- If you are hypersensitive (allergic) to selexipag or any of the other ingredients of UPTRAVI (listed in section 6).
- If you are taking gemfibrozil (medicine used to lower the level of fats (lipids) in the blood).

Warnings and precautions

Take special care with UPTRAVI if you:

- are taking medicines for high blood pressure
- have low blood pressure associated with symptoms such as dizziness
- have recently experienced significant blood loss or fluid loss such as severe diarrhoea or vomiting
- have problems with your thyroid gland
- have severe problems with your kidneys or are undergoing dialysis
- have or have had severe problems with your liver not working properly
- are taking clopidogrel, deferasirox, or teriflunomide.

Children and adolescents

Do not give UPTRAVI to children under 18 years of age, because UPTRAVI has not been tested in children.

Elderly patients

There is limited experience with UPTRAVI in patients older than 75 years. UPTRAVI should be used with caution in this group.

Other medicines and UPTRAVI

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Talk to your doctor or nurse if you are taking any of the following medicines:

- Gemfibrozil (medicine used to lower the level of fats [lipids] in the blood)
- 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)
- Carbamazepine (medicine used to treat some forms of epilepsy, nerve pain or to help control serious mood disorders when some other medicines do not work)
- Phenytoin (medicine used to treat epilepsy)
- Valproic acid (medicine used to treat epilepsy)
- Probenecid (medicine used to treat gout)
- Fluconazole, rifampicin or rifapentine (antibiotics used to treat infections).

UPTRAVI with food and drink

Take the tablets with meals as you might tolerate your medicine better. Swallow the tablets whole with a glass of water. Do not split, crush or chew the tablets.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have baby, please consult your doctor, pharmacist or other health care provider for advice before taking UPTRAVI. If you are a woman who can have children, you should use an effective contraceptive method while taking UPTRAVI.

UPTRAVI is not recommended during pregnancy and breastfeeding.

Driving and using machines

UPTRAVI can cause side effects such as headaches and low blood pressure, which may affect your ability to drive; the symptoms of your condition can also make you less fit to drive.

UPTRAVI contains mannitol

UPTRAVI contains mannitol. If you have been told that you have an intolerance to some sugars, you should not take UPTRAVI. UPTRAVI contains mannitol that may have a laxative effect or cause diarrhoea.

3. How to take UPTRAVI

Do not share medicines prescribed for you with any other person.

Always take UPTRAVI exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with UPTRAVI will last. Do not stop treatment early because your symptoms may return. If you have the impression that the effect of UPTRAVI is too strong or too weak, tell your doctor or pharmacist.

If you have poor vision or experience any type of blindness, get help from another person when taking UPTRAVI during the titration period.

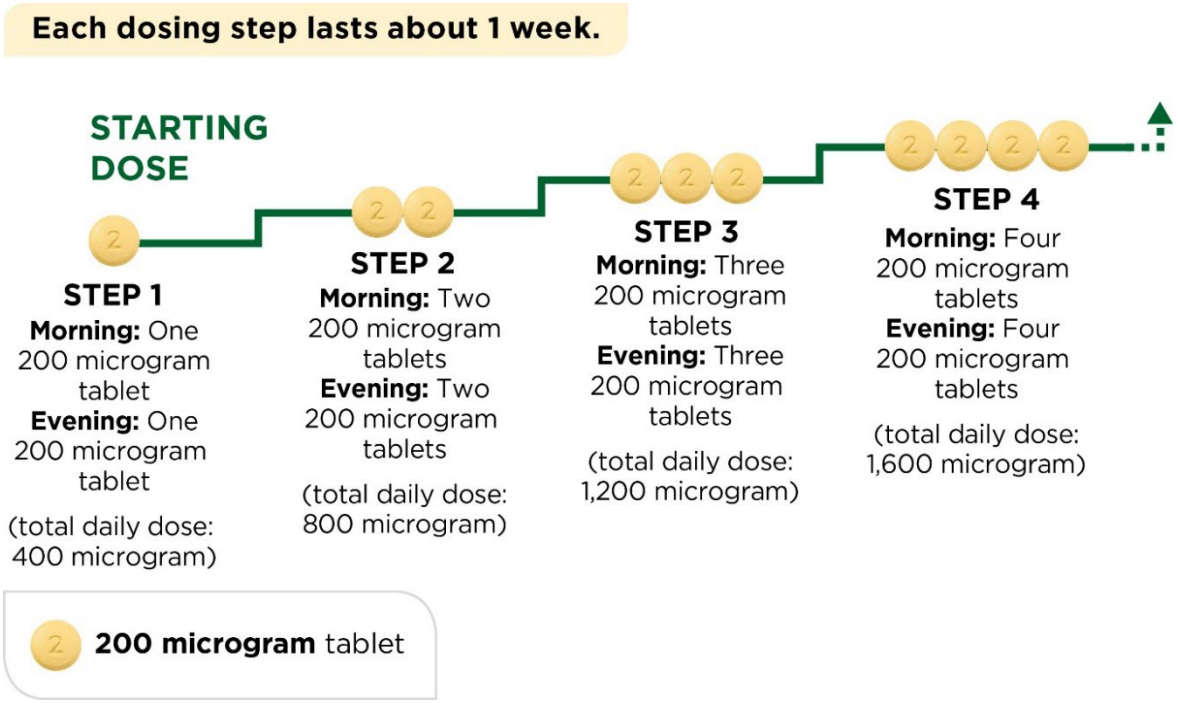
Finding the right dose for you

At the start of treatment, you will take the lowest dose. This is **one 200 microgram tablet in the morning and another 200 microgram tablet in the evening**. Treatment should be initiated in the evening. Your doctor will instruct you to 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 most appropriate dose. This will be the highest dose you can tolerate, which may reach the maximum dose of 1 600 micrograms in the morning and in the evening.

The first pack of tablets you receive will contain the light-yellow 200 microgram tablets. Your doctor will tell you to increase your dose in steps, usually every week but the interval between increases could be longer.

With each step, you will add one 200 microgram tablet to your morning dose and another 200 microgram tablet to your evening dose. The first intake of the increased dose should

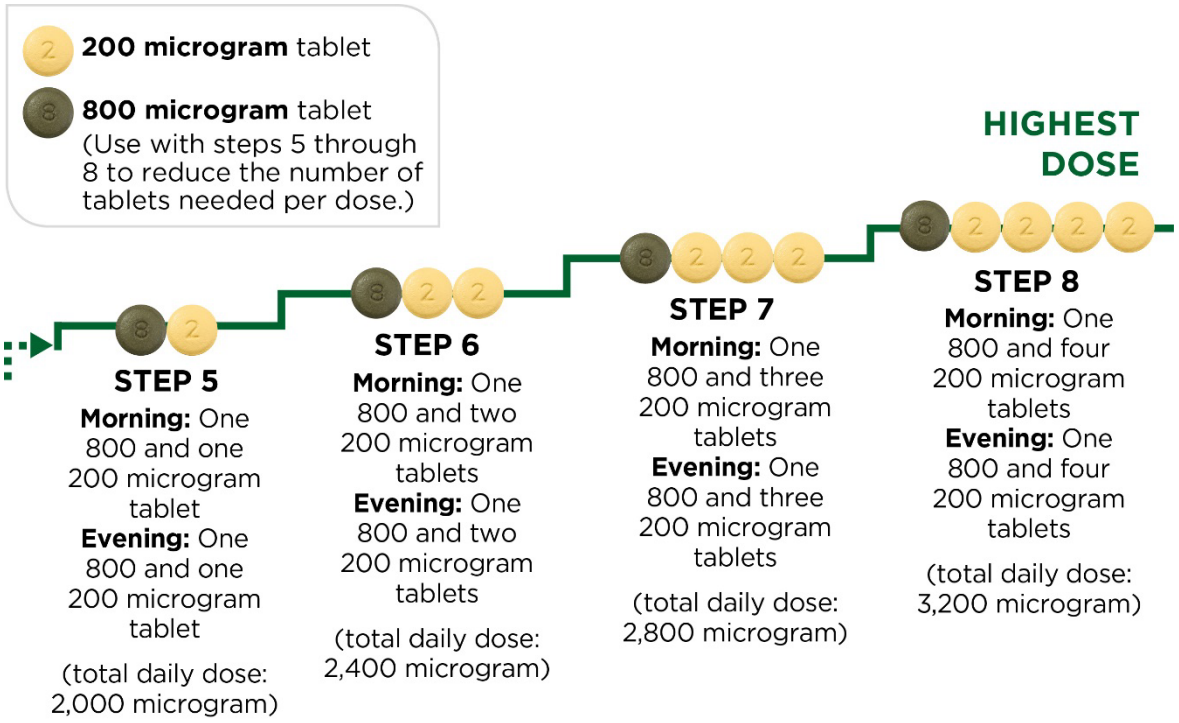
be in the evening. The diagram below shows the number of tablets to take **every morning** and **every evening** for the first 4 steps.



If your doctor instructs you to further increase your dose and move to step 5, this may be done by taking one green 800 microgram tablet and one light-yellow 200 microgram tablet in the morning and one 800 microgram tablet and one 200 microgram tablet in the evening.

If your doctor tells you to increase your dose further, you will add one 200 microgram tablet to your morning dose and one 200 microgram tablet to your evening dose with each new step. The first intake of the increased dose should be in the evening. The maximum dose of UPTRAVI is 1 600 micrograms in the morning and 1 600 micrograms in the evening. However, not every patient will reach this dose, because different patients require different doses.

The diagram below shows the number of tablets to take **every morning** and **every evening** at each step, starting with step 5.



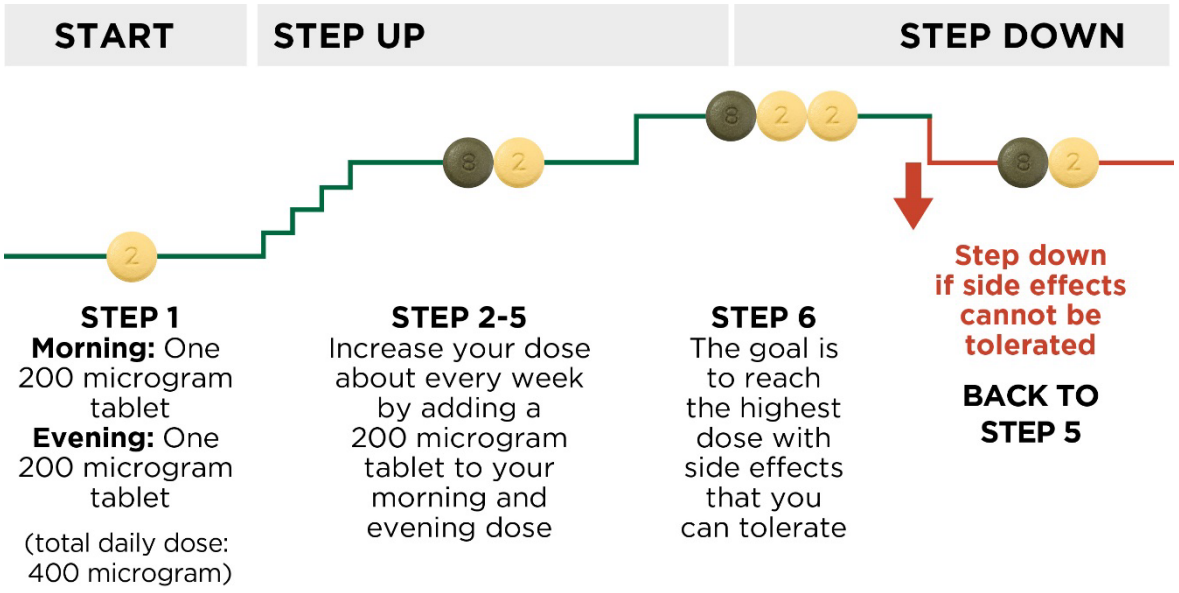
The titration pack also contains a titration guide providing information on the titration process and allowing you to record the number of tablets you take every day.

Remember to record the number of tablets you take every day in your titration diary. The titration steps usually last about 1 week. If your doctor instructs you to prolong each titration step longer than 1 week, there are additional diary pages to allow you to track this. **Remember to talk to your 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, diarrhoea, feeling sick (nausea), being sick (vomiting), jaw pain, muscle pain, leg pain, joint pain, or reddening of the face (see section 4). 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. For example, painkillers such as paracetamol may help treat pain and headache. Remember to speak to your healthcare professional first and/or refer to the paracetamol prescribing information for dosage and directions and further information.

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 the number of 200 microgram light-yellow tablets you take by one in the morning and by one in the evening. The diagram below shows stepping down to a lower dose. Do this only if instructed to do so by your doctor.



If your side effects are manageable after stepping down your dose, your doctor may

decide that you should stay on that dose. Please see the 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 that you should continue to take on a regular basis.

Your doctor will prescribe a suitable 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 each time.**

For a full description of UPTRAVI tablets, including colours and marking, please see the section 6 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 as your dose may need to be reduced. The doctor may then prescribe you a lower single-tablet strength. Please remember to dispose of unused tablets (see section 5).

Take UPTRAVI once in the morning and once in the evening, about 12 hours apart.

If you take more UPTRAVI than you should:

If you have taken more tablets than you have been told to take, ask your doctor for advice. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take UPTRAVI:

If you forget to take UPTRAVI, take a dose as soon as you remember, then continue to take your tablets at the usual times. If it is nearly time for your next dose (within 6 hours before you would normally take it), 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:

Suddenly stopping your treatment with UPTRAVI might lead to your symptoms getting worse. Do not stop taking UPTRAVI unless your doctor tells you to. Your doctor may tell you to reduce the dose gradually before stopping completely.

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 have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

UPTRAVI can have side effects.

Not all side effects reported for UPTRAVI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking UPTRAVI, please consult your health care provider for advice.

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, diarrhoea, feeling sick (nausea), being sick (vomiting), jaw pain, muscle pain, leg pain, joint pain, 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 maybe too high for you and may need to be reduced.

Frequent side effects

- Headache,
- Flushing (reddening of the face),
- Nausea and vomiting (feeling sick and being sick),

- Diarrhoea,
- Jaw pain, muscle pain, joint pain, leg pain,
- Nasopharyngitis (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,
- Changes in some blood test results including those measuring blood cell counts or your thyroid function,
- Rashes, including hives, may cause a burning or stinging sensation and skin redness.

Less frequent side effects:

- Increased heart rate.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of UPTRAVI.

Alternatively, you may report side effects experienced with UPTRAVI directly to Janssen Pharmaceutica (see section 'Holder of the Certificate of Registration' for contact details or visit www.janssen.com).

5. How to store UPTRAVI

Store at or below 30 °C.

Store film-coated tablets in the original blisters and keep the blisters in the outer carton until required for use.

Store all medicines out of reach of children.

Do not use UPTRAVI after the expiry date stated on blister and carton after "EXP." The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What UPTRAVI contains

The active substance is selexipag.

UPTRAVI 200 microgram film-coated tablets contain 200 micrograms of selexipag.

UPTRAVI 400 microgram film-coated tablets contain 400 micrograms of selexipag.

UPTRAVI 600 microgram film-coated tablets contain 600 micrograms of selexipag.

UPTRAVI 800 microgram film-coated tablets contain 800 micrograms of selexipag.

UPTRAVI 1 000 microgram film-coated tablets contain 1 000 micrograms of selexipag.

UPTRAVI 1 200 microgram film-coated tablets contain 1 200 micrograms of selexipag.

UPTRAVI 1 400 microgram film-coated tablets contain 1 400 micrograms of selexipag.

UPTRAVI 1 600 microgram film-coated tablets contain 1 600 micrograms of selexipag.

The other ingredients are:

In the tablet core: Maize starch, D-mannitol (E421), hydroxypropyl cellulose, low substituted hydroxypropyl cellulose and magnesium stearate.

In the film coat:

Carnauba wax, hypromellose, iron oxides (see below), propylene glycol and titanium dioxide (E171).

UPTRAVI 200 microgram film-coated tablets contain iron oxide yellow (E172).

UPTRAVI 400 microgram film-coated tablets contain iron oxide red (E172).

UPTRAVI 600 microgram film-coated tablets contain iron oxide red and iron oxide black (E172).

UPTRAVI 800 microgram film-coated tablets contain iron oxide yellow and iron oxide black (E172).

UPTRAVI 1 000 microgram film-coated tablets contain iron oxide red and iron oxide yellow (E172).

UPTRAVI 1 200 microgram film-coated tablets contain iron oxide black and iron oxide red (E172).

UPTRAVI 1 400 microgram film-coated tablets contain iron oxide yellow (E172).

UPTRAVI 1 600 microgram film-coated tablets contain iron oxide black, iron oxide red and iron oxide yellow (E172).

Contains sugar (mannitol).

What UPTRAVI looks like and the contents of the pack

UPTRAVI 200 microgram film coated tablets:

Round, 7,3 mm diameter, light-yellow, film-coated tablets with "2" debossed on one side.

UPTRAVI 400 microgram film coated tablets:

Round, 7,3 mm diameter, red, film-coated tablets with "4" debossed on one side.

UPTRAVI 600 microgram film coated tablets:

Round, 7,3 mm diameter, light-violet, film-coated tablets with "6" debossed on one side.

UPTRAVI 800 microgram film coated tablets:

Round, 7,3 mm diameter, green, film-coated tablets with "8" debossed on one side.

UPTRAVI 1 000 microgram film coated tablets:

Round, 7,3 mm diameter, orange, film-coated tablets with "10" debossed on one side.

UPTRAVI 1 200 microgram film coated tablets:

Round, 7,3 mm diameter, dark-violet, film-coated tablets with "12" debossed on one side.

UPTRAVI 1 400 microgram film coated tablets:

Round, 7,3 mm diameter, dark-yellow, film-coated tablets with "14" debossed on one side.

UPTRAVI 1 600 microgram film coated tablets:

Round, 7,3 mm diameter, brown, film-coated tablets with "16" debossed on one side.

UPTRAVI film-coated tablets are packed in alu/alu blisters with a desiccant consisting of:

- 25 µm Polyamide/ 45 µm aluminium/high-density polyethylene/polyethylene with an embedded desiccant agent/high-density polyethylene forming foil
- Aluminium lid foil, push through 20 µm.

The blisters are packed in an outer carton as secondary functional packaging.

Pack sizes:

UPTRAVI 200/ 400/ 600/ 800/ 1 000/ 1 200/ 1 400 & 1600 µg tablets are packed in blisters containing 60 tablets.

UPTRAVI titration pack comprises of 200 µg tablets only, packed in blisters containing 140 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration number

UPTRAVI 200 microgram: 53/7.1.3/0631

UPTRAVI 400 microgram: 53/7.1.3/0632

UPTRAVI 600 microgram: 53/7.1.3/0633

UPTRAVI 800 microgram: 53/7.1.3/0634

UPTRAVI 1 000 microgram: 53/7.1.3/0635

UPTRAVI 1 200 microgram: 53/7.1.3/0636

UPTRAVI 1 400 microgram: 53/7.1.3/0637

UPTRAVI 1 600 microgram: 53/7.1.3/0638

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.