READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr UPTRAVI®
Selexipag (film-coated) tablets

Read this carefully before you start taking **UPTRAVI** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **UPTRAVI**.

What is UPTRAVI used for?
UPTRAVI is used for the long-term treatment of 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).

How does UPTRAVI work?
UPTRAVI widens the arteries that carry blood from the heart to the lung and reduces their hardening. This makes it easier for the heart to pump blood through the pulmonary arteries.

What are the ingredients in UPTRAVI?
Medicinal ingredients: Selexipag**.**

Non-medicinal ingredients:

Strength	**Non-medicinal ingredients**
200 mcg	carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose, iron oxide yellow (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)
400 mcg	carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose, iron oxide red (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)
600 mcg	carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose, iron oxide black (E172), iron oxide red (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)
800 mcg	carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose, iron oxide black (E172), iron oxide yellow (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)
1000 mcg	carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose, iron oxide red (E172), iron oxide yellow (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)
1200 mcg	carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose, iron oxide black (E172), iron oxide red (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)
1400 mcg	carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose,

	iron oxide yellow (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)
1600 mcg	carnauba wax, corn starch, D-mannitol, hydroxypropyl cellulose, hypromellose, iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), low substituted hydroxypropyl cellulose, magnesium stearate, propylene glycol, titanium dioxide (E171)

UPTRAVI comes in the following dosage forms:

Strength	Description of the tablets
200 mcg	film-coated tablets (round, light-yellow, film-coated tablets with “2” marked on one side)
400 mcg	film-coated tablets (round, red, film-coated tablets with “4” marked on one side)
600 mcg	film-coated tablets (round, light-violet, film-coated tablets with “6” marked on one side)
800 mcg	film-coated tablets (round, green, film-coated tablets with “8” marked on one side)
1000 mcg	film-coated tablets (round, orange, film-coated tablets with “10” marked on one side)
1200 mcg	film-coated tablets (round, dark-violet, film-coated tablets with “12” marked on one side)
1400 mcg	film-coated tablets (round, dark-yellow, film-coated tablets with “14” marked on one side)
1600 mcg	film-coated tablets (round, brown, film-coated tablets with “16” marked on one side)

Do not use UPTRAVI if:
If you are allergic to selexipag or any of the other ingredients of this medicine.
If you are being treated with strong inhibitors of CYP2C8 (e.g., gemfibrozil).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take UPTRAVI. Talk about any health conditions or problems you may have, including if you:

- have low blood pressure
- have liver problems
- have kidney problems or are on dialysis
- have narrowing of the pulmonary veins, a condition called pulmonary veno-occlusive disease or PVOD
- have overactive thyroid gland
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed
- have any other medical conditions

Driving and using machines
UPTRAVI can cause side effects such as headaches and low blood pressure. Before driving or

using machines, make sure you know how you feel while taking UPTRAVI.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Taking other medicines may affect how UPTRAVI works.

Talk to your PAH doctor or nurse if you are taking any of the following medicines:
- Gemfibrozil (used to lower the level of fats [lipids] in the blood)
- Valproic acid (used to treat epilepsy)
- Rifampicin (antibiotic used to treat infections)

Tell your doctor if you are taking, have recently taken, or might take any other medicines.

How to take UPTRAVI:
- UPTRAVI should only be prescribed by a doctor experienced in the treatment of pulmonary arterial hypertension.
- Always take UPTRAVI exactly as your doctor has told you.
- Check with your doctor if you are not sure, or have any questions.
- Take UPTRAVI in the morning and in the evening, either with or without meals.
- You might tolerate the medicine better when you take it with meals.
- Swallow the tablets whole with a glass of water.
- Do not split, crush or chew the tablets.

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 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 most appropriate dose to treat you; this will be the highest dose you can tolerate.
- 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 to your stomach or throwing up, stomach ache or reddening of the face.
- If any of 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.**

Usual 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.

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.

After taking the same dose for a long time, you may experience side effects that you cannot tolerate or that have an effect on your normal daily activities. If this happens, contact your doctor. Your doctor may adjust your maintenance dose as needed.

Overdose:

If you think you have taken too much UPTRAVI, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- If you forget to take UPTRAVI, take a dose as soon as you remember. Continue to take your next dose at the usual time.
- If it is nearly time for your next dose (within 6 hours before you would normally take it), skip the missed dose. Continue to take your next dose at the usual time.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking UPTRAVI

- Keep taking UPTRAVI unless your doctor tells you to stop.
- **Contact your doctor right away if you miss doses for more than 3 days in a row.**
- Your doctor may decide to restart your treatment at a lower dose to avoid side effects. Your dose may be gradually increased to your previous maintenance dose.

What are possible side effects from using UPTRAVI?

These are not all the possible side effects you may feel when taking UPTRAVI. If you experience any side effects not listed here, contact your healthcare professional.

Like all medicines, UPTRAVI can cause side effects. You may experience side effects during the titration period and after taking the same dose for a long time.

If you experience any of these side effects below that you cannot tolerate or do not respond to treatment, talk to your doctor. The dose you are taking may be too high for you and may need to be reduced.

- headache
- jaw pain
- aching joints
- muscle pain or a general feeling of being in pain
- diarrhoea
- feeling sick to your stomach or throwing up
- stomach ache
- reddening of the face

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Headache	✓		
Flushing (reddening of the face)	✓		
Nausea and vomiting (feeling sick to your stomach and throwing up)	✓		
Diarrhoea	✓		
Jaw pain, muscle pain, joint pain	✓		
Rash	✓		
COMMON Anaemia (low red blood cell levels)		✓	
Hyperthyroidism (overactive thyroid gland)		✓	
Decreased appetite	✓		
Hypotension (low blood pressure)		✓	
Stomach pain	✓		
Pain	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
    - Fax to 1-866-678-6789 (toll-free), or
    - Mail to: Canada Vigilance Program
      Health Canada, Postal Locator 0701E
      Ottawa, ON
      K1A 0K9

      Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep out of reach and sight of children.
- Do not use UPTRAVI after the expiration date, which is stated on the carton and on the blister after "EXP." The expiration date refers to the last day of that month.
- Store at room temperature (15 to 30°C). Store UPTRAVI in its original package.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer require. These measures will help to protect the environment.

If you want more information about UPTRAVI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://www.hc.sc.gc.ca), the manufacturer's website (www.janssen.com/canada) or by calling 1-800-567-3331 and 1-800-387-8781.

This leaflet was prepared by Janssen Inc.

Last Revised: November 2018