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Educational brochure for healthcare professionals and diary for patients using Uptravi

Measures to prevent medication errors due to weekly dose increases during initial titration phase

Healthcare professionals expected to prescribe and dispense Uptravi (selexipag) will be given an educational brochure to ensure that the medicine is used correctly. Patients will be given a diary to help them remember which dose to take. In addition, prescribers will only be able to prescribe Uptravi once they have registered with the company that markets Uptravi and received appropriate information on the safe and effective use of Uptravi.

Uptravi is a medicine used to treat adults with pulmonary arterial hypertension (PAH, abnormally high blood pressure in the arteries of the lungs). It is available as tablets to be taken by mouth.

Treatment with Uptravi includes an initial titration phase, whereby the patient receives a low starting dose which is gradually increased over several weeks to a maintenance dose, which is continued long-term. Treatment should be started at a dose of 200 micrograms twice a day, in the morning and in the evening. If the patient tolerates the dose, the doctor may increase the dose every week by 200 micrograms twice daily, up to a maximum of 1,600 micrograms twice daily. If the patient does not tolerate the dose, the doctor may decrease the dose.

Uptravi is available in different strengths (200; 400; 600; 800; 1,000; 1,200; 1,400 and 1,600 micrograms). The 200 strength is used to step the dose up and down slowly during titration. Once a maintenance dose is established, the other strengths can be used to allow patients to take only one tablet in the morning and one in the evening, instead of multiple tablets each time.

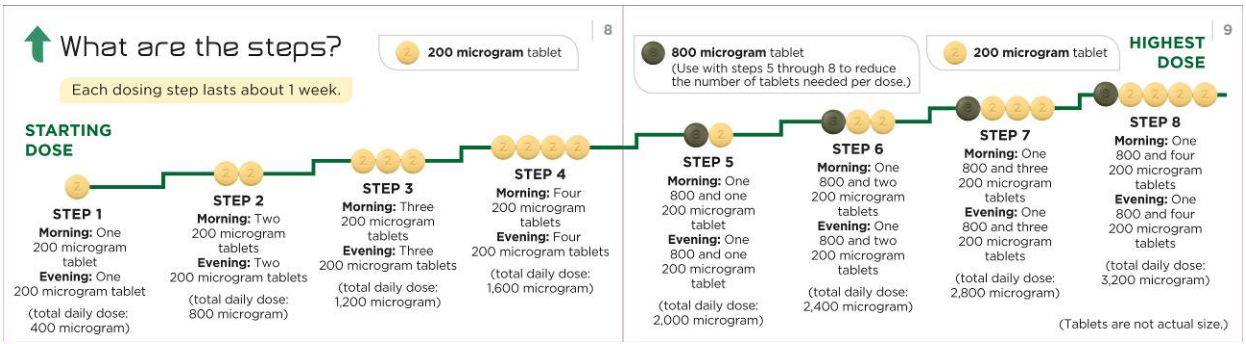
The fact that Uptravi is available in different strengths and that the dose is changed usually weekly during the titration phase may lead to confusion and errors by patients when taking the medicine. This could lead to patients receiving either too much (overdose) or too little (underdose) of the medicine. Underdosing may result in lack of effect whereas overdosing may lead to side effects such as headache, diarrhoea, nausea and vomiting.

Information for patients

- Uptravi is available as tablets in different strengths (200; 400; 600; 800; 1,000; 1,200; 1,400 and 1,600 micrograms).

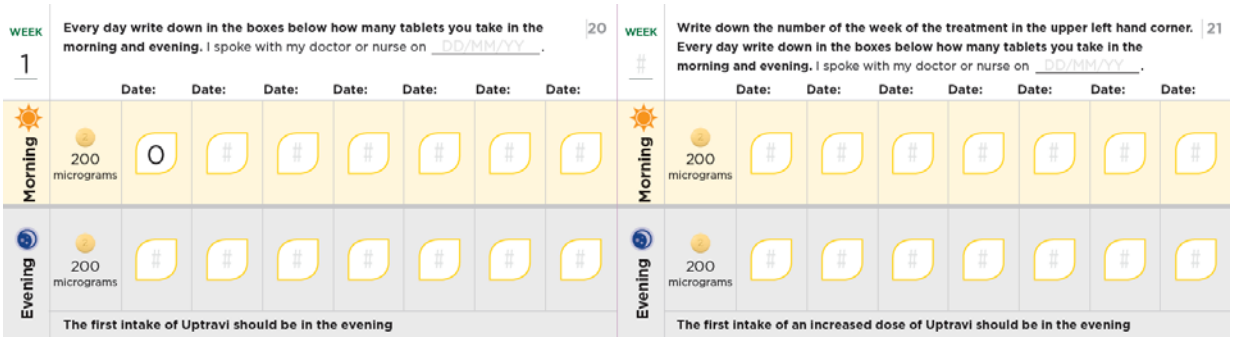
30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

- You will start treatment with one 200 microgram tablet twice a day, in the morning and in the evening (approximately 12 hours apart).
- If you tolerate this dose, your doctor will then increase your dose usually every week by 200 micrograms twice daily, up to a maximum of 1,600 micrograms twice daily as detailed in the following diagram:

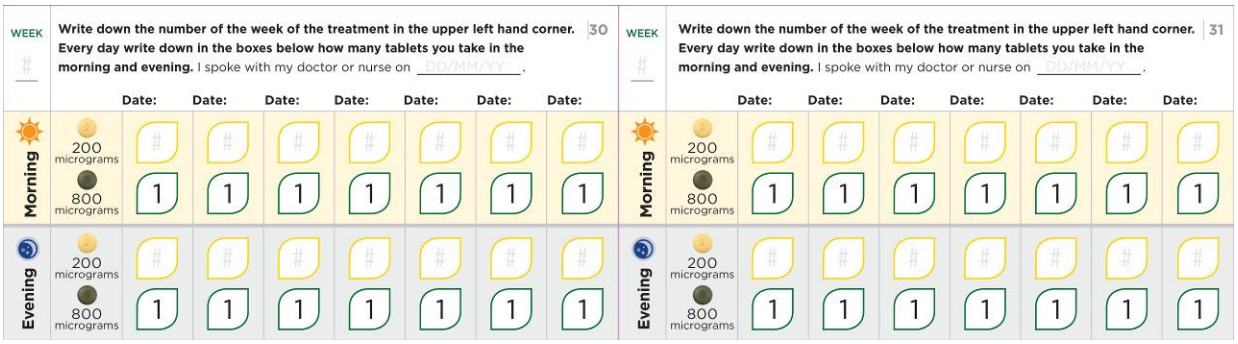


During the titration phase only the 200 and 800 microgram strengths are used. If you do not tolerate the dose, the doctor may decrease the dose to the previous step.

- The first dose of Uptravi should always be taken in the evening. When the dose is changed, the new dose should also be first taken in the evening.
- You will be given a diary to help you keep track of the number of tablets you need to take during the titration phase. Use the diary boxes corresponding to the strength of tablets you take. The diary contains for each strength two boxes for each day of treatment, one for the morning dose and one for the evening dose. Use these boxes to write down the number of tablets you take. In case you are only using the 200 microgram strength, the diary pages look as follows:



Once you have gone through the 4 steps of increasing the dose and are at step 5, you will be taking both the 200 microgram and the 800 microgram strengths at the same time. In this case you should refer to the following diary page to help you keep track of the number of tablets you need to take:



- If during titration it is difficult to tolerate certain side effects, your doctor may reduce the dose by reducing the number of tablets that you take. If side effects are manageable after stepping down the dose, your doctor may decide that you should stay on that dose.
- Once a suitable dose for you has been established (known as the maintenance dose), the doctor may prescribe a different strength of Uptravi tablet so you only need to take one tablet in the morning and one in the evening to get the right amount of the medicine.
- If you have any questions regarding your treatment, please contact your doctor, pharmacist or nurse.

Information for healthcare professionals

- Before prescribing Uptravi, healthcare professionals must register with the company's controlled access system.
- When prescribing Uptravi, healthcare professionals should follow the instructions provided in the summary of product characteristics and the educational material for Uptravi (brochure).
- Uptravi is available as tablets in different strengths (200; 400; 600; 800; 1,000; 1,200; 1,400 and 1,600 micrograms). Treatment should be started at a dose of 200 micrograms twice a day, approximately 12 hours apart.
- If the patient tolerates the dose, the dose can be increased weekly by 200 micrograms twice daily, up to a maximum of 1,600 micrograms twice daily. During titration, the 200 and 800 micrograms strengths are used. Once a maintenance dose has been established, a different strength may be prescribed so that the patient takes only a single tablet twice daily. If patients do not tolerate the dose, the dose may be decreased to the previous step.
- The first dose of Uptravi should always be taken in the evening. This also applies to any changes in the dose.
- Before prescribing or dispensing Uptravi, healthcare professionals should give patients a titration guide and diary to help them keep track of the number of tablets they take. The diary contains for each day and each strength two boxes for the patient to mark the number of tablets they take in the morning and evening.

More about the medicine

Uptravi is a medicine used to treat adults with pulmonary arterial hypertension (PAH, abnormally high blood pressure in the arteries of the lungs). PAH is a debilitating disease where there is severe narrowing of the blood vessels of the lungs. This leads to high blood pressure in the vessels taking blood from the heart to the lungs and reduces the amount of oxygen that can get into the blood in the lungs, making physical activity more difficult.

Uptravi contains the active substance selexipag.

More information on Uptravi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.