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Package leaflet: Information for the user

Selexipag STADA Arzneimittel AG 200 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 400 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 600 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 800 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 1.000 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 1.200 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 1.400 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 1.600 microgram filmomhulde tabletten

selexipag

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Selexipag STADA Arzneimittel AG is and what it is used for

Selexipag STADA Arzneimittel AG 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.

Selexipag STADA Arzneimittel AG 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. Selexipag STADA Arzneimittel AG 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 acting in a similar way to the natural substance prostacyclin, this medicine widens the pulmonary arteries and reduces their hardening. This makes it easier for the heart to pump blood through the pulmonary arteries. Selexipag STADA Arzneimittel AG lowers the pressure in the pulmonary arteries, it relieves the symptoms of PAH and slows down progression of PAH disease.

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2 What you need to know before you take Selexipag STADA Arzneimittel AG

Do not take Selexipag STADA Arzneimittel AG
- if you are **allergic to selexipag or any of the other ingredients** of this medicine (listed in section 6).
- if you have a heart problem, such as:
  - poor blood flow to the heart muscles (severe coronary heart disease or unstable angina); symptoms can include chest pain
  - heart attack within the last 6 months
  - weak heart (decompensated cardiac failure) that is not under close medical observation
  - severe irregular heartbeat
  - defect of the heart valves (inborn or acquired) that causes the heart to work poorly (not related to pulmonary hypertension)
- if you have had a stroke within the last 3 months, or any other occurrence that reduced the blood supply to the brain (e.g., transient ischaemic attack)
- if you are taking gemfibrozil (medicine used to lower the level of fats [lipids] in the blood)

Warnings and precautions
Talk to your doctor or nurse before taking Selexipag STADA Arzneimittel AG 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

If you notice any of the above signs or your condition changes, tell your doctor immediately.

Children and adolescents
Do not give this medicine to children under 18 years of age.

Elderly patients
There is limited experience with Selexipag STADA Arzneimittel AG in patients older than 75 years. Selexipag STADA Arzneimittel AG should be used with caution in this age group.

Other medicines and Selexipag STADA Arzneimittel AG
Tell your doctor if you are taking, have recently taken or might take any other medicines.

Talk to your PAH 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)

Pregnancy and breast-feeding
Selexipag STADA Arzneimittel AG is not recommended during pregnancy and breast-feeding. If you are a woman who can have children, you should use an effective contraceptive method while taking Selexipag STADA Arzneimittel AG . If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

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Driving and using machines
Selexipag STADA Arzneimittel AG can cause side effects such as headaches and low blood pressure (see section 4), which may affect your ability to drive; the symptoms of your condition can also make you less fit to drive.

3 How to take Selexipag STADA Arzneimittel AG

Selexipag STADA Arzneimittel AG should only be prescribed by a doctor experienced in the treatment of PAH. Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Tell your doctor if you experience side effects, as your doctor may recommend that you change your Selexipag STADA Arzneimittel AG dose.

Tell your doctor if you have problems with your liver not working properly or are taking other medicines as your doctor may recommend that you take a lower dose of Selexipag STADA Arzneimittel AG twice daily or take it only once daily.

If you have poor vision or experience any type of blindness, get help from another person when taking Selexipag STADA Arzneimittel AG during the titration period (process of gradually increasing your dose).

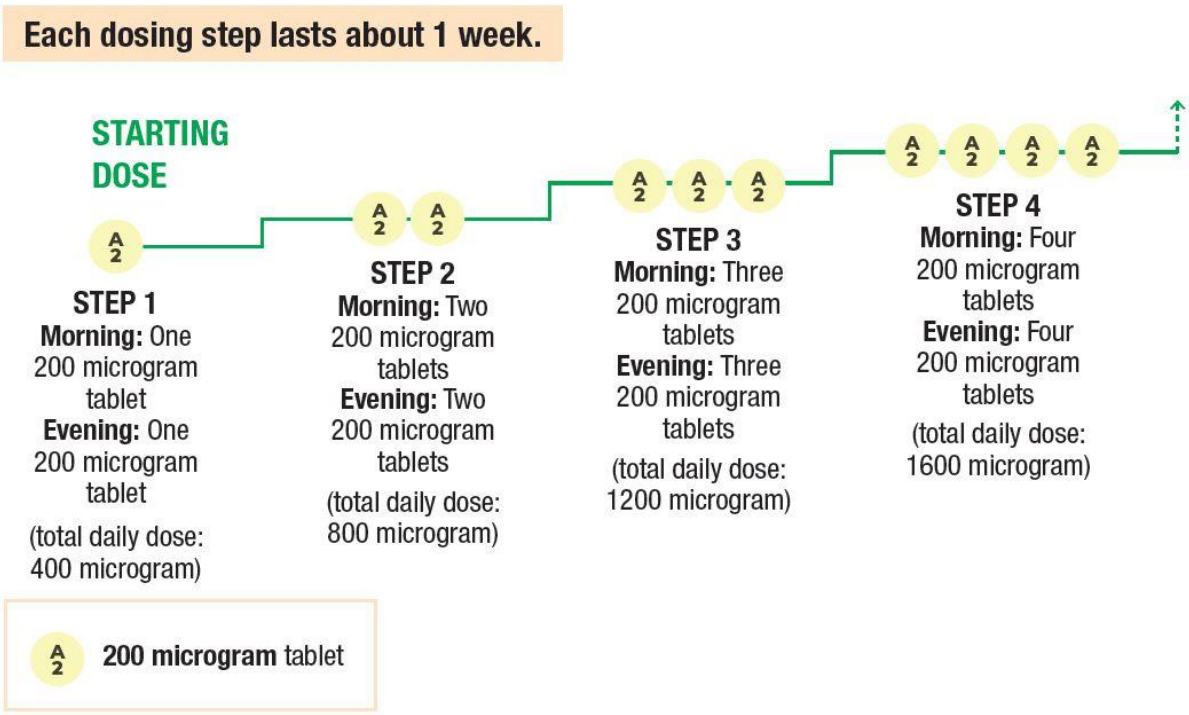
Finding the right dose for you

If your doctor prescribes 200-microgram tablets

At the start of treatment, most patients will take **a 200-microgram tablet in the morning and another 200-microgram tablet in the evening, about 12 hours apart**. It is recommended to initiate treatment 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 is recommended to be in the evening.** The diagram below shows the number of tablets to take **every morning** and **every evening** for the first 4 steps.

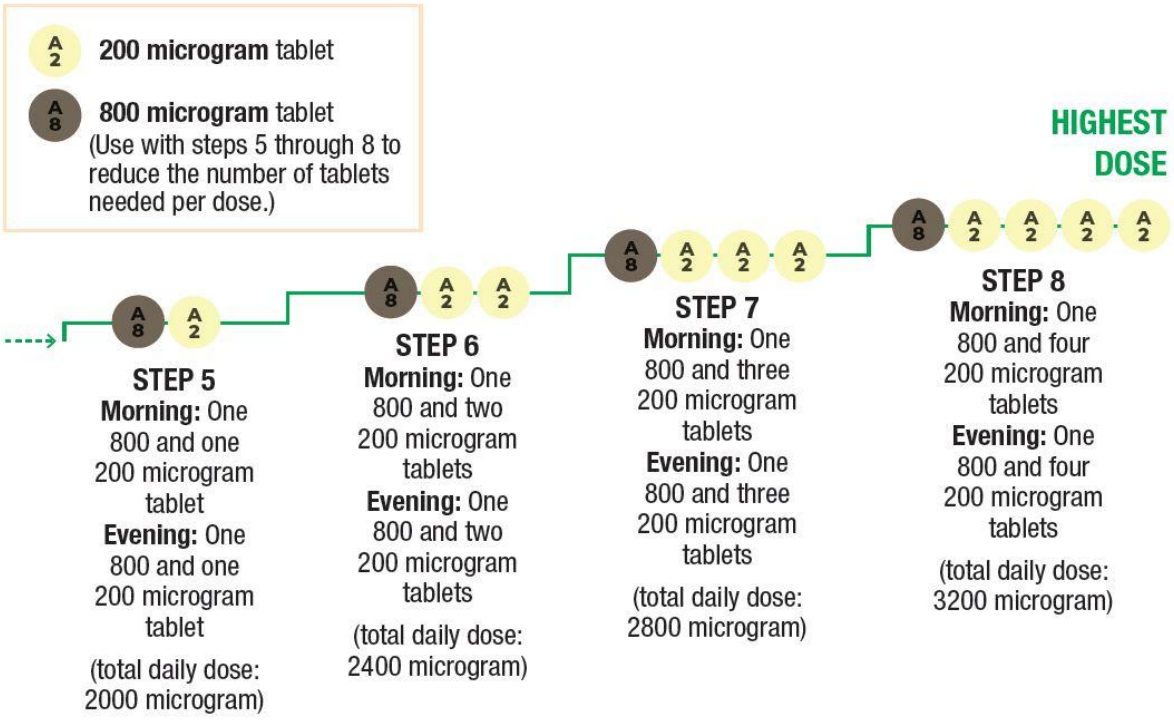


If your doctor tells you to increase your dose further, you will add one 200-microgram tablet to your morning dose and one 200-microgram tablet to your evening dose with each new step. The first intake of the increased dose is recommended to be in the evening.

If your doctor instructs you to further increase your dose and move to step 5, this may be done by taking one brown 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.

The maximum dose of Selexipag STADA Arzneimittel AG 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.



If your doctor prescribes 100 microgram tablets

This medicinal product is not available in 100 micrograms, therefore in case this strength is required, other medicinal products available on the market should be used.

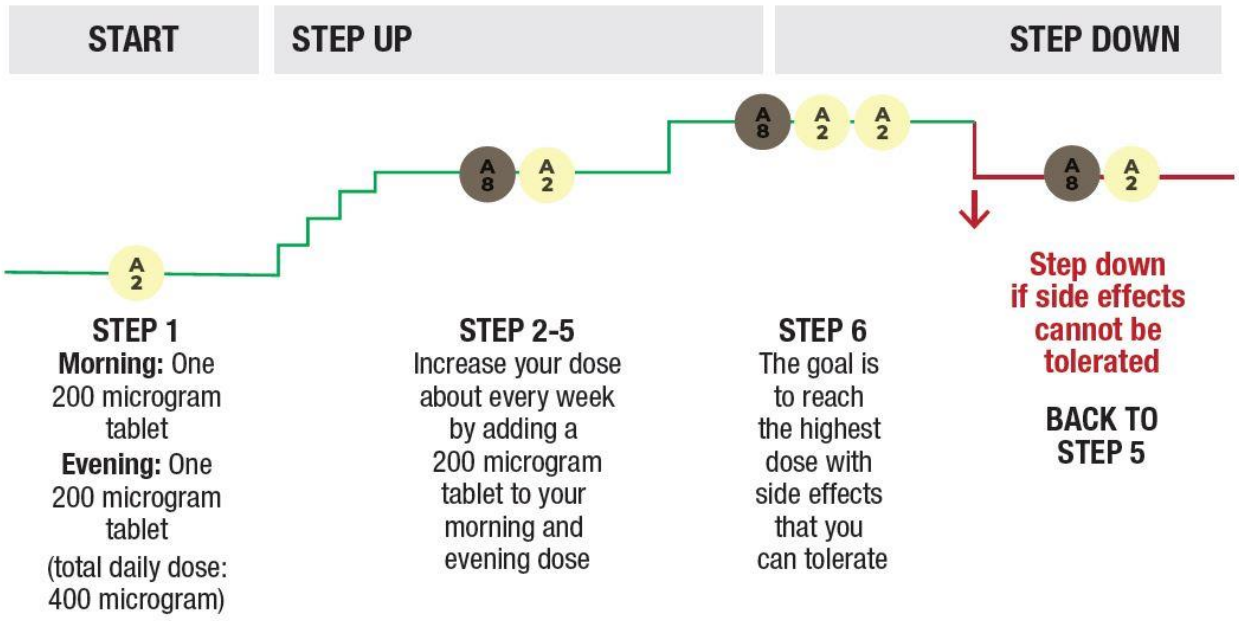
Using the titration guide during titration

You will receive the titration pack which contains a titration guide and patient leaflet. The titration guide is providing information on the titration process and is 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 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, 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.

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 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 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.

Your doctor will prescribe a suitable tablet strength for your maintenance dose. **This may allow you to take one tablet in the morning and one in the evening, instead of multiple tablets each time.**

For a full description of Selexipag STADA Arzneimittel AG tablets, including colours and marking, please see 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 dose. Please remember to dispose of unused tablets (see section 5).

Take Selexipag STADA Arzneimittel AG once in the morning and once in the evening, about 12 hours apart.
Take the tablets with meals as you might tolerate your medicine better. The tablet coating provides protection. Swallow the tablets whole with a glass of water. Do not split or crush the tablets.

If you take more Selexipag STADA Arzneimittel AG than you should
If you have taken more tablets than you have been told to take, ask your doctor for advice.

If you forget to take Selexipag STADA Arzneimittel AG
If you forget to take Selexipag STADA Arzneimittel AG , 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 Selexipag STADA Arzneimittel AG
Suddenly stopping your treatment with Selexipag STADA Arzneimittel AG might lead to your symptoms getting worse. Do not stop taking Selexipag STADA Arzneimittel AG 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 Selexipag STADA Arzneimittel AG 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

Like all medicines, this medicine can cause side effects, although not everybody gets them. 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 swollen face, lips, mouth tongue or throat, which may lead to difficulty swallowing or breathing (angioedema), you should contact your doctor immediately.

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 may be too high for you and may need to be reduced.

Very common side effects (may affect more than 1 in 10 people)
- 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)

Common side effects (may affect up to 1 in 10 people)
- Anaemia (low red blood cell levels)
- Hyperthyroidism (overactive thyroid gland)
- Reduced 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
- Angioedema and its symptoms as described at the beginning of this section

Uncommon side effects (may affect up to 1 in 100 people)
- Increased heart rate

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

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5 How to store Selexipag STADA Arzneimittel AG

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister after 'EXP'. The expiry date refers to the last day of that month.

Do not store 200- and 400-microgram tablets above 30°C. The 600-, 800-, 1 000-, 1 200-, 1 400- and 1 600-microgram tablets do not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Selexipag STADA Arzneimittel AG contains

- The active substance is selexipag.
  Selexipag STADA Arzneimittel AG 200 microgram filmomhulde tabletten: each tablet contains 200 micrograms of selexipag
  Selexipag STADA Arzneimittel AG 400 microgram filmomhulde tabletten: each tablet contains 400 micrograms of selexipag
  Selexipag STADA Arzneimittel AG 600 microgram filmomhulde tabletten : each tablet contains 600 micrograms of selexipag
  Selexipag STADA Arzneimittel AG 800 microgram filmomhulde tabletten: each tablet contains 800 micrograms of selexipag
  Selexipag STADA Arzneimittel AG 1000 microgram filmomhulde tabletten : each tablet contains 1 000 micrograms of selexipag
  Selexipag STADA Arzneimittel AG 1200 microgram filmomhulde tabletten: each tablet contains 1 200 micrograms of selexipag
  Selexipag STADA Arzneimittel AG 1400 microgram filmomhulde tabletten: each tablet contains 1 400 micrograms of selexipag
  Selexipag STADA Arzneimittel AG 1600 microgram filmomhulde tabletten : each tablet contains 1 600 micrograms of selexipag
- The other ingredients are mannitol, maize starch, hydroxypropylcellulose, methacrylic acid-methyl methacrylate copolymer (1:1), magnesium stearate (tablet core); hypromellose, propylene glycol (E1520), titanium dioxide (E171), iron oxides (E172), carnauba wax (tablet coating).

  Selexipag STADA Arzneimittel AG 200 microgram filmomhulde tabletten contain iron oxide yellow (E172).
  Selexipag STADA Arzneimittel AG 400 microgram filmomhulde tabletten contain iron oxide black and iron oxide red (E172).
  Selexipag STADA Arzneimittel AG 600 microgram filmomhulde tabletten contain iron oxide red (E172).
  Selexipag STADA Arzneimittel AG 800 microgram filmomhulde tabletten contain iron oxide black, iron oxide red and iron oxide yellow (E172).
  Selexipag STADA Arzneimittel AG 1000 microgram filmomhulde tabletten contain iron oxide red (E172).
  Selexipag STADA Arzneimittel AG 1200 microgram filmomhulde tabletten contain iron oxide black and iron oxide red (E172).
  Selexipag STADA Arzneimittel AG 1400 microgram filmomhulde tabletten contain iron oxide yellow (E172).
  Selexipag STADA Arzneimittel AG 1600 microgram filmomhulde tabletten contain iron oxide black, iron oxide red and iron oxide yellow (E172).

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What Selexipag STADA Arzneimittel AG looks like and contents of the pack
Selexipag STADA Arzneimittel AG 200 microgram filmomhulde tabletten: Round, light yellow, film-coated tablets (tablets) debossed with “A2” on one side and plain on the other side. The tablets are approximately 7 mm in diameter.

Selexipag STADA Arzneimittel AG 400 microgram filmomhulde tabletten: Round, purple, film-coated tablets (tablets) debossed with “A4” on one side and plain on the other side. The tablets are approximately 7 mm in diameter.

Selexipag STADA Arzneimittel AG 600 microgram filmomhulde tabletten: Round, red, film-coated tablets (tablets) debossed with “A6” on one side and plain on the other side. The tablets are approximately 7 mm in diameter.

Selexipag STADA Arzneimittel AG 800 microgram filmomhulde tabletten: Round, brown, film-coated tablets (tablets) debossed with “A8” on one side and plain on the other side. The tablets are approximately 5.5 mm in diameter.

Selexipag STADA Arzneimittel AG 1000 microgram filmomhulde tabletten: Round, red, film-coated tablets (tablets) debossed with “A10” on one side and plain on the other side. The tablets are approximately 5.6 mm in diameter.

Selexipag STADA Arzneimittel AG 1200 microgram filmomhulde tabletten: Round, purple, film-coated tablets (tablets) debossed with “A12” on one side and plain on the other side. The tablets are approximately 6.5 mm in diameter.

Selexipag STADA Arzneimittel AG 1400 microgram filmomhulde tabletten: Round, light yellow, film-coated tablets (tablets) debossed with “A14” on one side and plain on the other side. The tablets are approximately 6.6 mm in diameter.

Selexipag STADA Arzneimittel AG 1600 microgram filmomhulde tabletten: Round, brown, film-coated tablets (tablets) debossed with “A16” on one side and plain on the other side. The tablets are approximately 7 mm in diameter.

Selexipag STADA Arzneimittel AG 200 microgram filmomhulde tabletten are supplied in blister packs of 10 or 60 tablets and 60 or 140 tablets (titration packs), or in unit-dose blister packs of 10x1 or 60x1 tablets and 60x1 and 140x1 tablets (titration packs).

Selexipag STADA Arzneimittel AG 400 microgram and <600 microgram> <800 microgram> <1 000 microgram> <1 200 microgram> <1 400 microgram> <1 600 microgram> < filmomhulde tabletten > are supplied in blister packs of 60 tablets, or in unit-dose blister packs of 60x1 tablets.

Not all pack sizes may be marketed.

Vergunninghouder:
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

Fabrikant:
Synthon Hispania S.L.
Calle De Castello 1
08830 Sant Boi De Llobregat
Barcelona
Spanje

Synthon B.V.
Microweg 22

6545 CM Nijmegen
Nederland

Synthon s.r.o.
Brnenska 597/32
678 01 Blansko
Jihomoravsky
Tsjechië

In het register ingeschreven onder:
Selexipag STADA Arzneimittel AG 200 microgram filmomhulde tabletten: RVG 133604
Selexipag STADA Arzneimittel AG 400 microgram filmomhulde tabletten: RVG 133606
Selexipag STADA Arzneimittel AG 600 microgram filmomhulde tabletten: RVG 133607
Selexipag STADA Arzneimittel AG 800 microgram filmomhulde tabletten: RVG 133608
Selexipag STADA Arzneimittel AG 1.000 microgram filmomhulde tabletten: RVG 133609
Selexipag STADA Arzneimittel AG 1.200 microgram filmomhulde tabletten: RVG 133611
Selexipag STADA Arzneimittel AG 1.400 microgram filmomhulde tabletten: RVG 133612
Selexipag STADA Arzneimittel AG 1.600 microgram filmomhulde tabletten: RVG 133613

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denemarken
Selexipag STADA

Duitsland
Selexipag AL 200 Mikrogramm Filmtabletten
Selexipag AL 400 Mikrogramm Filmtabletten
Selexipag AL 600 Mikrogramm Filmtabletten
Selexipag AL 800 Mikrogramm Filmtabletten
Selexipag AL 1000 Mikrogramm Filmtabletten
Selexipag AL 1200 Mikrogramm Filmtabletten
Selexipag AL 1400 Mikrogramm Filmtabletten
Selexipag AL 1600 Mikrogramm Filmtabletten

Estland
Selexipag STADA

Ierland
Selexipag Clonmel 200 microgram film-coated tablets
Selexipag Clonmel 400 microgram film-coated tablets
Selexipag Clonmel 600 microgram film-coated tablets
Selexipag Clonmel 800 microgram film-coated tablets
Selexipag Clonmel 1000 microgram film-coated tablets
Selexipag Clonmel 1200 microgram film-coated tablets
Selexipag Clonmel 1400 microgram film-coated tablets
Selexipag Clonmel 1600 microgram film-coated tablets

IJsland
Selexipag STADA 200 µg filmuhúðuð tafla
Selexipag STADA 400 µg filmuhúðuð tafla
Selexipag STADA 600 µg filmuhúðuð tafla
Selexipag STADA 800 µg filmuhúðuð tafla
Selexipag STADA 1000 µg filmuhúðuð tafla
Selexipag STADA 1200 µg filmuhúðuð tafla
Selexipag STADA 1400 µg filmuhúðuð tafla
Selexipag STADA 1600 µg filmuhúðuð tafla

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Litouwen
Selexipag STADA 200 mikrogramų plėvele dengtos tabletės
Selexipag STADA 400 mikrogramų plėvele dengtos tabletės
Selexipag STADA 600 mikrogramų plėvele dengtos tabletės
Selexipag STADA 800 mikrogramų plėvele dengtos tabletės
Selexipag STADA 1000 mikrogramų plėvele dengtos tabletės
Selexipag STADA 1200 mikrogramų plėvele dengtos tabletės
Selexipag STADA 1400 mikrogramų plėvele dengtos tabletės
Selexipag STADA 1600 mikrogramų plėvele dengtos tabletės

Letland
Selexipag STADA 200 mikrogrami apvalkotās tabletes
Selexipag STADA 400 mikrogrami apvalkotās tabletes
Selexipag STADA 600 mikrogrami apvalkotās tabletes
Selexipag STADA 800 mikrogrami apvalkotās tabletes
Selexipag STADA 1000 mikrogrami apvalkotās tabletes
Selexipag STADA 1200 mikrogrami apvalkotās tabletes
Selexipag STADA 1400 mikrogrami apvalkotās tabletes
Selexipag STADA 1600 mikrogrami apvalkotās tabletes

Malta
Selexipag Clonmel 200 microgram film-coated tablets
Selexipag Clonmel 400 microgram film-coated tablets
Selexipag Clonmel 600 microgram film-coated tablets
Selexipag Clonmel 800 microgram film-coated tablets
Selexipag Clonmel 1000 microgram film-coated tablets
Selexipag Clonmel 1200 microgram film-coated tablets
Selexipag Clonmel 1400 microgram film-coated tablets
Selexipag Clonmel 1600 microgram film-coated tablets

Nederland
Selexipag STADA Arzneimittel AG 200 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 400 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 600 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 800 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 1.000 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 1.200 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 1.400 microgram filmomhulde tabletten
Selexipag STADA Arzneimittel AG 1.600 microgram filmomhulde tabletten

Noorwegen
Selexipag STADA

Polen
Selexipag STADA

Spanje
Selexipag STADA 200 mcg comprimidos recubiertos con película EFG
Selexipag STADA 400 mcg comprimidos recubiertos con película EFG
Selexipag STADA 600 mcg comprimidos recubiertos con película EFG
Selexipag STADA 800 mcg comprimidos recubiertos con película EFG
Selexipag STADA 1000 mcg comprimidos recubiertos con película EFG
Selexipag STADA 1200 mcg comprimidos recubiertos con película EFG
Selexipag STADA 1400 mcg comprimidos recubiertos con película EFG
Selexipag STADA 1600 mcg comprimidos recubiertos con película EFG

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Zweden
Selexipag STADA 200 mikrogram filmdragerade tabletter
Selexipag STADA 400 mikrogram filmdragerade tabletter
Selexipag STADA 600 mikrogram filmdragerade tabletter
Selexipag STADA 800 mikrogram filmdragerade tabletter
Selexipag STADA 1000 mikrogram filmdragerade tabletter
Selexipag STADA 1200 mikrogram filmdragerade tabletter
Selexipag STADA 1400 mikrogram filmdragerade tabletter
Selexipag STADA 1600 mikrogram filmdragerade tabletter

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2025.

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TITRATION GUIDE – TITRATION PACK

Page 1

Selexipag STADA Arzneimittel AG 200 microgram film-coated tablets
Selexipag [to be added in case of a branded product name]

Titration Guide

Starting Treatment with Selexipag STADA Arzneimittel AG

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 Selexipag STADA Arzneimittel AG dose. Tell your doctor if you are taking other medications as your doctor may recommend that you take Selexipag STADA Arzneimittel AG only once daily.

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How should you take Selexipag STADA Arzneimittel AG ?

Selexipag STADA Arzneimittel AG is a medicine taken every morning and evening for the treatment of pulmonary arterial hypertension, also called PAH.

The starting dose for Selexipag STADA Arzneimittel AG is 200 micrograms **once in the morning and once in the evening.**
The first intake of Selexipag STADA Arzneimittel AG should be in the evening**.**
You should take each dose with a glass of water, preferably during a meal.

Page 5

There are 2 phases of treatment with Selexipag STADA Arzneimittel AG :

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

Page 6

How should you step up your dose?

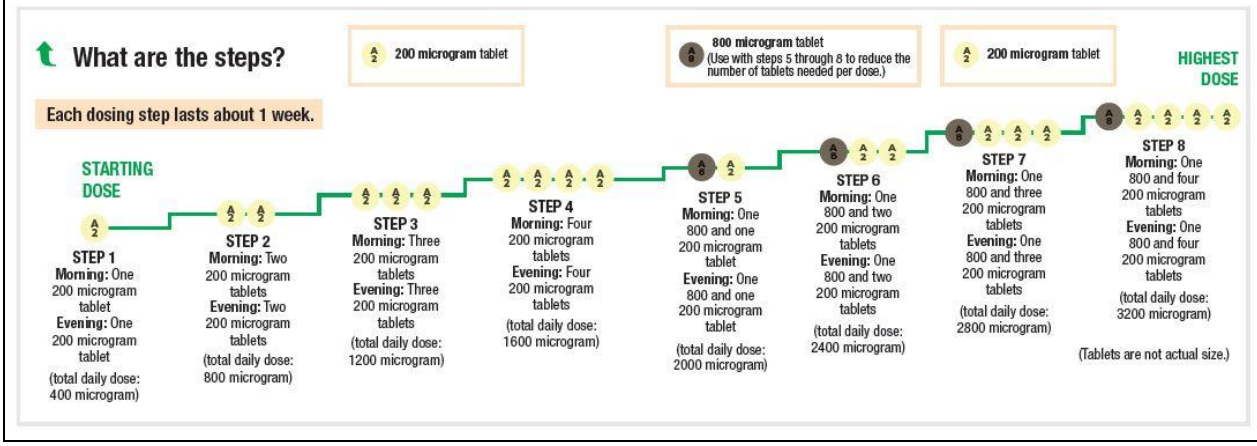
You will start at the 200 microgram dose in the morning and in the evening and after discussing with your doctor or nurse step up to the next dose.
The first intake of the increased dose should be in the evening. Each step usually lasts about 1 week. It could take several weeks to find the dose that 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.

Page 7

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.

Page 8 **Page 9**



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↓When should you step down?

As with all medicines, you may experience side effects with Selexipag STADA Arzneimittel AG 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 Selexipag STADA Arzneimittel AG are:
• Headache • Diarrhoea • Nausea • Vomiting • Jaw pain
• Muscle pain • Leg pain • Joint pain • Facial redness

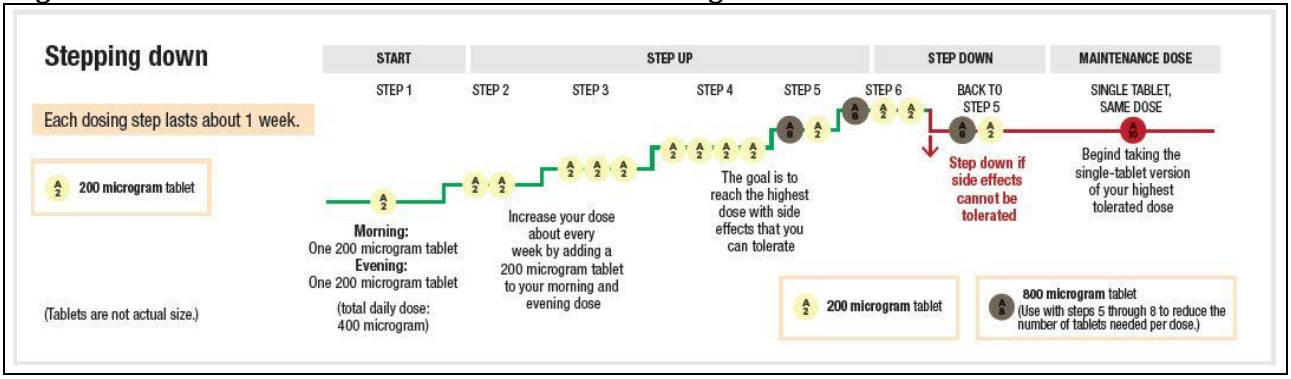
For a full list of side effects see package leaflet for further information.

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.

Page 12 **Page 13**



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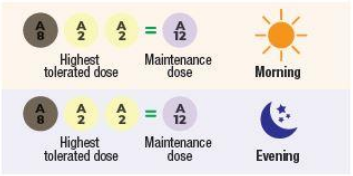
When you move to your maintenance dose

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.

Page 15

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.

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If you forget to take Selexipag STADA Arzneimittel AG

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.

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If you stop taking Selexipag STADA Arzneimittel AG

Do not stop taking Selexipag STADA Arzneimittel AG unless your doctor or nurse tells you to. If, for any reason, you stop taking Selexipag STADA Arzneimittel AG for more than 3 consecutive days (if you missed 6 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.

Page 18

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).

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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:

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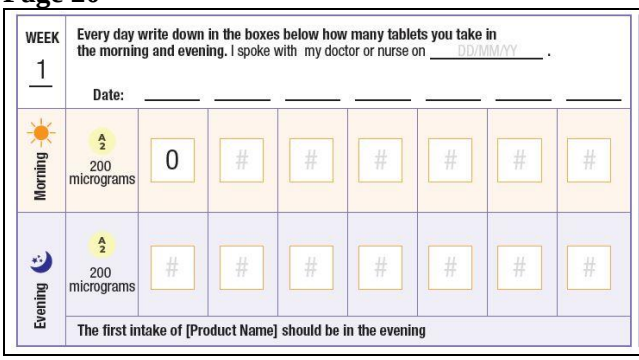

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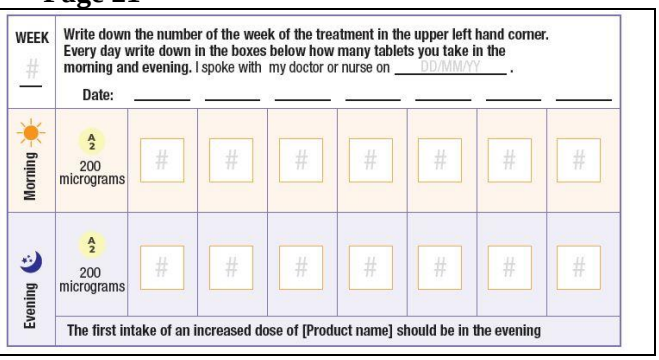

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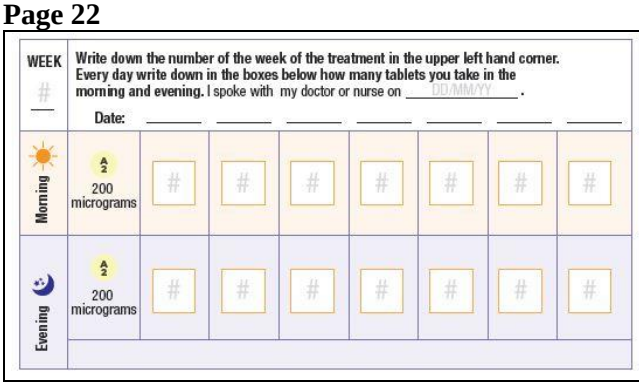

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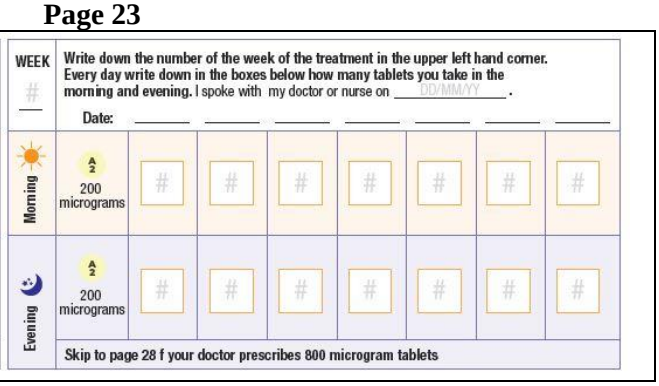

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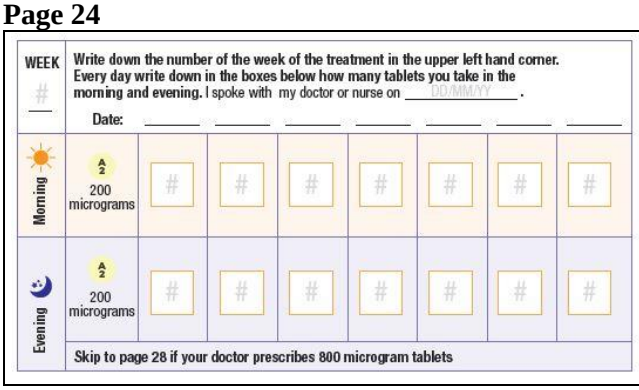

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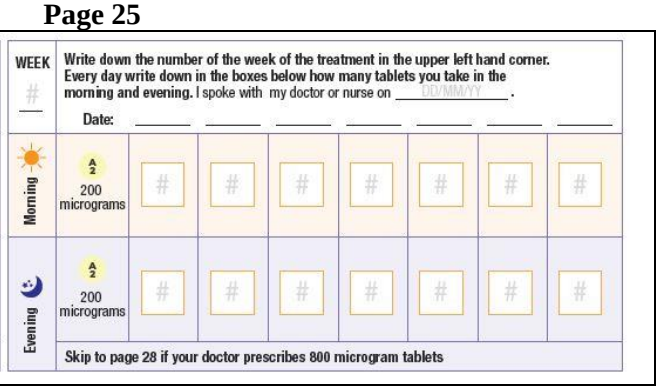

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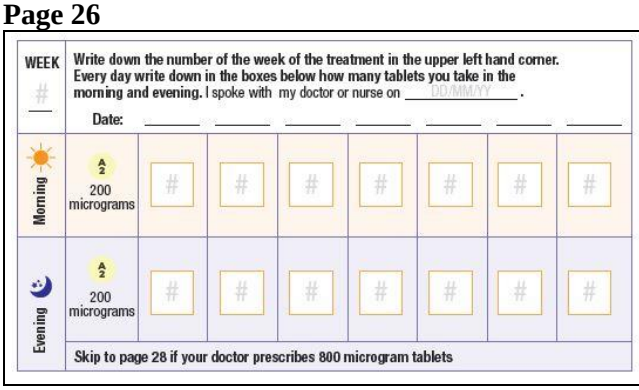

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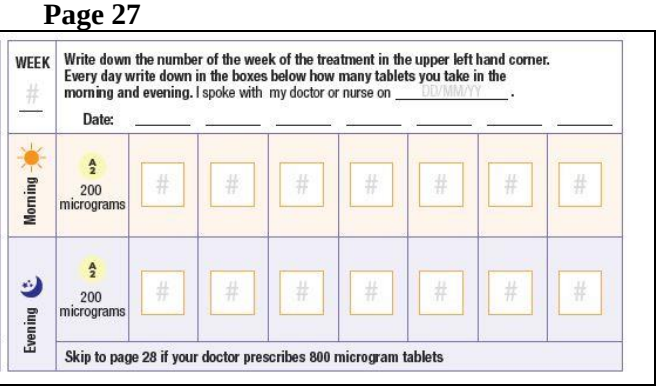

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Use the following diary pages if your doctor or nurse prescribes 800 microgram tablets in addition to your 200 microgram tablets.

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.

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Remember to talk to your PAH doctor or nurse regularly.

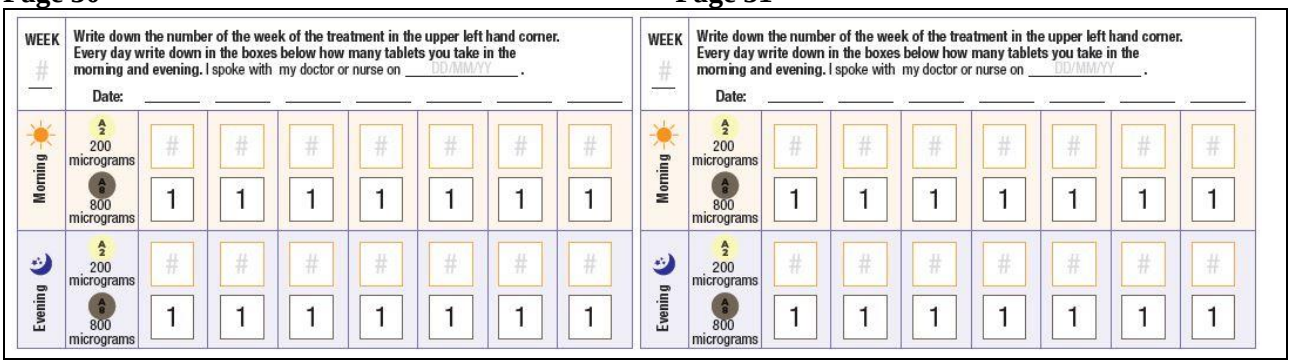
Write down your doctor or nurse's instructions:

Doctor's office telephone and e-mail:

Pharmacist's telephone:

Notes:

Page 30



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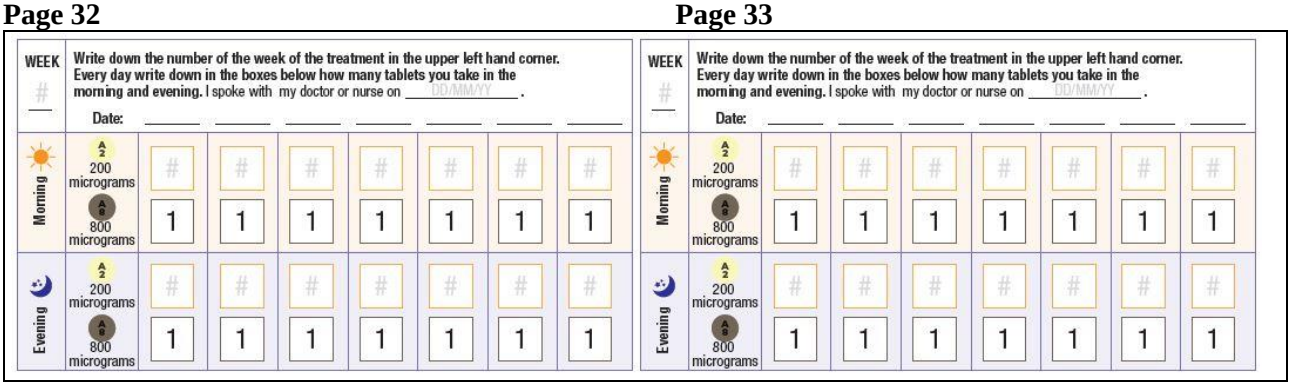

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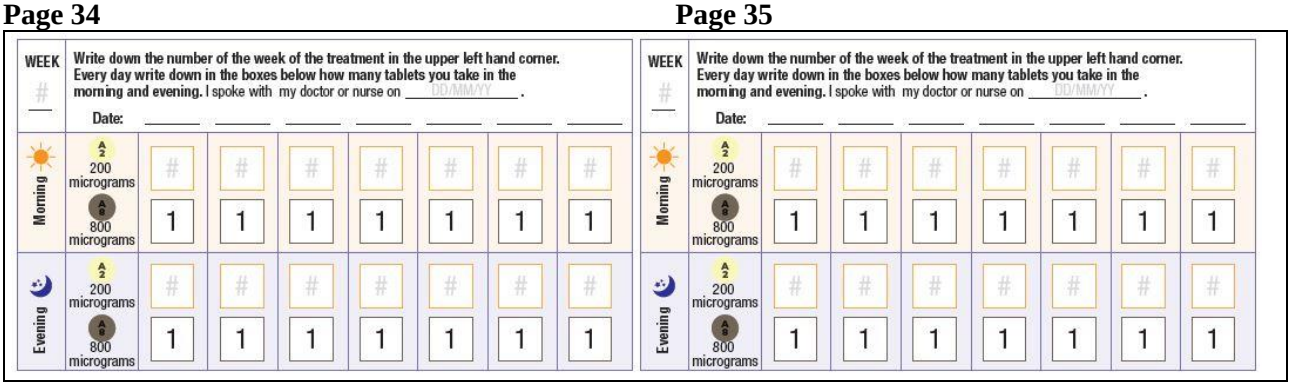

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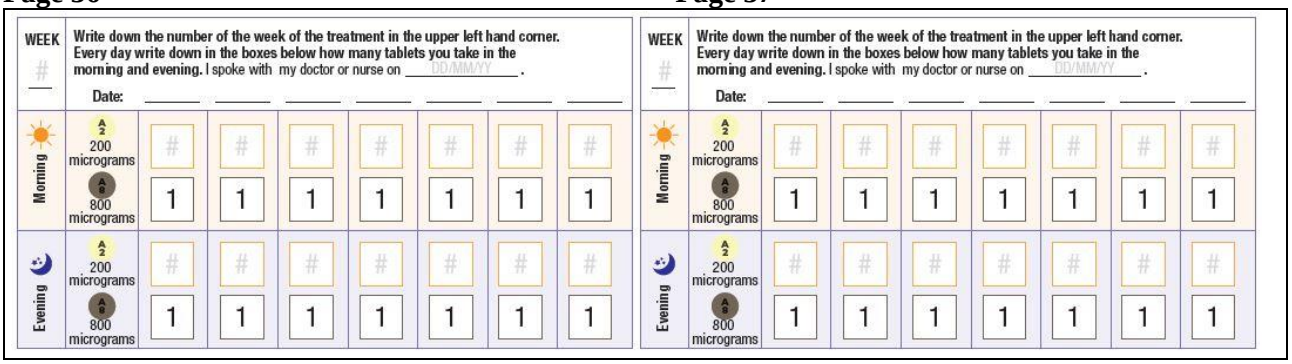

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