

Patient Medication Guide

Tracleer® film-coated tablets 62.5 mg and 125 mg

Read this Patient Medication Guide carefully before you take the medicine. This medicine has been prescribed for you, and you must not pass it on to others. The medicine could harm them, even if their symptoms are the same as yours. Keep this medication guide; you may want to read it again later.

What is Tracleer and what is it used for?

Tracleer contains the active substance bosentan, which belongs to the group of substances known as endothelin receptor antagonists. Endothelin is a powerful vasoconstrictor produced in the body. Tracleer prevents the effect of endothelin and is used in the treatment of the following diseases:

- pulmonary hypertension (high blood pressure in the arteries between the heart and the lungs)
- digital ulcers (finger ulcers) in patients with scleroderma (a disease of the vascular and connective tissue system). Tracleer reduces the number of new finger ulcers that appear.

Tracleer may only be used if prescribed by the doctor.

When shouldn't you use Tracleer?

You should not take Tracleer if you:

- **have moderate or severe impairment of the liver**
- **are pregnant or could become pregnant** and are not using a reliable method of contraception (see "Can Tracleer be taken during pregnancy or the breastfeeding period?")
- **are hypersensitive (allergic) to bosentan** or to any of the other ingredients of Tracleer
- **are being treated with cyclosporin A** (a medicine used after a transplant or to treat disorders of the immune system)
- **are being treated with glibenclamide** (a medicine used for diabetes)

Precautions with Tracleer use

Abnormal liver-function values and/or anaemia may occur during treatment with Tracleer. Your doctor will therefore arrange for regular blood tests before and during the Tracleer therapy. Depending on the liver-value results, he or she may reduce the dose of Tracleer, suspend the treatment for a certain period of time, or even discontinue the treatment entirely. In the event of anaemia, he or she will consider specific treatment for the anaemia, according to the situation.

Signs that your liver may not be working properly include:

- nausea (urge to vomit)
- vomiting
- fever (high temperature)
- pain in your stomach (abdomen)
- jaundice (yellowing of your skin or the whites of your eyes)
- dark-coloured urine
- itching of your skin
- lethargy or fatigue (unusual tiredness or exhaustion)
- flu-like syndrome (joint and muscle pain with fever)

If you notice any of these signs, **tell your doctor immediately**.

Tell your doctor if you put on weight within a short period or feel that you are retaining fluid.

Please note that, because of undesirable effects, such as dizziness, this medicine can adversely affect reaction speed, fitness to drive, and the ability to use machines.

If Tracleer and other medicines are used at the same time, they can affect each other. Such medicines include:

- hormonal contraceptives (see also “Can Tracleer be taken during pregnancy or the breastfeeding period?”),
- cyclosporin A and other medicines used to prevent rejection of a transplanted organ,
- the diabetes drug glibenclamide,
- fluconazole and other antifungals,
- anticoagulant drugs,
- medicines for lowering blood fat levels,
- rifampicin, which is used for the treatment of infectious diseases, including tuberculosis,
- digoxin, which is used for the treatment of heart diseases and medicines for the treatment of HIV infections.

Please tell your doctor if you are using these or other medicines. He or she will decide which medicines you must not use alongside Tracleer (see also “When shouldn’t you use Tracleer?”), which medicines may be combined with Tracleer without any problem, or whether the dose of Tracleer or of the other drug needs to be adjusted.

Tell your doctor or pharmacist if you

- have any other diseases,
- have any allergies, or
- are taking or applying any other medicines (including ones which you have bought yourself).

Can Tracleer be taken during pregnancy or the breastfeeding period?

Tell your doctor at once if you are pregnant or plan to become pregnant in the near future. Since Tracleer may harm the unborn child, you must not take this medicine during pregnancy. You must not become pregnant during Tracleer therapy either.

If you are a woman of child-bearing age, your doctor or gynaecologist will advise you regarding reliable methods of contraception during Tracleer therapy. Hormonal contraceptives (e.g. pill, injections, implants, vaginal ring, or skin patches) on their own are not reliable, as Tracleer can render these methods of contraception ineffective. Therefore, if you use hormonal contraceptives, you should in addition use a barrier method (e.g. female condom, diaphragm, vaginal contraceptive foam) or your partner should use a condom. The contraception must be continued for 3 months after the end of the Tracleer therapy. A pregnancy test to exclude pregnancy must be carried out before treatment with Tracleer is started, and monthly pregnancy tests during Tracleer therapy are recommended.

Tell your doctor at once if you are breastfeeding. You are advised to stop breastfeeding before you take Tracleer, as it is not known whether the active substance of Tracleer passes into breast milk.

How do you use Tracleer?

Always take Tracleer exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you take more Tracleer than you should:

If you take more film-coated tablets than prescribed, see a doctor or go to a hospital immediately.

If you forget to take Tracleer:

If you forget to take Tracleer, take the forgotten dosage as soon as you remember, and then resume taking the medicine at the usual times. Do not take a double dose to make up for the forgotten medication

Do not stop taking Tracleer without medical advice:

If you stop Tracleer therapy suddenly, your symptoms may get worse. Do not stop taking the medicine unless your doctor tells you to. The doctor may tell you to take a lower dose for a few days before you come off Tracleer completely.

What are the possible side effects of Tracleer?

If you notice yellowing of the skin or eyes (jaundice) or if you have fever with vomiting or nausea, see your doctor at once. These symptoms may indicate altered liver function or liver failure/cirrhosis of the liver.

The following other side effects may occur:

- headache,
- anaemia,
- decrease in the number of platelets in the blood,
- fainting,
- swelling of the legs and ankles as a result of fluid accumulation,
- palpitations,
- low blood pressure,
- feeling hot,
- abdominal pain,
- diarrhoea,
- constipation,
- vomiting,
- nausea,
- heartburn,
- itching,
- skin rash,
- reddening of the skin,
- allergic reactions.

In isolated cases, swelling of the face, lips, tongue, or throat (swallowing or breathing difficulties) can occur. Tell your doctor immediately in such instances.

If you notice any side effects not mentioned here while taking Tracleer or if any of the mentioned side effects worries you, please tell your doctor or pharmacist.

What else do I need to know?

Keep Tracleer out of the reach and sight of children. Do not store the film coated tablets above 25°C.

Do not use Tracleer after the date shown next to “EXP” on the container.

Further information can be obtained from your doctor or pharmacist, who has the detailed Prescribing Information.

What is in Tracleer?

One film-coated tablet of Tracleer contains 62.5 or 125 mg bosentan (in the form of bosentan monohydrate) as the active substance, plus other ingredients.