Information for the user

Read all of this patient information leaflet carefully before you start using this medicine.
This medicine has been prescribed for you personally and you should not pass it on to others. Even if they have the same disease symptoms as you, this medicine may harm them.
Keep this patient information leaflet, you may need to read it again later.

Tracleer® ***Film-coated tablets 62.5 mg and 125 mg***
Dispersible tablets 32 mg

What is Tracleer and what is it used for?

Tracleer contains the active ingredient bosentan, which belongs to the so-called endothelin receptor antagonist substance class. Endothelin is a potent endogenous vasoconstrictor. Tracleer inhibits the effect of endothelin and is used for the following diseases:

- for the treatment of pulmonary arterial hypertension (high blood pressure in the arteries between the heart and the lungs)
- for the treatment of digital ulcers (sores on the fingers) in patients with scleroderma (a connective tissue and vascular system disorder); Tracleer reduces the number of newly formed finger sores.

Tracleer should only be taken when prescribed by a doctor.

When should Tracleer not be used?

Do not take Tracleer, if you:

- **have a moderately severe or severe liver dysfunction**
- **are pregnant or may become pregnant** and are not using a reliable method of contraception (see “Should Tracleer be used during pregnancy or breastfeeding?”)
- **are hypersensitive** (allergic) **to bosentan** or another ingredient of Tracleer
- **are being treated with cyclosporine A** (a medicine that is used after a transplantation or for the treatment of immune disorders)
- **are being treated with glibenclamide** (a medicine that is used to treat diabetes)
- Tracleer dispersible tablets should not be used by patients **with the metabolic disorder phenylketonuria**, because they contain aspartame.

Precautions when taking Tracleer

Treatment with Tracleer may result in abnormal liver function values and/or anaemia (lack of blood). Therefore, your doctor will perform regular blood tests before starting and during treatment with Tracleer. Depending on the liver values, s/he may reduce the dose of Tracleer, interrupt the treatment for a certain amount

of time or even terminate the therapy. In case of anaemia, depending on the situation, s/he will consider specific treatment for anaemia.

Tell your doctor if you start gaining weight within a short period of time or think you are suffering from water retention.

Please note that, because of adverse effects such as nausea, this medicine can impair responsiveness, the ability to drive and the ability to use machines.

The concomitant use of Tracleer with other medicines can result in interactions. These include hormonal contraceptives (see also “Should Tracleer be used during pregnancy or breastfeeding?”), cyclosporine A and other medicines used to prevent rejection of a transplanted organ, glibenclamide for the treatment of diabetes, fluconazole and other antifungals, anticoagulants, medicines to reduce levels of fat in the blood, rifampicin for the treatment of infectious diseases including tuberculosis, digoxin for the treatment of heart diseases, medicines for the treatment of HIV infections or other medicines for the treatment of pulmonary arterial hypertension like sildenafil and tadalafil (also used for the treatment of erectile dysfunction in men).

Tell your doctor if you are taking any of these or other medicines. S/he will decide which medicines you are unable to take with Tracleer (see also “When should Tracleer not be used?”), which can easily be combined with Tracleer or if the dose of Tracleer or the other medicine needs to be adjusted.

Tell your doctor or pharmacist if you
- have another disease
- have allergies or
- are taking or applying other medicines (also ones you have bought yourself).

Should Tracleer be used during pregnancy or breastfeeding?

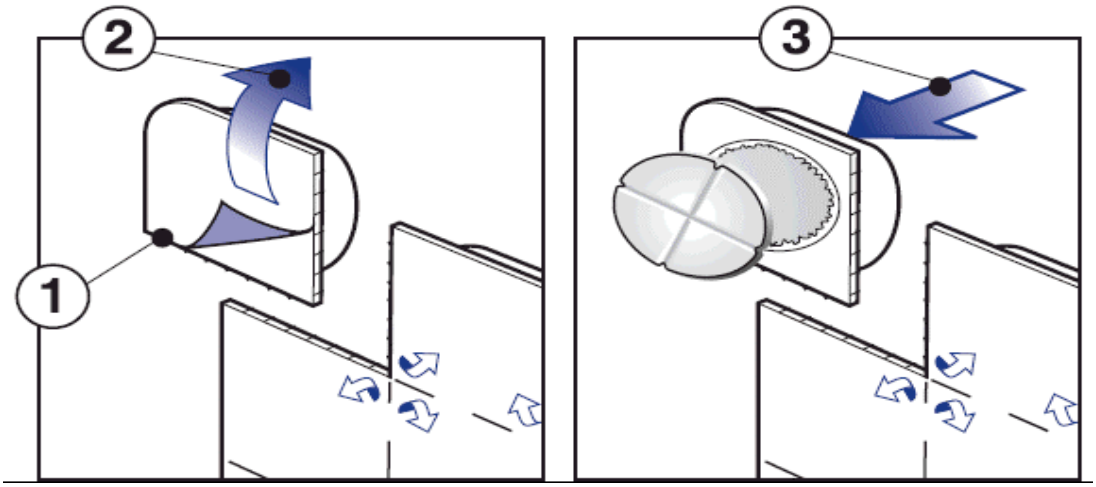
Tell your doctor at once if you are pregnant or plan to become pregnant in the near future. Because Tracleer may harm the unborn child, you should not take this medicine during pregnancy. You should also not get pregnant during treatment with Tracleer.

If you are a woman of childbearing age, your doctor or gynaecologist will advise you about reliable methods of contraception while taking Tracleer. Hormonal contraceptives (e.g. pills, injections, implants, vaginal rings or skin patches) alone are not reliable, because Tracleer can render these methods of preventing pregnancy ineffective. Therefore, if you are using hormonal contraception, you should use an additional barrier method (e.g. female condom, diaphragm, contraceptive sponge) or your partner should use a condom. Contraception should be continued for 3 months after termination of the treatment with Tracleer. Before starting to take Tracleer, pregnancy should be ruled out by means of a pregnancy test and monthly pregnancy tests are recommended when taking Tracleer.

Tell your doctor at once if you are breastfeeding. You are advised to stop breastfeeding before taking Tracleer, because it is not known if the active ingredient in Tracleer passes into breast milk.

Fertility
If you are a man and are taking Tracleer, it is possible that this medicine may lower your sperm count.
Also, in boys, a possible effect on sperm count when taking Tracleer cannot be ruled out in the long-term.

How to take Tracleer
Tracleer is taken twice daily (mornings and evenings) with or without food.
The recommended dose for adults is 1 film-coated tablet at 62.5 mg twice daily for the first four weeks, followed by 1 film-coated tablet at 125 mg twice daily.
In children aged 1 year or older, treatment with Tracleer is normally started at 2 mg per kg body weight twice daily (mornings and evenings). Your doctor will tell you about this dose.
Children aged over 1 year and adolescents are treated with the dispersible tablets, which are taken twice daily suspended in water. The doctor will determine the dose based on body weight and will say how much tablet this corresponds to.
The dispersible tablet in packaged in a child-resistant blister pack and is removed from the blister pack as follows:



1. Separate the individual tablet blister at the perforations
2. Peel off the upper layer
3. Push the tablet through the foil

To break it into halves, hold the tablet on both sides of one of the two break-lines, with the break-lines facing upwards, using thumbs and index fingers. The tablet should be broken apart along the break-line (see Figure). To break it into quarters, the halved tablet should be broken along the break-line in the same way.

The required amount of tablet should be suspended in some water in a glass or on a spoon. Wait for about one minute until the tablet has completely disintegrated. The whole suspension should then be drunk. Add some water to the residue in the glass or on the spoon and drink the remaining suspension, in order to ensure that the entire dose has been taken. If possible, a glass of water should be drunk afterwards.

Always take Tracleer exactly as your doctor has told you. Please ask your doctor or pharmacist, if you are not entirely sure.

If you take more Tracleer than you should
If more film-coated or dispersible tablets were taken than prescribed, go to a doctor or a hospital right away.

If you forget to take Tracleer
If you forget to take Tracleer, take the forgotten dose right away, as soon as you remember, then continue to take the medicine as usual.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Tracleer
Suddenly stopping your treatment with Tracleer may lead to your symptoms getting worse. Do not stop taking the medicine unless your doctor tells you to. Your doctor may tell you to first take a reduced dose over the next few days, before stopping Tracleer completely.

Do not change the prescribed dose on your own account. If you think that the effect of Tracleer is too strong or too weak, talk to your doctor or pharmacist.

Possible side effects when taking 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 abnormal liver function or liver failure/liver cirrhosis.
The following additional side effects may occur:
headache, anemia, reduced platelet count, fainting, swelling of the legs and ankles as a consequence of water retention, palpitations, low blood pressure, hot flushes, blocked nose, stomach pain, diarrhea, constipation, vomiting, nausea, acid reflux, allergic reactions, itching, skin rash and reddening of the skin.

In isolated cases, swelling of the face, lips, tongue or throat (swallowing or breathing difficulties) can occur. In such cases, tell your doctor at once.
If you notice side effects when taking Tracleer that are not described here, or if one of the side effects described above is troubling you, talk to your doctor or pharmacist.

Additional precautions
Keep Tracleer out of the reach and sight of children. The film-coated tablets should not be stored above 30ºC and the dispersible tablets not above 25ºC. The remaining parts of the divided dispersible tablets can be kept at room temperature and used within 7 days.
The desiccant in the bottles must not be ingested.

The medicine should only be used by the date on the container indicated with <<EXP>>.

Your doctor or pharmacist will provide you with further information. These individuals have access to the detailed summary of product characteristics.

Contents of Tracleer

One film-coated tablet contains 62.5 mg or 125 mg of the active ingredient bosentan (as bosentan monohydrate) as well as excipients.

One dispersible tablet of Tracleer contains 32 mg of the active ingredient bosentan (as bosentan monohydrate) as well as vanillin and other flavourings, aspartame, the preservative benzyl alcohol and other excipients.

Marketing authorisation number:
55'841, 59885 (Swissmedic)

Where is Tracleer available from? What packs are available?
From pharmacies with a medical prescription only.
Packs of 56 and 112 film-coated tablets (blister) at 62.5 mg or 125 mg
Packs of 56 film-coated tablets (bottles) at 62.5 mg or 125 mg
Packs of 56 dispersible tablets (with cross break-line) at 32 mg

This patient information leaflet was last validated by the medicines authority (Swissmedic) in June 2018.

Marketing authorisation holder
Actelion Pharmaceuticals Ltd
Gewerbestrasse 16
4123 Allschwil,
Switzerland

Manufacturer:
Haupt Pharma Wülfing GmbH
Bethelner Landstrasse 18
31028 Gronau,
Germany

To contact us, go to www.janssen.com/contact-us

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists