EMA/551446/2018
EMEA/H/C/002644

Stayveer (*bosentan)*

An overview of Stayveer and why it is authorised in the EU

What is Stayveer and what is it used for?

Stayveer is used to treat patients with class III pulmonary arterial hypertension (PAH) to improve exercise capacity (the ability to carry out physical activity) and reduce symptoms. PAH is abnormally high blood pressure in the arteries of the lungs. The 'class' reflects the severity of the disease: 'class III' PAH involves marked limitation of physical activity. The PAH can be:

- primary (with no identified cause or inherited);
- caused by scleroderma (also called systemic sclerosis, a disease where there is abnormal growth of the connective tissue that supports the skin and other organs);
- caused by congenital (inborn) heart defects with shunts (abnormal passageways) causing abnormal flow of blood through the heart and lungs.

Some improvement with Stayveer can also occur in patients with class II PAH. 'Class II' involves slight limitation of physical activity.

Stayveer can also be used in adults with systemic sclerosis in whom poor blood circulation caused by the disease has led to the development of digital ulcers (sores on the fingers and toes). Stayveer is given to reduce the number of new digital ulcers.

Stayveer contains the active substance bosentan. This medicine is the same as Tracleer, which is already authorised in the EU. The company that makes Tracleer has agreed that its scientific data can be used for Stayveer ('informed consent').

How is Stayveer used?

Stayveer can only be obtained with a prescription and treatment should only be started and monitored by a doctor who has experience in the treatment of PAH or systemic sclerosis.

Stayveer is available as film-coated tablets (62.5 mg and 125 mg). It is taken morning and evening. In adults, the starting dose is 62.5 mg twice a day for four weeks, which is increased to the usual dose of 125 mg twice a day.

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For more information about using Stayveer, see the package leaflet or contact your doctor or pharmacist.

How does Stayveer work?

The active substance in Stayveer, bosentan, blocks a naturally occurring hormone called endothelin-1 (ET-1), which causes blood vessels to narrow. Stayveer therefore prevents blood vessels from narrowing.

In PAH, severe narrowing of the blood vessels in the lungs increases blood pressure and reduces the amount of blood entering the lungs. By expanding these blood vessels, pressure is reduced and symptoms are improved.

In patients with systemic sclerosis and digital ulcer disease, there is narrowing of the blood vessels of the fingers and toes leading to ulcers. Bosentan improves blood circulation and thereby, prevents the development of new digital ulcers.

What benefits of Stayveer have been shown in studies?

Treatment of PAH

In PAH, Stayveer added to patient's current therapy was more effective than placebo (a dummy treatment) in improving the distance patients could walk in 6 minutes (a way of measuring exercise capacity) after 16 weeks of treatment.

This is based on two studies in a total of 245 adults with class III or IV disease that was either primary or caused by scleroderma. In the larger study patients were able to walk 44 metres further. Similar results were seen in a study in 54 adults with class III PAH that was associated with congenital heart defects. There were too few patients with class IV disease to support the use of the medicine in this group.

In a study in 185 patients with class II disease the distance the patients could walk over 6 minutes was similar in the Stayveer and placebo groups. However, Stayveer decreased the resistance to blood flow by 23%, indicating a widening of the blood vessels, compared with placebo after 6 months of treatment.

Treatment of systemic sclerosis with digital ulcers

Stayveer was more effective than placebo at reducing the development of new digital ulcers based on two studies in a total of 312 adults. In the first study, patients taking Stayveer had an average of 1.4 new digital ulcers after 16 weeks, compared with 2.7 in the patients taking placebo. Similar results were seen in the second study after 24 weeks. The second study which also looked at the effect of Stayveer on digital ulcer healing in 190 patients did not find any effect.

What are the risks associated with Stayveer?

The most common side effects with Stayveer (which may affect more than 1 in 10 people) are headache, fluid retention, anaemia (low levels of haemoglobin, the protein in red blood cells that carries oxygen around the body) and abnormal results of blood tests to check the liver. For the full list of side effects of Stayveer, see the package leaflet.

Stayveer must not be used in patients who have certain liver problems, who are pregnant or could become pregnant and who are not using reliable contraceptive methods or who are taking ciclosporin (a medicine that acts on the immune system). For the full list of restrictions, see the package leaflet.

Why is Stayveer authorised in the EU?

The European Medicines Agency decided that Stayveer's benefits are greater than its risks and recommended that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Stayveer?

The company that makes Stayveer will provide a patient alert card to remind patients of the need for regular blood tests for liver function and to use effective contraception to avoid pregnancy.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Stayveer have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Stayveer are continuously monitored. Side effects reported with Stayveer are carefully evaluated and any necessary action taken to protect patients.

Other information about Stayveer

Stayveer received a marketing authorisation valid throughout the EU on 24 June 2013.

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

This medicine overview was last updated in 10-2019.