

IMPORTANT SAFETY ALERTS FOR PATIENTS TAKING GONISTA® (BOSENTAN)

This card contains important information about Gonista® (Bosentan). Please read this card carefully before starting your treatment with Gonista® (Bosentan).

The name of your medicine is Gonista® and it will be referred to as Bosentan throughout this document.

Your name:

Prescribing doctor:

If you have questions about Bosentan ask your doctor.

■ **Pregnancy**

If you are a woman patient of childbearing age read this section carefully.

Bosentan may harm the development of the foetus. Therefore, you must not take Bosentan if you are pregnant and you must also not become pregnant while taking Bosentan. Moreover, if you are suffering from pulmonary hypertension disease, the occurrence of a pregnancy can severely deteriorates the symptoms of your disease. If you suspect you may be pregnant, tell your doctor or gynaecologist.

Contraception

Birth control based on hormones – such as oral contraceptives or birth control pills, hormone injections, implants, or birth control skin patches don't reliably prevent pregnancy in women who are taking Bosentan. You need to use a barrier form of birth control – like a condom, diaphragm or vaginal sponge – in addition to any of these kinds of hormonal birth control. Be sure to discuss any questions you may have with your doctor or your gynaecologist – complete the details on this card and take it to your doctor or gynaecologist at your next visit.

You should have a pregnancy test before initiation of Bosentan and every month during the treatment even if you think that you are not pregnant.

Date of first monthly test:

Contraception

Do you currently use or take contraceptives? Yes No

If Yes, write the names of these here:

Take this card to your doctor or your gynaecologist at your next visit and he/she will be able to advise you on whether you need to use additional or alternative contraceptive methods.

Blood Test for Liver Function

Some patients taking Bosentan were found to have abnormal liver function tests. During treatment with Bosentan, your doctor will arrange for regular blood tests to check for changes in your liver function.

Remember to have your liver blood test every month.

After an increase in dose, an additional test will be done after 2 weeks.

Date of first monthly test:

Your monthly liver blood test schedule:

January	February	March
April	May	June
July	August	September
October	November	December

References:

- 1. Gonista® Leaflet
- 2. [Internet]. Medicines.org.uk. [cited 27 January 2020]. Available from: <https://www.medicines.org.uk/emc/rmm/1109/Document>

For more information and for adverse event reporting you can contact us
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