

## GUIDELINES TO THE PATIENT FOR SAFE USE OF BOSENTAN

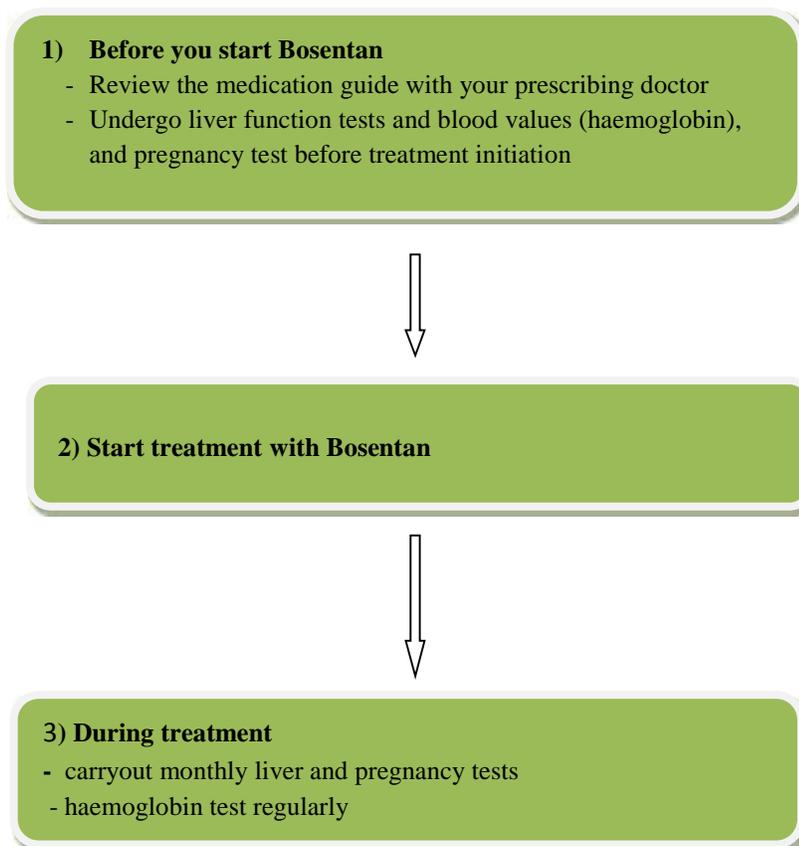
### Introduction

This document contains information for a safe use of the medicine. It includes important information about bosentan, which you must be aware of before starting treatment, including risks of liver damage and severe congenital malformations, decrease in blood haemoglobin concentrations. If you have any further questions, please ask the doctor who prescribed this medication. Please read all the information in the Information leaflet that is inside the package of Bosentan.

What Bosentan is and what it is used for?

Bosentan is a prescription only medicine used to treat Pulmonary arterial hypertension (PAH), which is high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs. Bosentan widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.

### Treatment with Bosentan



For all these tests please refer also to the Patient Alert Card (inside your pack of Bosentan tablets). It is important that you have these regular blood tests as long as you are taking Bosentan. We suggest you write the date of your most recent test and also of your next test (ask your doctor for the date) on the Patient Alert Card, to help you remember when your next test is due.

## Important information you should be aware of

### **Severe congenital malformations**

Studies carried out in animals show bosentan can cause damages to foetal development (teratogenicity). Thus, pregnant women should not take this medicine.

If you are a woman of child-bearing potential, your doctor will ask you to perform pregnancy tests:

- prior to initiation of treatment with bosentan.
- monthly during treatment with bosentan.

If it is possible that you could become pregnant, use a reliable form of birth control while you are taking bosentan. Hormonal contraception (e.g., oral, injection, implant, or skin patches), on its own is not reliable while taking bosentan. Therefore, if you use hormonal contraceptives you must also use a barrier method (e.g., female condom, diaphragm, contraceptive sponge, or your partner must also use a condom).

Tell your doctor immediately if you become pregnant while you are taking bosentan, or plan to become pregnant in the near future.

### **Liver injury (hepatotoxicity)**

Bosentan can cause hepatic injury (liver) which is shown by altered liver function tests.

You must carry out blood tests to assess liver function:

- prior to initiation of treatment with bosentan
- monthly during treatment with bosentan.
- 2 weeks after any dose increase, an additional test ,must be carried out.

**Tell your prescribing doctor if you have had liver problems, including during treatment with other drugs.**

Most common symptoms of liver injury include nausea, vomiting, fever, abdominal pain, jaundice, dark-coloured urine, itching of the skin, fatigue or flu-like syndrome. If you notice any of these signs while taking bosentan, tell your doctor immediately .

### **Anaemia (decreased haemoglobin levels)**

Bosentan can decrease haemoglobin concentrations in the blood - anaemia.

You must carry out blood tests to detect anaemia (low haemoglobin):

- before start of treatment
- monthly before the first months of treatment
- every 3 months after that

### **Other drugs and Bosentan**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It is especially important to inform your doctor if you are taking:

- hormonal contraceptives (since they are not effective as the sole method of contraception when you take bosentan). Inside your pack of bosentan tablets you will find a patient alert card which you should read carefully. Your doctor and/or gynaecologist will establish the contraception which is appropriate for you.
- cyclosporine A (a medicine used after transplants and to treat psoriasis), or any other medicines used after transplants (since these drugs may increase bosentan concentrations in your blood).

For more information refer to the Patient information leaflet or Patient Alert Card.