

## **Patient Information Booklet**

This booklet describes how you and your healthcare provider will work together to ensure the safe use of Bosentan Accord. Bosentan Accord can cause liver damage, including rare cases of liver failure. Bosentan Accord is very likely to cause serious birth defects if taken during pregnancy.

### **What is Bosentan Accord?**

Bosentan Accord is a prescription medicine used to treat people with certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the vessels of the lungs.

Bosentan Accord can improve your ability to exercise and can slow the worsening of your physical condition and symptoms. Bosentan Accord lowers high blood pressure in your lungs and lets your heart pump blood more efficiently.

### **Starting Treatment with Bosentan Accord**

To start treatment with Bosentan Accord, you must:

- Review safety information with your healthcare provider
- Agree to have important monthly tests

As a patient taking Bosentan Accord, you may be contacted about your understanding of the risks with the use of Bosentan Accord.

If you are going to be away from home and will miss your usual clinic for tests, you should speak to your healthcare provider to discuss what alternative arrangements should be made.

## What is the most important information I should know about Bosentan Accord?

Bosentan Accord can cause serious side effects including:

### **Liver damage**

- Liver damage may not cause symptoms at first. Only a blood test can show if you have early liver damage. You must have a blood test to check your liver function before you start Bosentan Accord and each month after that. Your healthcare provider will order these tests. Regular blood tests are important because they will help your healthcare provider adjust or stop your treatment before there is permanent damage.
- Tell your healthcare provider if you have had liver problems, including liver problems while taking other medicines. Call your healthcare provider right away if you have any of these symptoms of liver problems while taking Bosentan Accord: nausea, vomiting, fever, unusual tiredness, stomach area (abdominal) pain, or yellowing of the skin or the whites of your eyes (jaundice).

### **Decrease in haemoglobin**

Decrease in haemoglobin is usually defined as anaemia. It can also be defined as decrease in the amount of red blood cells (RBCs) or the amount of hemoglobin in the blood.

- Treatment with Bosentan is associated with decrease in haemoglobin. Only a blood test can show if you have decrease in haemoglobin level. You must have a blood test to check your blood haemoglobin level before you start Bosentan Accord and each month after that for first 4 months and quarterly thereafter. Your healthcare provider will order these tests. Regular blood tests are important because they will help your healthcare provider adjust or stop your treatment before there is change in haemoglobin level.

### Serious birth defects

- Bosentan Accord can cause serious birth defects if taken during pregnancy. You must not be pregnant when you start taking Bosentan Accord or at any time during Bosentan Accord treatment. Serious birth defects from Bosentan Accord can happen early in pregnancy. If you are able to get pregnant you must have a negative pregnancy test before starting treatment and each month during Bosentan Accord treatment.
- Talk with your healthcare provider or gynecologist (a doctor who specializes in female reproduction) to find out the best way for you to prevent pregnancy. Do not have unprotected sex. Tell your healthcare provider right away if you miss a menstrual period or think you may be pregnant.
- Women who are able to get pregnant must use birth control (contraception) during Bosentan Accord treatment. You must choose and use two reliable forms of birth control at the same time, unless you have had a tubal sterilization, or have a Copper T 380A IUD (intrauterine device) or levonorgestrel(LNg) 20 IUS (intrauterine system) inserted (which are sufficient by themselves).
- Birth control pills, shots, patches, and implants should not be used alone because they are not reliable when you are taking Bosentan Accord. You must choose and use two reliable forms of birth control at the same time.

Talk with your healthcare provider about which 2 methods of reliable birth control you should use. Your healthcare provider may recommend that you change your current method of birth control to help lower your risk of problems with your pulmonary arterial hypertension. See below for more information about reliable methods of contraception during

treatment with Bosentan Accord.

### Reliable methods of contraception during treatment with Bosentan Accord

Methods to use alone	Hormone (choose 1 and use with a barrier method)	Barrier (use both OR choose 1 and use with a hormone method)
<ul style="list-style-type: none"> <li>• Intrauterine devices (IUDs)               <ul style="list-style-type: none"> <li>—Copper T 380A IUD</li> <li>— LNG-20 IUS (progesterone IUD)</li> </ul> </li> <li>• Tubal sterilization</li> </ul>	<ul style="list-style-type: none"> <li>• Estrogen and progesterone               <ul style="list-style-type: none"> <li>—Oral contraceptives</li> <li>—Transdermal patch</li> <li>—Vaginal ring</li> </ul> </li> <li>• Progesterone only               <ul style="list-style-type: none"> <li>—Injection</li> <li>—Implant</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Male condom with spermicide</li> <li>• Diaphragm with spermicide</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>• Cervical cap with spermicide</li> </ul>
<p>A partner's vasectomy still requires 1 additional method of contraception.</p>		

### Reporting of suspected adverse reactions

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal>,

and sent by post or email to;

Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000  
 postlicensing.medicinesauthority@gov.mt