Bosentan Teva 62.5mg Tablets

Important safety alerts for patients taking Bosentan

If you are a woman of child bearing age read this page carefully

Pregnancy

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 deteriorate 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.

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.

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.

ADR Reporting

Suspected Adverse Drug Reactions or medication errors should be reported to the Malta Medicines Authority via the ADR reporting form, available online at http://www.medicinesauthority.gov.mt/adrportal. The ADR reporting form can be sent by post to Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or via email to postlicensing.medicinesauthority@gov.mt.

Alternatively, adverse drug reactions can also be reported to Central Procurement & Supplies Unit, (Head Office),UB002, Industrial Estate, San Gwann - SGN3000 or via email: info.cpsu@gov.mt.