

Bosentan Dr. Reddy's 62.5 and 125mg Film-coated Tablets

Patient leaflet

Important safety information regarding Bosentan Dr. Reddy's 62.5mg and 125mg Film coated Tablets

Your doctor has prescribed bosentan to treat your pulmonary arterial hypertension. Please read this booklet as it includes some important safety information regarding bosentan. You should also read the Package Leaflet inside the first pack of bosentan which you receive.

Bosentan film-coated tablets prescriber's kit

Women who could become pregnant

Do **NOT** take bosentan if you are pregnant or planning to become pregnant.

Bosentan has been shown to cause limb defects in the offspring of pregnant animals given bosentan. It may also cause limb defects to babies born of women who take bosentan during their pregnancy.

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

Pregnancy tests

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start taking bosentan, and regularly while you are taking bosentan.

Contraceptives

If it is possible that you could become pregnant, use a reliable form of birth control (contraception) while you are taking bosentan. Your doctor or gynaecologist will advise you about reliable contraceptive methods while taking bosentan. Because bosentan may make hormonal contraception (e.g. oral, injection, implant, or skin patches) ineffective, this method on its own is not reliable. 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).

Inside your pack of bosentan you will find a Patient Alert Card. You should complete this card and take it to your doctor at your next visit so that your doctor or gynaecologist can assess whether you need additional or alternative reliable contraceptive methods. Monthly pregnancy tests are recommended while you are taking bosentan and are of child-bearing age.

Blood tests for anaemia

Bosentan may cause low levels of haemoglobin. Your doctor will arrange for regular blood tests to check for changes in your haemoglobin level. These will be done every month for the first 4 months of treatment, then every 3 months after that.

If the results are abnormal, your doctor may decide to reduce your dose or stop treatment with bosentan.

Blood tests for liver function

Some patients taking bosentan have been found to have abnormal liver function tests. Your doctor will arrange for regular blood tests to check for changes in your liver function. These will be done every month for the duration of treatment with bosentan. After an increase in dose an additional test will be done after 2 weeks.

Inside your pack of bosentan you will find a Patient Alert Card. You should complete this card and take it to your doctor at your next visit.

If the results are abnormal, your doctor may decide to reduce your dose or stop treatment with bosentan.