

PATIENT CARD BOSENTOR

Important Safety Alerts for Patients taking BOSENTOR (bosentan)

This card contains important information about BOSENTOR. Please read this card carefully before starting your treatment with BOSENTOR.

YOUR NAME: _____

PRESCRIBING DOCTOR: _____

If you have questions about BOSENTOR ask your doctor.

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

You can also report any suspected side effects directly to:

The National Pharmacovigilance Centre (NPC)

Phone: +966-11-2038222,

Ext 2317-2356-2340

SFDA Call Center: 19999

Fax: +966-11-205-7662

E-mail: npc.drug@sFDA.gov.sa

Website: ade.sFDA.gov.sa



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If you are a woman of childbearing age read this page carefully

Pregnancy

BOSENTOR may harm the development of the foetus. Therefore, you must not take BOSENTOR if you are pregnant and you must also not become pregnant while taking BOSENTOR.

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 BOSENTOR. 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 the back of this card and take it to your doctor or gynaecologist at your next visit.

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

DATE OF FIRST MONTHLY TEST: _____

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Blood Test for Liver Function

Some patients taking BOSENTOR were found to have abnormal liver function tests. During treatment with BOSENTOR, 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:

- | | | | |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| <input type="radio"/> JAN _____ | <input type="radio"/> FEB _____ | <input type="radio"/> MAR _____ | <input type="radio"/> APR _____ |
| <input type="radio"/> MAY _____ | <input type="radio"/> JUN _____ | <input type="radio"/> JUL _____ | <input type="radio"/> AUG _____ |
| <input type="radio"/> SEP _____ | <input type="radio"/> OCT _____ | <input type="radio"/> NOV _____ | <input type="radio"/> DEC _____ |

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Contraceptions:

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.

The information in this Patient Alert Card has been approved by the Saudi Food and Drug Authority Version 1: March 2020.

