

Important Safety Alerts for Patients taking Bosentan Aurobindo

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

Your name: _____

Prescribing doctor: _____

If you have questions about Bosentan Aurobindo ask your doctor.

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

Pregnancy

Bosentan Aurobindo 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 Aurobindo.

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 Aurobindo. 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 Bosentan Aurobindo and every month during the treatment even if you think that you are not pregnant.

Date of first monthly test: _____

Important Safety Alerts for Patients taking Bosentan Aurobindo

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

Your name: _____

Prescribing doctor: _____

If you have questions about Bosentan Aurobindo ask your doctor.

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

Pregnancy

Bosentan Aurobindo 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 Aurobindo.

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 Aurobindo. 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 Bosentan Aurobindo and every month during the treatment even if you think that you are not pregnant.

Date of first monthly test: _____

Important Safety Alerts for Patients taking Bosentan Aurobindo

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

Your name: _____

Prescribing doctor: _____

If you have questions about Bosentan Aurobindo ask your doctor.

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

Pregnancy

Bosentan Aurobindo 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 Aurobindo.

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 Aurobindo. 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 Bosentan Aurobindo and every month during the treatment even if you think that you are not pregnant.

Date of first monthly test: _____

Important Safety Alerts for Patients taking Bosentan Aurobindo

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

Your name: _____

Prescribing doctor: _____

If you have questions about Bosentan Aurobindo ask your doctor.

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

Pregnancy

Bosentan Aurobindo 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 Aurobindo.

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 Aurobindo. 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 Bosentan Aurobindo and every month during the treatment even if you think that you are not pregnant.

Date of first monthly test: _____

Blood Test for Liver Function

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

Jan _____	May _____	Sep _____
Feb _____	Jun _____	Oct _____
Mar _____	Jul _____	Nov _____
Apr _____	Aug _____	Dec _____

Contraception

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.

Blood Test for Liver Function

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

Jan _____	May _____	Sep _____
Feb _____	Jun _____	Oct _____
Mar _____	Jul _____	Nov _____
Apr _____	Aug _____	Dec _____

Contraception

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.

Report any suspected adverse reactions to: Medicines Authority at <http://www.medicinesauthority.gov.mt/adrportal> Adverse reactions/events should also be reported to MAH: V.J. Salomone Pharma Ltd., Upper Cross Road, Marsa MRS1542, Malta, Tel:+356 21220174 and 24hr PV mobile +356 99644126
Date of approval: 20/Jan/2022; Version 1.0

Blood Test for Liver Function

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

Jan _____	May _____	Sep _____
Feb _____	Jun _____	Oct _____
Mar _____	Jul _____	Nov _____
Apr _____	Aug _____	Dec _____

Contraception

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.

Blood Test for Liver Function

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

Jan _____	May _____	Sep _____
Feb _____	Jun _____	Oct _____
Mar _____	Jul _____	Nov _____
Apr _____	Aug _____	Dec _____

Contraception

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.

Report any suspected adverse reactions to: Medicines Authority at <http://www.medicinesauthority.gov.mt/adrportal> Adverse reactions/events should also be reported to MAH: V.J. Salomone Pharma Ltd., Upper Cross Road, Marsa MRS1542, Malta, Tel:+356 21220174 and 24hr PV mobile +356 99644126
Date of approval: 20/Jan/2022; Version 1.0