Important Safety Alerts for Patients taking Bosentan Aurobindo

his card contains important information about Bosentan Aurobindo. Please
ead this card carefully before starting your treatment with Bosentan
urobindo.
our 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.

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Date of first monthly test:

Blood Test for Liver Function

Date of first monthly test: ___

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.

Your montnly	ver blood test schedule:
Jan Feb Mar Apr	May Sep Jun Oct Jul Nov Aug Dec
Contraception Do you current	use or take contraceptives?
[]Yes	[]No
If Yes, write the	names of these here:
and he/she will	your doctor or your gynaecologist at your next visit e able to advise you on whether you need to use mative contraceptive methods.
abnormal liver	Liver Function king Bosentan Aurobindo were found to have nction tests. During treatment with Bosentan doctor will arrange for regular blood tests to check f
Some patients abnormal liver Aurobindo, you changes in you	king Bosentan Aurobindo were found to have nction tests. During treatment with Bosentan doctor will arrange for regular blood tests to check fo
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Some patients abnormal liver Aurobindo, you changes in you can be a change of first more weeks. Date of first more weeks. Date of first more weeks. Your monthly Jan Feb Mar Apr Contraception Do you current [] Yes	king Bosentan Aurobindo were found to have notion tests. During treatment with Bosentan doctor will arrange for regular blood tests to check for iver function. Ave your liver blood test every month. The in dose, an additional test will be done after 2 thly test: Ver blood test schedule: May Sep Jun Oct Jul Nov Aug Dec use or take contraceptives?

Take this card to your doctor or your gynaecologist at your next vis 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

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weeks.	
Date of first monthly test:	
Your monthly liver blood test schedule:	
Feb Jun 0 Mar Jul N	Gep Oct Nov 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 gynaeche/she will be able to advise you on whethe or alternative contraceptive methods.	
Blood Test for Liver Function Some patients taking Bosentan Aurobindo v liver function tests. During treatment with Bodoctor will arrange for regular blood tests to liver function.	osentan Aurobindo, your
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