Patient Alert Card For Macitentan

This card contains important safety information you need to be aware of when receiving treatment with Macitentan. Carry this card with you at all times and show it to any doctor involved in your medical care.

For more information on Macitentan, please read the patient information leaflet carefully. If you have any questions about your treatment, ask your doctor or pharmacist.

It is important that you report immediately to your prescribing doctor, a pregnancy or any side effects that may occur during treatment with Macitentan.

Treatment centre:
Name of prescribing doctor:
Phone number of prescribing doctor:

This document is approved by the Executive Directorate of Pharmacovigilance at SFDA

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Pregnancy

- Macitentan may harm developing unborn babies. Therefore, you must not take Macitentan if you are pregnant and you must also not become pregnant while taking Macitentan. Moreover, if you are suffering from pulmonary arterial hypertension, the occurrence of a pregnancy can severely deteriorates the symptoms of your disease.

Contraception

- You need to use a reliable form of birth control (contraception) while you are taking Macitentan. Be sure to discuss any questions you may have with your doctor.
- You should have a pregnancy test before initiation of Macitentan and every month during treatment even if you think that you are not pregnant.

Blood tests for anaemia and liver function

- Like other medicines of this class, Macitentan can reduce the number of red cells in your blood (anaemia) and can have effects on the liver. Your doctor will check this with a blood test before and during your treatment.

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Signs that your liver may not be working properly include:

- nausea (urge to vomit)
- vomiting
- fever (high temperature)
- pain in your stomach (abdomen)
- jaundice (yellowing of your skin or the whites of your eyes)
- dark-coloured urine
- itching of your skin
- lethargy or fatigue (unusual tiredness or exhaustion)
- flu-like syndrome (joint and muscle pain with fever)

If you notice any of these signs, tell your doctor immediately. If you have any questions about your treatment, ask your doctor or pharmacist.

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To report any suspected adverse reactions to, kindly contact:

The National Pharmacovigilance Centre **Saudi Food and Drug Authority**	**Saudi Amarox contact details:**
Call Center: 19999 E-mail: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa/	Razan Almalki- Qualified Person for Pharmacovigilance Al Jamiyah Street, Al Malaz - Riyadh code 12629, Saudi Arabia E-mail: PVsaudi@Amaroxpharma.com Phone: +966 11 226 8850 Mobile: +966531215235

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