

It is important to contact your prescribing doctor immediately if you become pregnant or experience any side effects during treatment with **Maacy**<sup>®</sup>

Treatment centre : \_\_\_\_\_

Name of prescribing doctor : \_\_\_\_\_

Phone number of prescribing doctor : \_\_\_\_\_

The recommended dose of **Maacy**<sup>®</sup> is one 10 mg tablet, once a day. Swallow the tablet whole, with a glass of water, do not chew or break the tablet. You can take **Maacy**<sup>®</sup> with or without food. If you forget to take **Maacy**<sup>®</sup>, take a dose as soon as you remember, then continue to take your tablets at the usual time. Do not take a double dose to make up for a forgotten tablet.

For more information on **Maacy**<sup>®</sup>, please read the patient information leaflet carefully. If you have any questions about your treatment, ask your doctor or pharmacist.

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For the treatment of pulmonary arterial hypertension

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

**Maacy**<sup>®</sup>  
**Macitentan** 10mg  
film coated tablet

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This Document is approved by Executive Directorate of Pharmacovigilance at Saudi Food & Drug Authority (SFDA)

### **Pregnancy:**

**Maacy**<sup>®</sup> may harm unborn babies. Therefore you must not take **Maacy**<sup>®</sup> if you are pregnant and you must also not become pregnant while taking **Maacy**<sup>®</sup> or soon after stopping. Pregnancy can also lead to severe deterioration in pulmonary arterial hypertension symptoms.

### **Contraception:**

You need to use a reliable form of birth control (contraception) while you are taking **Maacy**<sup>®</sup>. Be sure to discuss any questions you may have with your doctor.

You should have a pregnancy test before initiation of **Maacy**<sup>®</sup> and every month during treatment even if you think that you are not pregnant.

### **Blood tests for anaemia and liver function:**

**Maacy**<sup>®</sup> can induce anaemia (a reduced number of red blood cells) and can cause liver injury. You will have blood tests before you start treatment and regularly during treatment to check:

- whether you have anaemia
- whether your liver is working properly

### **Signs that your liver may not be working properly include:**

- nausea (feeling sick) 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 get any side effects, talk to your doctor, nurse or pharmacist.

Please report suspected adverse drug reactions (ADRs) to

Saudi Food and Drug Authority (SFDA) via:

Website: <https://ade.sfda.gov.sa>

Email: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)

Call center: 19999

Also, report to Sudair Pharma, by

Telephone on : +966.920001432 ext.107.

email : [pharmacovigilance@sudairpharma.com](mailto:pharmacovigilance@sudairpharma.com)

reporting side effects you can help provide more information on the safety of this medicine.