Prescribing Checklist

Macimit (Macitentan Tablets 10 mg)

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

Summary of Recommendations (Important Safety Information). See the SmPC for full Prescribing Information.

Patient Name:_____ Patient Birth Date: _____

Indication:_____ Dose:_____

Prescribing Doctor's Name: _____ Prescribing Doctor's telephone: _____

Pulmonary Arterial Hypertension (PAH) Functional Class II to III? ☐ Yes ☐ No, If yes follow further.

This Prescriber Checklist is prepared to support the appropriate prescription of a concerned product Macimit. Treatment should only be initiated or maintained after full evaluation of the possible benefits and risks and review if there are no in these checkboxes.

Contraindications	
Please note that the following conditions are contraindicated if present:	
Hypersensitivity to the active substance, soya or to any of the excipients listed in the package leaflet.	☐ Yes ☐ No
Pregnancy	☐ Yes ☐ No
Women of childbearing potential who are not using reliable contraception	☐ Yes ☐ No
Breastfeeding	☐ Yes ☐ No
Patients with severe hepatic impairment (with or without cirrhosis)	☐ Yes ☐ No
Baseline values of hepatic aminotransferases (aspartate aminotransferases (AST) and/or alanine aminotransferase (ALT) > 3 × ULN)	☐ Yes ☐ No
Warnings and Precautions	
Teratogenicity: Female Patients to be communicated on the risks to the foetus in case of pregnancy from PAH and from Macimit drug	☐ Yes ☐ No
Caution should be exercised when Macimit is administered concomitantly with strong CYP3A4 inhibitors	☐ Yes ☐ No
The combination of Macimit with strong CYP3A4 inducers should be avoided	☐ Yes ☐ No
Women of childbearing potential: Advice patient on reliable contraception	☐ Yes ☐ No
Please mention the contraception method used by the patient	
If patient is lactating, advise discontinuing nursing	☐ Yes ☐ No
Date of last negative pregnancy test:	DD / MM/ YYYY
Hepatotoxicity : Liver function tests (LFTs): Patients to be communicated about the rare but potentially serious risk of hepatotoxicity (including the need for liver function tests before and periodically during treatment, patient education about signs and symptoms of liver disease, and the need to contact doctor if these develop during treatment)?	☐ Yes ☐ No

Version no: 1, Oct 2022

Liver function tests (LFTs): **Date of last Liver Function Test** **Bilirubin level** **AST Value** **ALT Value**	 DD / MM/ YYYY _____mg ----------mg ----------mg
Anemia : Patients to be communicated on risk of anaemia (including the need of blood tests before and periodically during treatment)? **Date of latest Hb Test:** **Result/ Hb Value Test:**	☐ Yes ☐ No DD / MM/ YYYY ----------mg

Macimit should be discontinued if either pregnancy or significant liver injury is suspected.

To Report Side Effects:

Saudi Food and Drug Authority (SFDA) **SFDA call centre: 19999** **E-mail: npc.drug@sfda.gov.sa** **Website: http://ade.sfda.gov.sa/**	**Pharmacovigilance Department (PPI)** **E-mail: Abdulrahman@pharma.com.sa** **Mobile: +966 5803038**