

Maacy® (10 mg) prescribing checklist

See the SmPC for full Prescribing Information.

Date of 1st prescription: Today's date:

Patient name:

Physician name:

Patient age: Patient gender:

Maacy®

Macitentan 10mg film coated tablet

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

Signature:

Is the patient with WHO Group I Pulmonary Arterial Hypertension (PAH) Functional Class II to III? YES NO

DO NOT PRESCRIBE Maacy® if any of the following applies to your patient

Liver enzyme tests and haemoglobin concentration should be measured prior to initiation of therapy, monthly monitoring of AST and ALT is recommended and haemoglobin tests should be repeated as clinically indicated. The absence of pregnancy should be verified prior to initiation of treatment, and it is recommended that these are repeated monthly to allow early detection. Appropriate advice on contraception should be provided, and reliable contraception practised by the patient.

Woman of childbearing potential NOT using reliable contraception?	Hypersensitivity to the active substance, soya or any of the excipients?	Pregnancy?	Lactation?	Patients with severe hepatic impairment (with or without cirrhosis)	Baseline values of AST and/or ALT >3 x ULN
<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO	<input type="checkbox"/> YES <input type="checkbox"/> NO

IF NONE OF THESE, PROCEED BELOW

Concomitant use of Maacy® with strong CYP3A4 inducers should be avoided and concomitant use with strong CYP3A4 inhibitors undertaken with caution. There is limited clinical experience of Maacy® in patients over the age of 75 years, caution should be used in the population.

Precautionary conditions: Women of childbearing potential, please refer to the SmPC.

<p>Advise patient on reliable contraception: <input type="checkbox"/> DONE</p> <p>If patient is lactating, advise to discontinue nursing <input type="checkbox"/> DONE</p> <p>Date of last negative pregnancy test:</p>	<p>For women of childbearing potential, tick the method of contraception practised*:</p> <table border="0"> <tr> <td><input type="checkbox"/> Oral contraceptive, either combined or progestogen alone</td> <td><input type="checkbox"/> Intrauterine device (IUD) or intrauterine system (IUS)</td> <td><input type="checkbox"/> Double barrier method: condom and occlusive cap (diaphragm or cervical vault caps) plus vaginal spermicidal agent (foam, gel, film, cream or suppository)</td> </tr> <tr> <td><input type="checkbox"/> Injectable progestogen</td> <td><input type="checkbox"/> Male partner sterilisation (vasectomy with documentation of azoospermia)</td> <td><input type="checkbox"/> Absolute and continuous abstinence</td> </tr> <tr> <td><input type="checkbox"/> Implants of levonorgestrel</td> <td><input type="checkbox"/> Tubal ligation</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Oestrogenic vaginal ring</td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Percutaneous contraceptive patches</td> <td></td> <td></td> </tr> </table>	<input type="checkbox"/> Oral contraceptive, either combined or progestogen alone	<input type="checkbox"/> Intrauterine device (IUD) or intrauterine system (IUS)	<input type="checkbox"/> Double barrier method: condom and occlusive cap (diaphragm or cervical vault caps) plus vaginal spermicidal agent (foam, gel, film, cream or suppository)	<input type="checkbox"/> Injectable progestogen	<input type="checkbox"/> Male partner sterilisation (vasectomy with documentation of azoospermia)	<input type="checkbox"/> Absolute and continuous abstinence	<input type="checkbox"/> Implants of levonorgestrel	<input type="checkbox"/> Tubal ligation		<input type="checkbox"/> Oestrogenic vaginal ring			<input type="checkbox"/> Percutaneous contraceptive patches		
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Was the Patient Reminder Card given out? DONE

Remind women of childbearing potential that they should always carry the Patient Reminder Card. Provide electronic version if appropriate. DONE

Precautionary conditions: Follow checklist for all patients and refer to section 4.4 "Special warnings and precautions for use" of the SmPC

Liver function tests (LFTs)	Date of latest LFTs :	
	Bilirubin :	
	ALT :	
	AST :	
	Was information communicated to patient on rare but potentially serious risk of hepatotoxicity (including need for liver function tests before and periodically during treatment, patient education about signs and symptoms of liver disease, and need to contact doctor if these develop during treatment)?	<input type="checkbox"/> DONE
Haemoglobin concentration	Date latest Hb test:	
	Result of last Hb test :	
	Was information communicated to patient on risk of anaemia (including the need of blood tests Done before and periodically during treatment)?	<input type="checkbox"/> DONE

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

For additional copies of this checklist please contact, Sudair Pharma Company, pharmacovigilance@sudairpharma.com, Tel: +966 920001432 ext.107.