# OPSUMIT (10 mg) prescribing checklist

See the SmPC for full Prescribing Information.

Opsumit® 10 mg
macitentan

Date of 1st prescription: DD/MM/YYYY  Today's date: DD/MM/YYYY

Patient name:

Physician name:

Patient age:  Patient gender:

Signature:

Is the patient with WHO Group I Pulmonary Arterial Hypertension (PAH) Functional Class II to III? ☐ Yes ☐ No **If Yes, proceed below**

**DO NOT PRESCRIBE OPSUMIT if any of the following applies to your patient**

| Woman of childbearing potential NOT using reliable contraception? | Hypersensitivity to OPSUMIT 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 |
|---|---|---|---|---|---|
| ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No |

**If none of these, proceed below**

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

Advise patient on reliable contraception ☐ Done

If patient is lactating, advise to discontinue nursing ☐ Done

Date of last negative pregnancy test: DD/MM/YYYY

**For women of childbearing potential, tick the method of contraception practiced*:**

- ☐ Oral contraceptive, either combined or progestogen alone
- ☐ Injectable progestogen
- ☐ Implants of levonorgestrel
- ☐ Oestrogenic vaginal ring
- ☐ Percutaneous contraceptive patches
- ☐ Intrauterine device (IUD) or intrauterine system (IUS)
- ☐ Male partner sterilization (vasectomy with documentation of azoospermia)
- ☐ Tubal ligation
- ☐ Double barrier method: condom and occlusive cap (diaphragm or cervical vault caps) plus vaginal spermicidal agent (foam, gel, film, cream or suppository)
- ☐ Absolute and continuous abstinence

*Other methods of contraception are not considered reliable. Women of childbearing potential should use one of the methods of contraception listed above during treatment with OPSUMIT.

Was information communicated to the patient on the risks to the foetus in case of pregnancy both from PAH and from the drug, including birth control methods to use during treatment, need for monthly pregnancy tests, and, in case of pregnancy during treatment, need for the patient to contact her doctor immediately? ☐ Done

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: DD/MM/YYYY

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)? ☐ Done

### Haemoglobin concentration

Date latest Hb test: DD/MM/YYYY

Result of last Hb test

Was information communicated to patient on risk of anaemia (including the need of blood tests before and periodically during treatment)? ☐ Done

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

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Suspected Adverse Drug Reactions (side effects)
or medication errors may be reported using
the Medicines Authority ADR reporting form available online at
http://www.medicinesauthority.gov.mt/adrportal and sent
to Pharmacovigilance Section at Post-Licensing Directorate,
Medicines Authority, Sir Temi Żammit Buildings, Malta
Life Sciences Park, San Ġwann SĠN or sent by email to:
"postlicensing.medicinesauthority@gov.mt"

Alternatively, kindly contact directly Mr Nigel Cauchi
at A.M. Mangion Ltd, Mangion Building,
New Street Off Valletta Road, Luqa LQA 6000, Malta
or on phone number 00356 23976333
or email at pv@ammangion.com

**Actelion, a Division of Janssen-Cilag International NV,**
**represented by Actelion Hellas**
56 Eirinis Avenue, Pefki, GR 15121, Athens, Greece
Phone: +302106752500, Fax: +302106752532

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OF Johnson&Johnson