

OPSUMIT (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: 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

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?

 Yes No

Hypersensitivity to the active substance, soya or any of the excipients?

 Yes No

Pregnancy?

 Yes No

Lactation?

 Yes No

Patients with severe hepatic impairment (with or without cirrhosis)

 Yes No

Baseline values of AST and/or ALT >3 x ULN

 Yes No

If none of these, proceed below

Concomitant use of OPSUMIT with strong CYP3A4 inducers should be avoided and concomitant use with strong CYP3A4 inhibitors undertaken with caution. There is limited clinical experience of Opsumit 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.

Advise patient on reliable contraception

 Done

If patient is lactating, advise to discontinue nursing

 Done

Date of last negative pregnancy test:

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

- Oral contraceptive, either combined or progestogen alone
 Intrauterine device (IUD) or intrauterine system (IUS)
 Intrauterine system (IUS)
 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
 Injectable progestogen
 Male partner sterilisation (vasectomy with documentation of azoospermia)
 Implants of levonorgestrel
 Oestrogenic vaginal ring
 Percutaneous contraceptive patches
 Tubal ligation

*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: 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: 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.