OPSUMIT 10mg film-coated tablets PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Macitentan

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): Mono or combination therapy for long-term treatment of pulmonary arterial hypertension (PAH), in adults of WHO Functional Class (FC) II & III. Efficacy shown in idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.

DOSAGE & ADMINISTRATION: Treatment should only be initiated and monitored by a physician experienced in the treatment of PAH. To be administered orally, once daily with/without food. Tablets should be swallowed whole, with water. ***Elderly patients:*** No dose adjustment required in patients >65 years. ***Paediatric patients:*** Safety and efficacy not yet established in children and adolescents below 18 years. ***Hepatic impairment:*** Mild/moderate: no dose adjustment. Severe: contraindicated. ***Renal impairment:*** Caution advised in in PAH patients with severe renal impairment. Not recommended in dialysis patients.

CONTRAINDICATIONS: Hypersensitivity to active substance, soya or to any of the excipients. Pregnancy, women of childbearing potential not using reliable contraception, breastfeeding, severe hepatic impairment or baseline hepatic aminotransferase (AST/ALT) >3X upper limit of normal (ULN).

SPECIAL WARNINGS & PRECAUTIONS: Benefit/risk not established in WHO FC I. Patients with rare hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption or hypersensitivitity to soya, should not take macitentan. ***Hepatic insufficiency*****:** Record baseline hepatic AST/ALT prior to initiation of Opsumit with monthly monitoring recommended. ***Haemoglobin (Hgb)*****:** Record baseline Hgb and monitor as clinically indicated. Treatment not recommended in patients with severe anaemia. ***Renal impairment:*** Monitoring of blood pressure and Hgb should be considered in patients with renal impairment. ***Pulmonary veno-occlusive disease*** **(PVOD):** If signs of pulmonary oedema, consider possibility of PVOD. ***Women of child bearing potential*****:** Only initiate treatment in women of childbearing potential, using reliable contraception, who have a negative pregnancy test *immediately* prior to treatment and thereafter monthly during treatment. **CYP3A4 inducers/inhibitors:** Avoid concomitant use with strong CYP3A4 ***inducers*** (e.g. rifampicin, St. John's wort, carbamazepine, and phenytoin) as efficacy could be reduced. Use caution with concomitant use of strong CYP3A4 ***inhibitors*** (e.g., itraconazole, ketoconazole, voriconazole, clarithromycin, telithromycin, nefazodone, ritonavir, and saquinavir). **Dual/combined CYP3A4 and CYP2C9 inhibitors:** Use caution with concomitant use of moderate ***dual inhibitors*** of CYP3A4 and CYP2C9 (e.g., fluconazole and amiodarone). Use caution with concomitant use of ***both*** a moderate CYP3A4 ***inhibitor*** (e.g., ciprofloxacin, cyclosporine, diltiazem, erythromycin, verapamil) and moderate CYP2C9 ***inhibitor*** (e.g., miconazole, piperine).

SIDE EFFECTS: ***Very common:*** nasopharyngitis, bronchitis, headache, anaemia, haemoglobin decrease, oedema, fluid retention. ***Common:*** pharyngitis, influenza, urinary tract

infection, leukopenia, thrombocytopenia, AST/ALT elevations, hypotension, flushing, nasal congestion. ***Other side effects:*** hypersensitivity.
Refer to SmPC for other side effects.

FERTILITY:
Decreases in sperm count have been observed in patients taking ERAs. Macitentan, like other ERAs, may have an adverse effect on spermatogenesis in men.

LEGAL CATEGORY: Prescription Only Medicine (POM)

PRESENTATIONS, PACK SIZES & MARKETING AUTHORISATION NUMBER(S)

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)
10mg tablets	30 Tablets	EU/1/13/893/002

MARKETING AUTHORISATION HOLDER: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

FURTHER INFORMATION IS AVAILABLE FROM: Janssen Sciences Ireland UC, Barnahely, Ringaskiddy, IRL - Co. Cork, P43 FA46.

Prescribing information last revised: December 2022

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse events via:
HPRA Pharmacovigilance
Website: www.hpra.ie

Adverse events should also be reported to Janssen Sciences Ireland UC on 1800 709 122 or at dsafety@its.jnj.com.