UPTRAVI® 200-1600 µg film-coated tablets PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): selexipag

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

INDICATION(s): Long-term treatment of pulmonary arterial hypertension (PAH) in adult patients with WHO FC II-III, either as combination therapy in patients insufficiently controlled with an endothelin receptor antagonist and/or a phosphodiesterase type 5 inhibitor, or as monotherapy in patients who are not candidates for these therapies. Efficacy has been shown in idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease.

DOSAGE & ADMINISTRATION: Only a PAH experienced physician should initiate and monitor treatment. **Individualised dose titration:** Up-titrate patients to the highest individually tolerated dose, which can range from 200 to 1600 microgram (µg) given twice daily (BD). The recommended starting dose is 200 µg BD approximately 12 hours apart. Increase dose in increments of 200 µg BD, usually at weekly intervals, based on tolerability. During titration some adverse reactions reflecting the mode of action of selexipag may occur, these are usually transient or manageable with symptomatic treatment. If a patient reaches a dose that cannot be tolerated, the dose should be reduced to the previous dose level. **Individualised maintenance dose**: Maintain the highest tolerated dose a patient can take with tolerable adverse events. **Administration:** Take each tablet orally, morning and evening with food to improve tolerability. During the up-titration phase take the first increased dose in the evening.

CONTRAINDICATIONS: Hypersensitivity to active substance/excipients, severe coronary heart disease, unstable angina, myocardial infarction within 6 months, decompensated cardiac failure, severe arrhythmias, cerebrovascular events within 3 months, congenital or acquired valvular defects, concomitant use with strong CYP2C8 inhibitors (e.g. gemfibrozil).

SPECIAL WARNINGS & PRECAUTIONS: Hypotension: Vasodilatory properties may reduce blood pressure. Before prescribing Uptravi, carefully consider whether patients with certain underlying conditions could be adversely affected by vasodilatory effects. Hyperthyroidism: has been observed, monitor thyroid function if clinically indicated. Pulmonary veno-occlusive disease: If signs of pulmonary oedema occur consider possibility of pulmonary veno-occlusive disease which has been reported with vasodilators (mainly prostacyclins), if confirmed discontinue treatment. Elderly (≥65 yrs): There is limited clinical experience in patients over 75 yrs, therefore Uptravi should be used with caution in this population. Renal impairment: Caution should be exercised during dose titration in patients with severe renal impairment. Hepatic impairment: Do not treat patients with severe liver impairment (Child-Pugh class C). In patients with moderate hepatic impairment, Uptravi should be dosed once daily. Women of childbearing potential: should practice effective contraception while taking selexipag. Co-administration of Moderate CYP2C8 Inhibitors: When co-administered with moderate CYP2C8 inhibitors, reduce the dosing of Uptravi to once daily.

SIDE EFFECTS: Very common: Headache, flushing, nasopharyngitis, diarrhoea, vomiting, nausea, jaw pain, myalgia, arthralgia & pain in extremity. **Common:** Anaemia, decreased haemoglobin, hyperthyroidism, decreased thyroid-stimulating hormone, decreased appetite, weight decrease, hypotension, nasal congestion, abdominal pain, rash, urticaria, erythema, pain.
Refer to SmPC for other side effects.

LEGAL CATEGORY: POM

PRESENTATIONS, PACK SIZES & MARKETING AUTHORISATION NUMBER(S)

PRESENTATIONS	PACK SIZES	MARKETING AUTHORISATION NUMBER(S)
200 µg tablets (Titration pack)	140 tablets	EU/1/15/1083/003
200 µg tablets	60 tablets	EU/1/15/1083/002
400 µg tablets	60 tablets	EU/1/15/1083/004
600 µg tablets	60 tablets	EU/1/15/1083/005
800 µg tablets	60 tablets	EU/1/15/1083/006
1000 µg tablets	60 tablets	EU/1/15/1083/007
1200 µg tablets	60 tablets	EU/1/15/1083/008
1400 µg tablets	60 tablets	EU/1/15/1083/009
1600 µg tablets	60 tablets	EU/1/15/1083/010

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, Tel: 1800 709 122

Prescribing information last revised: December 2020

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 on 1800 709 122 or at dsafety@its.jnj.com.