REQUIP Once-daily MODUTAB®
ropinirole prolonged release tablets

# Switching from

## Requip film-coated (immediate-release) tablets TO Requip-Modutab (prolonged-release) tablets

**Patients may be switched overnight**

**Dose of Requip-Modutab tablets should be based on the total daily dose of Requip film-coated tablets that the patient was taking**

**TABLE below shows the recommended dose of Requip-Modutab tablets for patients switching from Requip film-coated tablets:**

| Requip film-coated tablets<br>*Total Daily Dose in mg*<br>*(3 times daily)* | Requip-Modutab tablets<br>*Total daily dose in mg*<br>*(once daily)* |
|---|---|
| 0.75 – 2.25 | 2 |
| 3 – 4.5 | 4 |
| 6 | 6 |
| 7.5 – 9 | 8 |
| 12 | 12 |
| 15 – 18 | 16 |
| 21 | 20 |
| 24 | 24 |
| *After switching to Requip-Modutab prolonged-release tablets, the dose may be adjusted depending on the therapeutic response* | |

# Abridged Prescribing Information

*Please refer to full Summary of Product Characteristics (SPC) before prescribing.*

**TRADE NAME: Requip-Modutab prolonged-release tablets. ACTIVE INGREDIENT**: Ropinirole. **PHARMACEUTICAL FORM**: Prolonged release-tablets. **THERAPEUTIC INDICATIONS:** Treatment of Parkinson's disease under the following conditions: Initial treatment as monotherapy, in order to delay the introduction of levodopa, In combination with levodopa, over the course of the disease, when the effect of levodopa wears off or becomes inconsistent and fluctuations in the therapeutic effect occur ("end of dose" or "on-off" type fluctuations). **POSOLOGY AND METHOD OF ADMINISTRATION:** Once daily. Not recommended for use in children under 18 years of age. In patients aged 75 years and above, slower titration during treatment initiation may be considered. Individual dose titration against efficacy and tolerability is recommended. The starting dose of ropinirole prolonged-release tablets is 2 mg once daily for the first week; this should be increased to 4 mg once daily from the second week of treatment. A therapeutic response may be seen at a dose of 4 mg once daily of ropinirole prolonged-release tablets. Patients should be maintained on the lowest dose of ropinirole prolonged-release tablets that achieve symptomatic control. If sufficient symptomatic control is not achieved or maintained at a dose of 4 mg once daily of ropinirole prolonged-release tablets, the daily dose may be increased by 2 mg at weekly or longer intervals up to a dose of 8 mg once daily of ropinirole prolonged-release tablets. If sufficient symptomatic control is still not achieved or maintained at a dose of 8 mg once daily of ropinirole prolonged-release tablets, the daily dose may be increased by 2 mg to 4 mg at two weekly or longer intervals. The maximum daily dose of ropinirole prolonged-release tablets is 24 mg. Refer to full SPC for detailed information on concomitant administration with other agents and switching from alternative formulations. **CONTRAINDICATIONS:** Hypersensitivity, Severe renal impairment without regular haemodialysis, hepatic impairment. **PRECAUTIONS FOR USE:** Sudden onset of sleep during daily activities, in some cases without awareness or warning signs, has been reported uncommonly. Patients must be informed of this and advised to exercise caution while driving or operating machines during treatment with ropinirole. Reduction of dosage or termination of therapy may be considered. Patients with major psychiatric or psychotic disorders, or a history of these disorders, should not be treated with dopamine agonists unless the potential benefits outweigh the risks. Patients should be regularly monitored for the development of impulse control disorders. Requip Modutab tablets are designed to release medication over a 24hr period. If rapid gastrointestinal transit occurs, there may be risk of incomplete release of medication, and of medication residue being passed in the stool. Due to the risk of hypotension, blood pressure monitoring is recommended, particularly at the start of treatment, in patients with severe cardiovascular disease (in particular coronary insufficiency). This medicinal product also contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**DRUG INTERACTIONS**: There is no pharmacokinetic interaction between ropinirole and levodopa or domperidone which would necessitate dosage adjustment of these medicinal products. Neuroleptics and other centrally active dopamine antagonists, such as sulpiride or metoclopramide, may diminish the effectiveness of ropinirole and therefore, concomitant use of these medicinal products should be avoided. Increased plasma concentrations of ropinirole have been observed in patients treated with high doses of oestrogens. In patients already receiving hormone replacement therapy (HRT), ropinirole treatment may be initiated in the normal manner. However, it may be necessary to adjust the ropinirole dose, in accordance with clinical response, if HRT is stopped or introduced during treatment with ropinirole. Ropinirole is principally metabolised by the cytochrome P450 isoenzyme CYP1A2. A pharmacokinetic study (with a ropinirole film-coated (immediate-release) tablet dose of 2 mg, three times a day) in Parkinson's disease patients, revealed that ciprofloxacin increased the Cmax and AUC of ropinirole by 60% and 84% respectively, with a potential risk of adverse events. Hence, in patients already receiving ropinirole, the dose of ropinirole may need to be adjusted when medicinal products known to inhibit CYP1A2, e.g. ciprofloxacin, enoxacin or fluvoxamine, are introduced or withdrawn. A pharmacokinetic interaction study in patients with Parkinson's disease between ropinirole (with a ropinirole film-coated (immediate-release) tablet dose of 2 mg, three times a day) and theophylline, a substrate of CYP1A2, revealed no change in the pharmacokinetics of either ropinirole or theophylline. Smoking is known to induce CYP1A2 metabolism, therefore if patients stop or start smoking during treatment with ropinirole, dose adjustment may be required. In patients receiving the combination of vitamin K antagonists and ropinirole, cases of unbalanced INR have been reported. Increased clinical and biological surveillance (INR) is warranted. **PREGNANCY AND LACTATION:** *Pregnancy:* No adequate data available. *Breastfeeding:* Should not be used. **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:** Avoid driving or using machines if affected. **UNDESIRABLE EFFECTS:** In monotherapy & in adjunct therapy *(Very common)*: Somnolence, Nausea; *(Common)*: Hallucinations, Constipation, heartburn, Dizziness, Oedema peripheral; *(Uncommon)*: Psychotic reactions, Sudden onset of sleep, Excessive daytime somnolence. For full list kindly refer to full SPC. **OVERDOSE:** The symptoms of ropinirole overdose are related to its dopaminergic activity. These symptoms may be alleviated by appropriate treatment with dopamine antagonists such as neuroleptics or metoclopramide.

**LOCAL PRESENTATION:** Requip-Modutab prolonged-release tablets 2mg, 4mg, 8mg
**MARKETING AUTHORISATION HOLDER:** GlaxoSmithKline (Ireland) Ltd..
**MARKETING AUTHORISATION NUMBERS:** 192/00106, 192/00108, 192/00109
**DATE OF PREPARATION:** July 2014

## Reporting Adverse Events (AEs)

***Malta & Gibraltar:*** **If you become aware of any AEs, medication errors and/or use during pregnancy in association with GSK products, please report the event promptly to:** GSK (Malta) Limited, 1, De la Cruz Avenue, Qormi QRM 2458, Malta (Tel: +356 21238131)

***Malta:*** **alternatively, any suspected AEs and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system:** Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to the Malta Medicines Authority, Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

***Gibraltar:*** **alternatively, any suspected AEs and medication errors can also be reported via the UK regulatory authority (MHRA):** https://yellowcard.mhra.gov.uk/

**In order to ensure that this product Information reflects the most up-to-date clinical and post-marketing surveillance data, please always refer to the latest SPC which is available from GSK (Malta) Ltd: Tel 21 238131**

**References**

Requip Modutab, Summary of Product Characteristics May 2014

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