| | Early Therapy | | Adjunct Therapy | |
|---|---|---|---|---|
| | REQUIP® N = 157 % occurrence | Placebo N = 147 % occurrence | REQUIP® N = 208 % occurrence | Placebo N = 120 % occurrence |
| **Heart Rate and Rhythm** | | | | |
| Extrasystoles | 1.9 | 0.7 | – | – |
| Tachycardia | 1.9 | 0.0 | 1.0 | 0.0 |
| Fibrillation Atrial | 1.9 | 0.0 | – | – |
| Tachycardia Supraventricular | 1.3 | 0.0 | – | – |
| Bradycardia | – | – | 1.0 | 0.0 |
| **Liver and Biliary System** | | | | |
| Gamma - GT Increased | 1.3 | 0.7 | 1.0 | 0.0 |
| Hepatic Enzymes Increased | 1.3 | 0.0 | – | – |
| **Metabolic and Nutritional** | | | | |
| Alkaline Phosphate Increased | 2.5 | 1.4 | 1.0 | 0.0 |
| Weight Decrease | – | – | 2.4 | 0.8 |
| Hypoglycemia | 1.3 | 0.0 | – | – |
| **Musculoskeletal System** | | | | |
| Arthralgia | – | – | 6.7 | 5.0 |
| Arthritis | – | – | 2.9 | 0.8 |
| Arthritis Aggravated | 1.3 | 0.0 | 1.4 | 0.0 |
| **Myocardial, Endocardial, Pericardial Valve** | | | | |
| Myocardial Ischemia | 1.3 | 0.7 | – | – |
| **Psychiatric** | | | | |
| Somnolence | 40.1 | 6.1 | 20.2 | 8.3 |
| Anxiety | – | – | 6.3 | 3.3 |
| Confusion | 5.1 | 1.4 | 8.7 | 1.7 |
| Hallucination | 5.1 | 1.4 | 10.1 | 4.2 |
| Nervousness | – | – | 4.8 | 2.5 |
| Yawning | 3.2 | 0.0 | – | – |
| Amnesia | 2.5 | 1.4 | 4.8 | 0.8 |
| Dreaming Abnormal | – | – | 2.9 | 1.7 |
| Depersonalization | – | – | 1.4 | 0.0 |
| Paranoid Reaction | – | – | 1.4 | 0.0 |
| Agitation | 1.3 | 0.7 | 1.0 | 0.0 |
| Concentration Impaired | 1.9 | 0.0 | 1.0 | 0.0 |
| Illusion | 1.3 | 0.0 | – | – |
| Thinking Abnormal | – | – | 1.4 | 0.8 |
| Apathy | – | – | 1.0 | 0.0 |
| Increased Libido | – | – | 1.0 | 0.0 |
| Personality Disorder | – | – | 1.0 | 0.0 |
| ***Red Blood Cell*** | | | | |
| Anemia | – | – | 2.4 | 0.0 |
| **Reproductive Male** | | | | |
| Impotence | 2.5 | 1.4 | – | – |
| Prostatic Disorder | – | – | 1.0 | 0.0 |
| Penis Disorder | – | – | 1.3 | 0.0 |
| **Resistance Mechanism** | | | | |
| Upper Respiratory Tract Infection | – | – | 8.7 | 8.3 |
| Infection Viral | 10.8 | 3.4 | 7.2 | 6.7 |
| **Respiratory System** | | | | |
| Pharyngitis | 6.4 | 4.1 | – | – |
| Rhinitis | 3.8 | 2.7 | – | – |
| Sinusitis | 3.8 | 2.7 | – | – |
| Dyspnea | 3.2 | 0.0 | 2.9 | 1.7 |
| Bronchitis | 2.5 | 1.4 | – | – |
| Respiratory Disorder | 1.9 | 1.4 | 1.9 | 0.0 |
| Pneumonia | 1.3 | 0.7 | 1.0 | 0.8 |
| Coughing | – | – | 1.4 | 0.8 |
| **Skin/Appendages** | | | | |
| Pruritis | – | – | 1.0 | 0.0 |
| **Urinary System** | | | | |
| Urinary Tract Infection | 5.1 | 4.1 | 6.3 | 2.5 |
| Cystitis | 1.3 | 0.7 | – | – |
| Micturition Frequency | – | – | 1.4 | 0.0 |
| Pyuria | – | – | 1.9 | 0.8 |
| Urinary Incontinence | – | – | 1.9 | 0.8 |
| Urinary Retention | 1.3 | 0.7 | – | – |
| Dysuria | – | – | 1.0 | 0.0 |
| **Vascular Extracardiac** | | | | |
| Peripheral Ischemia | 2.5 | 0.0 | – | – |
| **Vision** | | | | |
| Vision Abnormal | 5.7 | 3.4 | – | – |
| Eye Abnormality | 3.2 | 1.4 | – | – |
| Diplopia | – | – | 1.9 | 0.8 |
| Xerophthalmia | 1.9 | 0.0 | 1.4 | 0.8 |
| Cataract | – | – | 1.4 | 0.8 |
| Lacrimation Abnormal | – | – | 1.4 | 0.0 |
| **White Cell and Reticuloendothelial System** | | | | |
| Eosinophilia | – | – | 1.4 | 0.0 |

a: Incidence of adverse event <1%.

**Post-Marketing Experience -** Patients treated with REQUIP® have rarely reported suddenly falling asleep while engaged in activities of daily living, including operation of motor vehicles which has sometimes resulted in accidents (see WARNINGS).

**DOSAGE AND ADMINISTRATION:** REQUIP® (ropinirole hydrochloride) should be taken three times daily. While administration of REQUIP® with meals may improve gastrointestinal tolerance, REQUIP® may be taken with or without food. The recommended starting dosage is 0.25 mg three times daily. Based on individual patient response, dosage should then be titrated by weekly increments of 0.25 mg per dose as described in the table below. After week 4, daily dosage may be increased by 0.5 to 1.0 mg per dose on a weekly basis until an optimal therapeutic response is established. Smaller dose increments are recommended for patients who may be at risk for orthostatic symptoms.

| | Week | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| Unit Dose (mg) | 0.25 | 0.5 | 0.75 | 1.0 |
| Total Daily Dose (mg) | 0.75 | 1.5 | 2.25 | 3.0 |

In clinical trials, initial benefits were observed with 3 mg/day and higher doses. Doses greater than 24 mg/day have not been included in clinical trials. In a 5-year, double-blind study of early therapy in Parkinson's disease patients, the average daily dose of REQUIP® (based on the observed data set) was 10.1 mg at 6 months (median dose = 9.0 mg), 14.4 mg at 3 years (median dose = 15.0 mg), and 16.6 mg at 5 years (median dose = 18.0 mg), regardless of levodopa supplementation. When REQUIP® is administered as adjunct therapy to levodopa, the dose of levodopa may be decreased gradually as tolerated once a therapeutic effect with REQUIP® has been observed. REQUIP® should be discontinued gradually over a 7-day period. The frequency of administration should be reduced from three times daily to twice daily for 4 days. For the remaining 3 days, the frequency should be reduced to once daily prior to complete withdrawal of REQUIP®. **Renal and Hepatic Impairment:** In patients with mild to moderate renal impairment, REQUIP® may be titrated in the recommended manner according to clinical response. Patients with severe renal impairment or on hemodialysis have not been studied and administration of REQUIP® to such patients is not recommended. Patients with hepatic impairment have not been studied and administration of REQUIP® to such patients is not recommended. **Estrogen Replacement Therapy:** In patients already receiving estrogen replacement therapy, REQUIP® may be titrated in the recommended manner according to clinical response. However, if estrogen replacement therapy is stopped or started during treatment with REQUIP®, adjustment of the REQUIP® dosage may be required. **AVAILABILITY OF DOSAGE FORM:** REQUIP® is supplied as a pentagonal film-coated Tiltab® tablet with beveled edges containing ropinirole (as ropinirole hydrochloride) as follows: 0.25 mg – white imprinted with SB and 4890; 1.0 mg – green imprinted with SB and 4892; 2.0 mg – pale pink imprinted with SB and 4893; 5.0 mg – blue tablets imprinted with SB and 4894. REQUIP® is available in bottles in the pack size of 100 tablets. Full Product Monograph available to practitioners upon request.

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