DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-008S-001

SmithKline Beecham d/b/a/GlaxoSmithKline
Attention: Elizabeth McConnell, Pharm.D.
Associate Director, Regulatory Affairs, Neurology
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. McConnell:

Please refer to your supplemental new drug application dated July 1, 2008, received July 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Requip XL (ropinirole extended-release tablets).

This supplemental new drug application provides for a new 12 mg dosage strength.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 22-008/S-001**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: labeling

- Keep REQUIP out of the reach of children**.**

Other Information about REQUIP

- Do not share REQUIP with other people, even if they have the same symptoms you have.
- Studies of people with Parkinson's disease show that they may be at an increased risk of developing melanoma, a form of skin cancer, when compared to people without Parkinson's disease. It is not known if this problem is associated with Parkinson's disease or the medicines used to treat Parkinson's disease. REQUIP is one of the medicines used to treat Parkinson's disease, therefore, patients being treated with REQUIP should have periodic skin examinations.

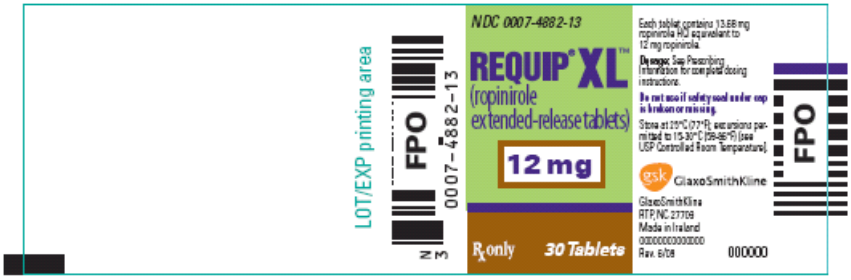
This patient information leaflet summarizes important information about REQUIP for Restless Legs Syndrome. Medicines are sometimes prescribed for purposes other than those listed in this leaflet. Do not take REQUIP for a condition for which it was not prescribed. For more information, talk with your healthcare provider or pharmacist. They can give you information about REQUIP that is written for healthcare professionals. For more information call 1-888-825-5249 (toll-free) or visit www.requip.com.

What are the ingredients in REQUIP?

The following ingredients are in REQUIP:
Active ingredient: ropinirole (as ropinirole hydrochloride)
Inactive ingredients: croscarmellose sodium, hydrous lactose, magnesium stearate, microcrystalline cellulose, and one or more of the following: carmine, FD&C Blue No.2 aluminum lake, FD&C Yellow No. 6 aluminum lake, hypromellose, iron oxides, polyethylene glycol, polysorbate 80, titanium dioxide.

GlaxoSmithKline
Research Triangle Park, NC 27709

RXL:
(Date of Issue)


LOT/EXP printing area
FPO
0007-4882-13
NDC 0007-4882-13
REQUIP® XL™
(ropinirole
extended-release tablets)
12 mg
Rx only
30 Tablets
Each tablet contains 13.66 mg ropinirole HCl equivalent to 12 mg ropinirole.
Dispense: See Prescribing Information for complete dosing instructions.
Do not use if safety seal under cap is broken or missing.
Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].
GlaxoSmithKline
RTP, NC 27709
Made in Ireland
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Rev. 6/08
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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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