*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Summary of investigation results

## Pramipexole hydrochloride hydrate

Aug 6, 2014

### Non-proprietary Name

Pramipexole hydrochloride hydrate

### Brand Name (Marketing Authorization Holder)

a. BI・Sifrol tablets 0.125 mg, 0.5 mg, (Nippon Boehringer Ingelheim Co., Ltd.) and the others

b. Mirapex-LA tablets 0.375 mg and 1.5 mg (Nippon Boehringer Ingelheim Co., Ltd.)

### Indications

a. Parkinson's disease and moderate to severe primary Restless Legs Syndrome

b. Parkinson's disease

### Summary of revision

'Hepatic dysfunction' should be added in Clinically significant adverse reactions section.

### Background of the revision and investigation results

Cases of hepatic dysfunction have been reported in patients treated with pramipexole in Japan. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package inserts was necessary.

### The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan

A total of 4 cases associated with hepatic dysfunction has been reported (including 2 cases in which causality could not be ruled out). Of the 4 cases, no fatality has been reported.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp