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Flutamide – warning concerning severe hepatic dysfunction

Japan. On 7 August, the Pharmaceutical and Medical Safety Bureau instructed the manufacturer of flutamide in Japan (Odyne®: Nihon-kayaku) to revise the package insert leaflet for flutamide and to send a Dear Doctor letter regarding hepatic dysfunction caused by flutamide, since 5 fatal cases of hepatic dysfunction (including fulminant hepatitis) have been reported this year.

The revised package insert should include hepatic dysfunction as an additional contraindication and a warning should be included with the following requirements:

- The patient's liver function should be monitored periodically (at least once a month).
- Medication should be stopped when disorder of the patient's hepatic function is observed.
- Patients should be informed, prior to medication, of the possiblility of its causing hepatic dysfunction and they should be instructed to stop the medication and consult their doctor immediately when symptoms of hepatic dysfunction appear.

Reference: Facsimile communication from the Safety Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare, Tokyo.

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