WORLD HEALTH ORGANIZATION ORGANISATION MONDIALE DE LA SANTE

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PHA Information Exchange System

ALERT

SUSPENSION OF REGISTRATION

CRONASSIAL^{R}: (MIXED BOVINE BRAIN GANGLIOSIDES) MADAUS

The Federal Health Office of the Federal Republic of Germany has suspended the marketing authorization for Cronassial^{R} solution for injection (Madaus) until 31 December 1990. In the interim, the need for further regulatory action will be considered in the light of all available evidence.

The product, which was first marketed in the Federal Republic of Germany in June 1985, is indicated "for supportive treatment following surgery for intervertebral herniation, lesions of the peripheral nervous system, and alcoholic, diabetic or uraemic neuropathy". Its suspension results from its possible association with Guillain-Barré syndrome characterized by mixed polyneuropathy and in some instances, flaccid paralysis. During the period of suspension, its use will be restricted to administration within the context of approved clinical trials.

Doctors are asked to report all such cases to the Federal Health Office, and patients currently under therapy are advised to consult their doctor.

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