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Information Exchange System

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Sertindole (Serdolect®) - suspended : cardiac arrhythmias and sudden cardiac death

United Kingdom. The Committee on Safety of Medicines has informed doctors and pharmacists that the manufacturer of the limbic selective antipsychotic agent, sertindole (Serdolect®: Lundbeck), has voluntarily suspended its availability from 2 December 1998. Sertindole is indicated for the treatment of schizophrenia. This suspension is due to concerns about reports of cardiac arrhythmias and sudden cardiac death associated with its use.

In the light of this information, the availability of sertindole will be suspended pending a full evaluation of its risks and benefits in collaboration with the UK Medicines Control Agency (MCA) and other European regulatory authorities.

Prescribers are advised as follows:

- No new patients should be initiated on sertindole.
- Existing patients should be recalled for review by the psychiatrist.
- NO patient should have sertindole stopped until a suitable alternative treatment has been prescribed.
- Sertindole should be withdrawn and replaced with an alternative treatment.
- Sertindole may be stopped immediately and the patient transferred straight away to an alternative treatment, such as another atypical antipsychotic.
- Alternatively, if the psychiatrist judges it appropriate for a particular patient, sertindole may be tapered off by a stepwise reduction over a period of up to two weeks whilst the replacement antipsychotic therapy is initiated.

Doctors or hospital pharmacists who suspect that one of their patients has suffered an adverse drug reaction while taking sertindole should report this to the MCA/Committee on Safety of Medicines. The agency will continue to review all available data on sertindole and with make new recommendations if necessary.

Further information may be obtained from:

- Lundbeck Ltd, tel.: +44-1908 649966
- MCA, tel.: +44-171-2730000.

Reference: "Dear Doctor/Pharmacist" letter, Professor M. Rawlins, Chairman, Committee on Safety of Medicines, London, 2 December 1998. [http://www.open.gov.uk/mca/csm/serdolect.htm]

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