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Use of Scandonest and associated names (mepivacaine) to be harmonised

Information for doctors and patients to be aligned across EU

On 31 May 2018, the European Medicines Agency (EMA) completed a review of Scandonest and associated names and recommended changes to the prescribing information in order to harmonise the way the medicine is used in the EU.

What is Scandonest?

Scandonest is a local anaesthetic, a medicine used to block sensation and pain in part of the body during medical procedures. Scandonest is given by injection. It contains the active substance mepivacaine.

Scandonest is also available in the EU under the trade names Biocaine and Scandicaine.

The company that markets these medicines is Septodont.

Why was Scandonest reviewed?

Scandonest has been authorised in the EU via national procedures. This has led to inconsistency across Member States in the way the medicine is produced and can be used, as seen in the differences in the prescribing information [summary of product characteristics (SmPC), labelling and package leaflet] in the countries where the medicine is marketed.

On 25 August 2017, Septodont, the company that markets Scandonest, referred the matter to EMA in order to harmonise the marketing authorisations for Scandonest in the EU.

What is the outcome of the review?

After considering the available data on the use of Scandonest, the Agency concluded that the SmPC should be harmonised. The areas harmonised include:

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4.1 Therapeutic indications

Scandonest is now authorised for use as local anaesthetic in dental surgery in adults, adolescents and children above 4 years of age (weighing around 20 kg).

Scandonest should no longer be used as local anaesthetic during chiropody procedures (treatment of corns, verrucae, etc.), because the data presented by the company were considered not sufficient to support this use.

4.2 Posology and method of administration

The recommended dose of Scandonest depends on the patient's age and body weight. In adults, the maximum recommended dose is 4.4 mg per kg body weight, up to a maximum total dose of 300 mg. In children, the recommended dose is 0.75 mg/kg.

4.3 Contraindications

Scandonest must not be used in patients who are allergic to the active substance mepivacaine or any of the other ingredients of the medicine. In addition, it must not be used in children below 4 years of age, in patients with severe problems affecting the heart's electrical activity which are not resolved by a pace-maker, and in epileptic patients whose disease is not adequately controlled.

After review of the available data, a number of other contraindications which were only valid in some countries were considered not to be supported by sufficient data, or to be redundant and already included in the current list above. Where justified by data, some of the previous contraindications have been included in section 4.4 Special warnings and precautions for use.

Other changes

Other harmonised sections of the SmPC include sections 4.4 (special warnings and precautions for use) 4.5 (interactions), 4.6 (fertility, pregnancy and lactation), 4.7 (effects on ability to drive and use machines), and 4.8 (side effects).

The package leaflet will be updated accordingly.

The amended information to doctors and patients is available here.

In addition, Module 3 of the medicine dossier (which describes how the medicine is produced and its quality controlled) has also been harmonised.

More about the procedure

The review of Scandonest was initiated at the request of the marketing authorisation holder, Septodont, under Article 30 of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

The European Commission issued an EU-wide legally binding decision to implement these changes on 2 August 2018.