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Use of Septanest and associated names (articaine / adrenaline solutions for injection) to be harmonised in EU

On 28 March 2019, the European Medicines Agency (EMA) completed a review of Septanest (also known by various other names) and recommended changes to the prescribing information in order to harmonise the way the medicine is used in the EU.

What is Septanest?

Septanest is a local anaesthetic (a medicine for preventing pain and discomfort in a part of the body during medical procedures). It is given by injection. Septanest contains the active ingredient articaine together with adrenaline (epinephrine), which helps prolong articaine's effects and restrict it to a particular area of the body.

Septanest is also available in the EU under other trade names including Septanest Forte, Septanest N, Septanest Normal, Septanest SP, Septanest Special, Septanest with Adrenaline, Septanestepi and Septocaine.

The company that markets these medicines is Septodont.

Why was Septanest reviewed?

Septanest 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 - that is, the summary of product characteristics (SmPC), labelling and package leaflet - in the countries where the medicine is marketed.

On 4 June 2018, Septodont, the company that markets Septanest, referred the matter to EMA in order to harmonise the marketing authorisations for Septanest in the EU.

What is the outcome of the review?

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

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4.1 Therapeutic indications

Septanest is now authorised for use as a local anaesthetic in dental procedures in adults, adolescents and children above 4 years of age (or weighing at least 20 kg).

4.2 Posology and method of administration

The recommended dose of Septanest depends on the patient's body weight. The maximum recommended dose in all ages is 7 mg of articaine per kg body weight, up to a maximum total dose of 500 mg in adults and 385 mg in children.

4.3 Contraindications

Septanest must not be used in patients who are allergic to articaine or similar local anaesthetics (known as amide-type local anaesthetics) or to any other ingredient of the medicine. It must also not be given to patients with epilepsy who are not adequately controlled by treatment.

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 were considered redundant. 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 section 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), 4.8 (side effects), and 4.9 (overdose).

The package leaflet has been updated accordingly.

The amended information to doctors and patients is available here.

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

More about the procedure

The review of Septanest was initiated on 29 June 2018 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.

A European Commission decision valid throughout the EU was issued on 27/05/2019.