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EMA starts review of Septanest (articaine / adrenaline solutions for injection) and associated names

The European Medicines Agency (EMA) has started a review of the medicine Septanest (also known by various other names). Septanest contains the active substance articaine, a local anaesthetic (a medicine used to prevent pain and discomfort in a part of the body), together with adrenaline, which helps prolong articaine's effects and restrict it to a particular area of the body.

Septanest has been authorised in several member states of the EU via national procedures. This has led to divergences across member states in the way the medicine is produced and can be used, as seen in the differences in the prescribing information (summaries of product characteristics, labelling and package leaflets).

EMA will consider the available data on Septanest and will amend the prescribing information to harmonise the way Septanest is used in the countries where it is available.

The amended information for doctors and patients will be available on the EMA website once the review is concluded.

More about the medicine

Septanest is a local anaesthetic, a medicine which blocks sensation. It is used to prevent pain and discomfort in the mouth during dental procedures and is given by injection.

Septanest contains the active substance articaine. It also contains adrenaline, which constricts blood vessels, prolonging and localising the effects of the anaesthetic.

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

More about the procedure

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

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The review is being carried out by the EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in EU Member States.