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EMA starts review of Scandonest (mepivacaine 30 mg/ml solution for injection)

The European Medicines Agency (EMA) has started a review of the medicine Scandonest, a local anaesthetic (a medicine used to block pain in a part of the body) that contains the active substance mepivacaine.

Scandonest 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) in the countries where the medicine is available.

EMA will consider the available data on Scandonest and will amend the prescribing information to harmonise the way Scandonest is used in the EU.

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

More about the medicine

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 and can be used during dental and chiropody (treatment of corns, verrucae, etc.) procedures.

Scandonest is also available in the EU under the trade names Biocaine and Scandicaine. It contains the active substance mepivacaine.

More about the procedure

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

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.

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The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in EU Member States.