

Summary Public Assessment Report

Pentocur (thiopenthal sodium)

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(thiopental sodium)

Powder for solution for injection

This is a summary of the public assessment report (PAR) for Pentocur. It explains how Pentocur was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Pentocur.

For practical information about using Pentocur, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pentocur and what is it used for?

Pentocur is a 'generic medicine'. This means that Pentocur is similar to a 'reference medicine' already authorised in the European Union (EU) called Pentothal Natrium.

Pentocur is used:

- to start general anaesthesia (a state of heavy sleep e.g. during surgery),
- to provide hypnosis (you are sleepy but not completely asleep) during anaesthesia together with other anaesthetic agents
- as part of treatment for cramps (including those caused by local anaesthetics)
- to reduce pressure in the skull (intracranial pressure) in patients where the pressure is increased (if assisted ventilation is provided)

How does Pentocur work?

Pentocur contains the active substance "thiopental sodium". Pentocur is a thiobarbiturate with rapid onset for intravenous administration. Thiopental induces hypnosis and anesthesia, but not analgesia. Hypnosis is produced within 30 to 40 seconds.

How is Pentocur used?

The pharmaceutical form of Pentocur is Powder for solution for injection.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Pentocur have been shown in studies?

No additional studies were needed as Pentocur is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Pentothal Natrium.

What are the possible side effects of Pentocur?

Because Pentocur is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Pentocur approved?

It was concluded that, in accordance with EU requirements, Pentocur has been shown to have comparable quality and to be similar to the reference medicine Pentothal Natrium. Therefore, the Medical Products Agency in Sweden decided that, as for Pentothal Natrium, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Pentocur?

A risk management plan has been developed to ensure that Pentocur is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Pentocur, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Pentocur

The full PAR for Pentocur can be found on the following website:
<http://mri.medagencies.org/Human/>. For more information about treatment with Pentocur, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2023-02.