

Package leaflet: Information for the user

Pentocur 0.5 g powder for solution for injection Pentocur 1 g powder for solution for injection

thiopental sodium

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pentocur is and what it is used for
2. What you need to know before you are given Pentocur
3. How Pentocur is given
4. Possible side effects
5. How to store Pentocur
6. Contents of the pack and other information

1. What Pentocur is and what it is used for

Pentocur contains the active substance “thiopental sodium”. It is a thiobarbiturate with rapid onset for intravenous administration.

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 respiratory assistance is provided)

2. What you need to know before you are given Pentocur

Pentocur should not be given to you:

- if you are allergic to thiopental, barbiturates or any of the other ingredients of this medicine (listed in section 6)
- in case of obstruction of the airways (respiratory obstruction)
- if you have acute asthma (severe asthma attack)
- if you suffer from hereditary muscle degeneration (myotonic dystrophy)
- if you are in severe shock
- if you have porphyria

Warnings and precautions

Talk to your doctor or nurse before you are given Pentocur. The health care professionals should be extra careful and may have to adjust your dose, if you have/are:

- increased pressure in your skull
- asthma or other severe respiratory disease
- inflammation in the mouth, jaw and throat – this could lead to airway problems during the use of Pentocur

- any heart or blood vessel disease or high blood pressure
- inflammation of the heart sac
- low levels of fluids in the body (hypovolaemia) or are dehydrated
- severe bleeding or burns
- myasthenia gravis (a disease which makes the muscles very weak)
- reduced function of the adrenocortical gland, even when treated with cortisone
- feeling generally ill, are undernourished and have lost weight
- increased level of urea, toxins or potassium in your blood
- severe anemia
- in shock
- liver or kidney impairment
- any metabolic disorder, such as thyrotoxicosis, myxedema and diabetes
- addicted to alcohol or drugs of abuse

Other medicines and Pentocur

Tell your doctor or nurse if you are using, have recently used or might use any other medicines.

The following medicines can affect or can be affected by this injection and may need to be adjusted before or after receiving this injection:

- Aminophylline and theophylline (for the treatment of asthma)
- Midazolam (a sedative medicine)
- Opioid analgesics (strong painkillers)
- Probenecid (a gout medicine)
- Sufentanil (an anaesthetic medicine)
- Muscle relaxants
- MAO-inhibitors and tricyclic antidepressants (for the treatment of depression), e.g. citalopram, amitriptyline
- Medicines that have a depressive effect on the central nervous system (CNS)
- Metoclopramide and droperidol (for the treatment of nausea and vomiting)
- Medicines containing St John's Wort
- Androgens (for treatment of male infertility)
- Medicine for epilepsy
- Glucocorticoids (antiinflammatory agents)
- Medicines to treat bacterial infections such as metronidazole, sulphafurazole, isoniazid, vancomycin
- Estrogen (for the treatment of menopause)
- Medicines for the treatment of diabetes, taken by mouth
- Medicines used for the treatment of high blood pressure e.g. captopril, enalapril, terazosin, felodipine, hydralazine, losartan, methyldopa, moxonidine and diuretics
- Acetylsalicylic acid (Aspirin) and other painkilling medications
- Antipsychotic medications such as promethazine or quetiapine; lithium
- Diazoxide (for the treatment of low blood sugar)
- Tablets or spray used for the treatment of angina pectoris
- Medicines used to thin the blood (anticoagulants taken by mouth)

Pentocur with alcohol

The dose of Pentocur may need to be increased if you are addicted to or regularly consume large amounts of alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pentocur should be given to a pregnant woman only if the doctor considers it to be clearly necessary.

Thiopental is excreted to breast milk; breastfeeding should be temporarily suspended (for at least 12 hours after the use of thiopental) or breast milk expressed before the use of Pentocur.

Driving and using machines

Pentocur has major influence on the ability to drive and use machines. Although recovery is relatively quick, you may experience periods of vertigo, disorientation and sedation. Patients therefore must not drive and use machines within 24 to 36 hours after the use of Pentocur.

Pentocur contains sodium

One vial of Pentocur 0.5 g contains 51-56 mg (or 2.2-2.4 mmol) sodium (main component of cooking/table salt) and one vial of Pentocur 1 g contains 102-112 mg (or 4.4-4.9 mmol) sodium. This is equivalent to 2.8% (0.5 g vial) and 5.6 % (1 g vial) of the recommended maximum daily dietary intake of sodium for an adult.

3. How Pentocur is given

Pentocur will be given to you by a healthcare professional trained in anaesthesiology, who will be constantly available during the administration of Pentocur as will emergency resuscitative equipment.

Pentocur will be given directly into one of your blood vessels, a vein (intravenously).

A test dose will be given in order to adjust the dose according to your needs.

Anaesthesia

Your individual dose will be determined by the doctor and it will be based on your age, sex, body weight and general condition. You will receive a dose to start the anaesthesia and additional injections to maintain the anaesthesia.

Seizures/convulsions

The injection of Pentocur should be given as soon as possible after the convulsion begins. Further doses may also be required to control convulsions.

Intracranial pressure

You will receive a dose based on your body weight in order to reduce elevations of pressure in the skull (respiratory assistance is provided).

Impaired liver or kidney function

Your doctor will reduce the dose of Pentocur if you have impaired liver or kidney function.

If you are given more Pentocur than you should

It is unlikely that you receive an excessive dose, since healthcare personnel takes care of the administration of Pentocur.

Overdose may occur from too many injections or if Pentocur is administered too quickly. In the event of suspected or apparent overdose, the drug should be discontinued. Symptoms of overdose include: alarming fall in blood pressure, shock. In addition apnea, coughing and other breathing difficulties may occur (this however, can also be a sign of underdosing).

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor **immediately** if you notice any of the following symptoms - you may need urgent medical treatment:

- Difficulty breathing, wheezing, rash, itching, hives and dizziness. This could be a severe allergic reaction (frequency not known, cannot be estimated from the available data).
- Swelling of the face, tongue or throat, difficulty in swallowing and fall in blood pressure (angioedema and anaphylactoid reactions) are rare side effects which may affect up to 1 in 1,000 people.

Other side effects that may occur:

Common: may affect up to 1 in 10 people

- Irregular heartbeats (heart arrhythmia)
- Heart disorder
- Low blood pressure
- Sleepiness
- Delayed waking from the anaesthesia
- Breathing difficulties
- Hyperventilation
- Difficulty in swallowing
- Coughing
- Snoring
- Shivering

Not known: frequency cannot be estimated from the available data

- Increased potassium in your blood (hyperkalaemia)
- Decreased potassium in your blood (hypokalaemia)
- lack or loss of appetite (Anorexia)
- Feeling generally unwell, weakness (malaise)
- Tiredness (fatigue)
- Headache
- Dizziness
- Allergic reactions, skin reactions hypersensitivity

At the beginning when given Pentocur, laryngeal spasm, coughing and sneezing may occur. After the operation and use of Pentocur, vomiting is uncommon but persistent drowsiness, confusion, amnesia and shivering may occur.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Pentocur

Before the first opening: The medicinal product does not require any special storage conditions.

After reconstitution: Store in a refrigerator (2–8 °C) for a maximum of 24 hours.

Store in room temperature for a maximum of 6 hours

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Pentocur contains**

- The active substance is thiopental sodium.

Each vial of Pentocur 0.5 g powder for solution for injection contains 500 mg thiopental sodium (as thiopental sodium and sodium carbonate).

Each vial of Pentocur 1 g powder for solution for injection contains 1000 mg thiopental sodium (as thiopental sodium and sodium carbonate).

- The other ingredient is sodium carbonate.

What Pentocur looks like and contents of the pack

Glass vial with bromobutyl rubber stopper and aluminium seal, in a carton box.

Content of the pack:

Pentocur powder for solution for injection 0.5 g: 1 x 1 vial, 10 x 1 vial, 20 x 1 vial or 50 x 1 vial

Pentocur powder for solution for injection 1 g: 1 x 1 vial, 10 x 1 vial, 20 x 1 vial or 50 x 1 vial

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

< To be completed nationally >

This leaflet was last revised in -2023-05-26

The following information is intended for healthcare professionals only:

Preparation of solution

Pentocur powder for solution for injection should be prepared aseptically with one of the three following diluents:

- water for injections (according Ph.Eur.)
- 0.9% sodium chloride solution for infusion (9 mg/ml)
- 5% dextrose solution for infusion (50 mg/ml)

Clinical concentrations used for intermittent intravenous administration vary between 2.0% and 5.0%. A 2.0% or 2.5% solution is most commonly used. A 3.4% concentration in water for injections is isotonic; concentrations less than 2.0% in this diluent are not used because they cause hemolysis. For continuous intravenous drip administration, concentrations of 0.2% or 0.4% are used. Solutions may be prepared by adding thiopental to 5% water solution of dextrose or to 0.9% solution of sodium chloride.

CALCULATIONS FOR VARIOUS CONCENTRATIONS

Desired concentration		Amounts to use	
%	mg/ml	g of Pentocur	ml of diluent
0.2	2	1	500
0.4	4	1	250
		2	500
2.0	20	5	250
		10	500
2.5	25	1	40
		5	200
5.0	50	1	20
		5	100

Since Pentocur contains no added bacteriostatic agent, extreme care in preparation and handling should be exercised at all times to prevent the introduction of microbial contaminants. Solutions should be freshly prepared and used promptly; when reconstituted for administration to several patients; unused portions should be discarded after 24 hours. Sterilization by vapour should not be attempted.

Pentocur is administered by the intravenous route only. Avoid extravasation or intra-arterial injection. A person qualified in the use of anaesthetics should be constantly available during the administration of the

medicinal product. Keep endotracheal intubation equipment, oxygen and resuscitative equipment readily available.

The following corrective measures in case of intra-arterial injection have been suggested (controlling investigations are missing):

1. Dilute the injected Pentocur by removing the tourniquet and any restrictive garments.
2. Leave the intravenous cannula in place, if possible.
3. Inject the artery with a dilute solution of papaverine, or lidocaine, to inhibit smooth muscle spasm.
4. If necessary, perform sympathetic block of the brachial plexus and/or stellate ganglion to relieve pain and assist in opening collateral circulation. Papaverine can be injected into the subclavian artery, if desired.
5. Unless otherwise contraindicated, treat with heparin to prevent thrombus formation.
6. Consider local infiltration of an alpha-adrenergic blocking agent such as phentolamine into the vasospastic area.
7. Provide additional symptomatic treatment as required.

Any solution of Pentocur powder for solution for injection, with a visible precipitate should not be administered.

Incompatibilities

The stability of Pentocur powder for solution for injection solutions depends upon several factors, including the diluent, temperature of storage and the amount of carbon dioxide from room air that gains access to the solution. Any factor or condition which tends to lower pH (increase acidity) of Pentocur powder for solution for injection solutions will increase the likelihood of precipitation of thiopental acid. Such factors include the use of diluents which are too acidic and the absorption of carbon dioxide which can combine with water to form carbonic acid.

Solutions of suxamethonium, tubocurarine or other drugs which have an acid pH should not be mixed with Pentocur powder for solution for injection solutions.

The most stable solutions are those reconstituted in water and/or isotonic saline and/or solution of dextrose, kept under refrigeration and tightly stoppered.