Package leaflet: Information for the user

Thiopental 0.5 g powder for solution for injection
Thiopental 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.

The name of your medicine is Thiopental 0.5/1 g powder for solution for injection (called Thiopental Injection in this leaflet).

What is in this leaflet

1. What Thiopental Injection is and what it is used for

Thiopental Injection contains the active substance "thiopental sodium". It is a thiobarbiturate with rapid onset for intravenous administration.

Thiopental Injection 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 Thiopental Injection

Thiopental Injection should not be given to you:
- if you are allergic to thiopental sodium, 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 Thiopental Injection. 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 Thiopental Injection
- 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 Thiopental Injection
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)
- Sufentanile (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
- Glucocorticoides (antiinflammatory agents)
- Medicines to treat bacterial infections such as metronidazole, sulphafurazole, isoniazid, vancomycin
- Estrogen (for the treatment of menopauses)
- 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).

Thiopental Injection with alcohol
The dose of Thiopental Injection 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.

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

Thiopental is excreted in 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 Thiopental Injection.

Driving and using machines
Thiopental Injection 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 Thiopental Injection.

Thiopental Injection contains sodium
One vial of Thiopental Injection 0.5 g contains 51-56 mg (or 2.2-2.4 mmol) sodium (main component of cooking/table salt) and one vial of Thiopental Injection 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 Thiopental Injection is given

Thiopental Injection will be given to you by a healthcare professional trained in anaesthesiology, who will be constantly available during the administration of Thiopental Injection as will emergency resuscutative equipment.
Thiopental Injection 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 Thiopental Injection 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 Thiopental Injection if you have impared liver or kidney fuction.

If you are given more Thiopental Injection than you should
It is unlikely that you receive an excessive dose, since healthcare personnel takes care of the administration of Thiopental Injection.
Overdose may occur from too many injections or if Thiopental Injection 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 wakening 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 Thiopental Injection, laryngeal spasm, coughing and sneezing may occur. After the operation and use of Thiopental Injection, 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 via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Thiopental Injection

Before the first opening: The medicinal product does not require any special storage conditions.
After reconstitution: Store in a refrigerator (2°C–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 Thiopental Injection contains

- The active substance is thiopental sodium.
  Each vial of Thiopental 0.5 g powder for solution for injection contains 500 mg thiopental sodium (as thiopental sodium and sodium carbonate).
  Each vial of Thiopental 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 Thiopental Injection looks like and contents of the pack

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

Content of the pack:
Thiopental Injection 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
Thiopental Injection 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

Mercury Pharmaceuticals Limited
Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer

VUAB Pharma a.s.
Vltavská 53
252 63 Roztoky
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The following information is intended for healthcare professionals only:

Preparation of solution

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

- water for injections (according to 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 Thiopental Injection	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 Thiopental Injection 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.

Thiopental Injection 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 Thiopental Injection 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 Thiopental Injection powder for solution for injection, with a visible precipitate should not be administered.

Incompatibilities

The stability of Thiopental Injection 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 Thiopental Injection 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 Thiopental Injection 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.