Package leaflet: Information for the patient

Thiopental 500mg and 1g
powder for solution for injection

thiopental sodium and sodium carbonate

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Thiopental is and what it is used for

This medicine contains the active ingredient thiopental sodium and sodium carbonate. It is a thiobarbiturate with rapid onset for intravenous administration (into the vein).

Thiopental 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)

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

You should not be given Thiopental:
- if you are allergic to thiopental, barbiturates or any of the other ingredients of this medicine (listed in section 6);
- if you have an 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 (a rare blood disorder).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using this medicine. 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 this medicine
- 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 anaemia
- in shock
- liver or kidney problems
- any metabolic disorder, such as thyrotoxicosis, myxedema and diabetes
- addicted to alcohol or drugs of abuse

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

The following medicines can affect, or 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 anesthetic 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 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 lithium, promethazine or quetiapine
- Diazoxide (for the treatment of low blood sugar)
- Tablets or spray used for the treatment of angina pectoris (severe chest pain)
- Medicines used to thin the blood (anticoagulants taken by mouth)

Thiopental with alcohol
The dose of this medicine 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, pharmacist or nurse for advice before being given this medicine.

This medicine 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 this medicine.

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

Thiopental contains sodium
This medicine contains 4.6 mmol (or 106 mg) sodium per 1g vial; 2.3 mmol (or 53 mg) per 500 mg vial. To be taken into consideration by patients on a controlled sodium diet.

3. How Thiopental is given

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

This medicine 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.

The following information is intended for healthcare professionals only:

This medicine should be prepared aseptically with one of the three following diluents:
- Sterile Water for Injection
- Sodium chloride 9 mg/ml (0.9%)
- Dextrose 50 mg/ml (5%)

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 sterile water for injection 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	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 this medicine 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.

- **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 or convulsions**

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

- **Intracranial pressure**

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

- **Liver or kidney problems**

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

If you are given more Thiopental than you should

It is unlikely that you receive an excessive dose, since healthcare personnel takes care of the administration of this medicine.
Overdose may occur from too many injections or if the medicine is administered too quickly. In the event of suspected or apparent overdose, the medicine 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, pharmacist or nurse.

4. Possible side effects

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

Contact your doctor or nurse immediately if you experience any of the following symptoms:
- Swelling of the face, tongue or throat, difficulty swallowing; hives; breathing difficulties and fall in blood pressure (angioedema and anaphylactoid reactions).

These are rare side effects which may affect up to 1 in 1,000 people.

Other side effects:

Common (may affect up to 1 in 10 people):
- Heart arrhythmia
- Heart disorder
- Low blood pressure
- Sleepiness
- Delayed wakening from the anaesthesia
- Breathing difficulties
- Overbreathing (hyperventilation)
- Difficulty in swallowing
- Coughing
- Snoring
- Shivering
- Blood clotting within blood vessels
- Inflammation of vein
- Pain at administration site

Rare (may affect up to 1 in 1000 people):
- Severe, life-threatening allergic type reaction

Not known (frequency cannot be estimated from the available data):
- Increased potassium in your blood (hyperkalaemia)
- Decreased potassium in your blood (hypokalaemia)
- Loss of appetite (anorexia)
- Feeling generally unwell, weakness (malaise)
- Tiredness (fatigue)
- Headache
- Dizziness
- Allergic reactions, skin reactions, hypersensitivity
- Nausea
- Kidney disorder
- Unpleasant dreams
- Change in mood

At the beginning when given this medicine, laryngeal spasm, coughing and sneezing may occur. After the operation and use of this medicine, vomiting is uncommon but persistent drowsiness, confusion, loss of memory (amnesia) and shivering may occur.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system 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

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 pack. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After reconstitution:
Chemical and physical in-use stability has been demonstrated for 9 hours below 25°C and 24 hours at 2°C to 8°C.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C.

Do not throw away 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 contains

The active substance is thiopental sodium and sodium carbonate.
Each 500 mg vial contains thiopental sodium and sodium carbonate (equivalent to 470 mg of thiopental sodium).
Each 1 g vial contains thiopental sodium and sodium carbonate (equivalent to 0.94 g of thiopental sodium).

What Thiopental looks like and contents of the pack

20 mL glass vials made from colourless type III glass with a rubber stopper, aluminium seal and a polypropylene flip-off cap.

Thiopental injection is packed in 1, 10, 25 and 50 vials.
Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder
PANPHARMA
Z.I. du Clairay
35133 Luitré
FRANCE

Manufacturer
PANPHARMA
10 rue du Chênot
Parc d'activité du Chênot
56380 Beignon
FRANCE

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This medicine is administered by the intravenous route only. Avoid extravasation or intra-arterial injection. A person qualified in the use of anesthetics should be constant available during the administration of the medicine. 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 medicine 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 this medicine with a visible precipitate should not be administered.

Incompatibilities:
The stability of this medicine solution 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 this medicine solution 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 this medicine solution.

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

Any unused medicine or waste material should be disposed of in accordance with local requirements.