

PACKAGE LEAFLET: INFORMATION FOR THE USER

THIOPENTAL SODIUM 500 mg Powder for Solution for Injection

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

- Please keep this leaflet. You may need to read it again.
- If you have any further questions, ask the 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.

What is in this leaflet:

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

1. WHAT THIOPENTAL INJECTION IS AND WHAT IT IS USED FOR

Thiopental injection contains the active ingredient thiopental sodium (as thiopental sodium and sodium carbonate) which is also known as thiopentone sodium. It is an anaesthetic agent, which may be given:

- as a general anaesthetic or to make you sleepy before using another anaesthetic agent
- before using agents to prevent pain or to relax muscles
- to control fits
- to reduce intracranial pressure.

This injection is usually given to you by a doctor directly into a vein.

2. WHAT YOU NEED TO KNOW BEFORE THIOPENTAL INJECTION IS GIVEN

You MUST NOT be given Thiopental Injection if you:

- are **allergic** to thiopental sodium or have had reactions to thiopental or to other barbiturates (such as some anaesthetics)
- have any **respiratory abnormalities** (including difficulty in breathing), such as an obstruction in your lungs or in the tubes leading to them
- have **acute asthma** (short term asthma)
- are in **severe shock**
- have **myotonic dystrophy** - a muscular disease
- have the condition known as **porphyria** - a metabolic disorder.

If any of these apply to you, tell the doctor or nurse, they will usually decide to use another medicine instead.

Take special care with Thiopental injection

Tell your doctor before you are given thiopental if you have any of the following, as your dose may need to be adjusted:

- **heart disease** or **circulatory problems**, as these can suddenly be made more severe by thiopental
- severe **anaemia**, blood pressure problems (high **blood pressure** or low **blood pressure**), raised **blood potassium**, increased **blood urea**, **bacterial infection** in the blood, **severe bleeding**
- **liver or kidney disease**
- increased **pressure in the brain**
- **muscle weakness** or **degeneration** (such as myasthenia gravis or muscular dystrophies)
- **thyroid gland** problems
- **diabetes**
- **dehydration, malnutrition** or **wasting**
- underproduction of steroid hormones by the **adrenal gland** (even when controlled by cortisone)
- **a metabolic disorder** caused by an underactive thyroid gland (a reduced dose may be required)
- **asthma**
- **burns**
- **shock**
- **hypovolaemia** – a low level of fluids in the body
- are **elderly** (a reduced dose may be required)
- are taking **opioid analgesics** - strong pain relievers.
- are on a **sodium controlled diet**, as this product contains 53.5mg sodium per vial.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- antibiotics (used to treat infections), such as vancomycin, isoniazid and sulphonamides
- sulphafurazole (an antibiotic) - smaller doses of thiopental given more frequently may be required
- antihypertensives (used to treat high blood pressure or heart problems), such as ACE inhibitors, angiotensin-II receptor antagonists, alpha blockers, beta-blockers, calcium antagonists, diuretics, vasodilating anti-hypertensives, alpha adrenergic neurone blockers
- nitrates (used to treat angina)
- antidepressants (used to treat depression), such as monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants
- benzodiazepines, such as midazolam, to treat anxiety
- lithium (used to treat mania, manic depressive illness or depression)
- analgesics (used to treat pain) such as aspirin
- opioid analgesics (strong pain relievers) such as morphine, fentanyl and pethidine
- phenothiazines (used to treat psychosis and nausea) such as promethazine
- drugs that have an effect on the gastrointestinal tract (gut), such as metoclopramide or droperidol
- drugs that have an effect on the central nervous system (CNS)
- cyclizine (used to treat dizziness, nausea and vomiting)
- drugs to treat high blood pressure, such as diazoxide, methyldopa, moxonidine, hydralazine, minoxidil and nitroprusside
- probenecid (used to treat gout and high uric acid in the blood)
- oral anticoagulants (used to thin your blood)
- oestrogens (oral contraceptives or hormone replacement therapy)
- herbal medicines, such as Valerian or St John's Wort.

Thiopental sodium with alcohol

The effect of alcohol may be increased in the period after treatment with thiopental sodium (for at least the first 24 hours).

Pregnancy and breast-feeding

Breast-feeding should be temporarily stopped or breast milk expressed before being given Thiopental injection.

If you are pregnant or breast feeding, think you may be pregnant or are planning to become pregnant, your doctor will consider the risks and benefits of giving Thiopental injection to you.

Driving and using machines

You may experience dizziness (vertigo), disorientation and sedation; these will wear off quite quickly. Do not drive or operate machinery, especially during the first 24 to 36 hours after the injection.

3. HOW THIOPENTAL INJECTION IS GIVEN

This injection is usually given to you directly into a vein by a doctor, but can be given via a drip into a vein.

If thiopental is accidentally injected into an artery instead of a vein, it can cause damage to your tissues. Your doctor should treat these effects (a similar problem can occur if thiopental leaks from the vein into surrounding tissue). If you feel severe pain near where the drug was injected tell the doctor or nurse **immediately** so that treatment can be started quickly.

Dose

The sterile powder is made into a solution and **must not be mixed** with other acidic injections.

This solution should be discarded after 7 hours.

The dosage will be adjusted according to your **age, sex, and weight** as well as your response to the drug.

Anaesthesia:

Adults: 100mg - 150mg, injected over 10 to 15 seconds.

Elderly: as for adults, although smaller doses may be required.

Children: the calculated dose will usually be 2 to 7mg/kg.

You will normally feel the effects within 30 seconds and be asleep within one minute. Further small doses will be given to you as necessary (you will normally be asleep during this process).

Convulsions (fits):

75mg to 125mg, given as soon as possible after the convulsion begins. Further doses may be required and your doctor will decide the best dose to give.

Neurological patients with raised intracranial pressure: Intermittent injections of 1.5 to 3mg/kg.

Reduced doses may be needed if you have:

- liver disease (including jaundice), shock, dehydration, severe anaemia, high blood level of potassium, infection in your blood
- myxoedema (a metabolic disorder caused by an underactive thyroid gland).
- received morphine or similar medicines before you are given thiopental
- received a medicine called sulfafurazole – your doctor may need to give you smaller and more frequent doses of thiopental.

Increased doses may be needed if you:

- are a heavy and frequent drinker of alcohol

- regularly take non-prescribed drugs.

The dose of thiopental may need to be increased or given with another medicine to increase its effect.

If you are given more thiopental than you should

This product will be given to you under medical supervision, it is therefore unlikely that you will be given too much. However, if you feel unwell you should tell your doctor immediately. *Symptoms could be:* rapid shallow breathing or feeling faint or dizzy.

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

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor right away if you notice any of the following symptoms – you may need urgent medical treatment:

Difficulty breathing, wheezing, rash, itching, hives, dizziness, difficulty swallowing, and swelling of the face, lips, tongue or throat, or any other allergic reaction. This could be a severe allergic reaction (frequency not known, cannot be estimated from the available data).

When it is injected, thiopental can cause the following (frequencies not known):

- coughing, sneezing or spasm of the airways; difficulty in breathing
- fall in blood pressure - often seen when thiopental is first given
- drowsiness, nausea with or without vomiting, anorexia (poor appetite), malaise (general sense of unwellness), fatigue, dizziness, headache
- delirium (sudden severe confusion)
- shivering, low body temperature and severely reduced brain function can occur with excessive doses of thiopental.

Other effects include (frequencies not known):

- confusion, amnesia (loss or disruption of memory)
- reduced pumping action of the heart or irregular heartbeats
- low blood pressure or other circulatory effects
- thiopental has been associated with reports of decreased potassium blood levels during infusion and increased potassium blood levels after stopping thiopental infusion.
- tissue damage if the injection leaks into surrounding tissue. **If you experience severe pain at the site of injection, inform your doctor immediately.**

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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.

United Kingdom: Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 6764971, Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie.

5. HOW TO STORE THIOPENTAL INJECTION

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

Before reconstitution:

Do not store above 25°C. Keep in outer carton.

After reconstitution:

This product contains no preservatives and should be used immediately. If the solution is stored, keep it upright and store between 2°C and 8°C. The reconstituted solution must be used within 7 hours. Use once following reconstitution and discard any residue.

Do not use this medicine if you notice that the solution is discoloured.

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 to protect the environment.

6. FURTHER INFORMATION

What Thiopental Injection contains

Each vial contains 500mg of thiopental sodium (as thiopental sodium and sodium carbonate).

What Thiopental injection looks like and contents of the pack

The product is a dry, yellow-white powder contained in a glass vial with a rubber closure. Each vial contains 500mg thiopental sodium (as thiopental sodium and sodium carbonate).

Thiopental injection is packed in 1, 10 or 25 glass vials.

Marketing Authorisation Holder

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