Only for the use of Medical Professionals

Thiopen®

Thiopental Na 500mg and 1g powder for I.V. injection

Description

Thiopen® is a thiobarbiturate, the sulphur analog of pentobarbital.

Thiopen® is an ultra short-acting depressant of the central nervous system which induces hypnosis and anaesthesia, but not analgesia. It produces hypnosis within 30 to 40 seconds of intravenous injection. Recovery after a small dose is rapid, with some somnolence and retrograde amnesia.

Indications

Thiopen® is used for the induction of general anaesthesia or anaesthesia of short duration, reduction of raised intracranial pressure if ventilation; status epilepticus. It is also used for hypnosis and for the control of convulsive states.

Dose and administration

Thiopen® is administered by intravenous route only.

Induction of general anesthesia: (by intravenous injection) usually as a 2.5% (25mg/ml) solution; in fit pre-medicated adults, initially 100-150mg (reduced in elderly or debilitated), followed by further quantity if necessary according to response after 30-60 seconds; or upto 4mg/kg (max. 500mg). Children: induction 2-7mg/kg.

Raised intracranial pressure, by intravenous injection, 1.5-3 mg/kg repeated as required.

Status epilepticus (only if other measure fail), by intravenous injection as a 2.5% (25mg/kg) solution, 75-125mg as a single dose.

For inducing anesthesia, 100-150mg as a 2.5% or occasionally 5% solution is injected over 10 to 15 seconds; if relaxation has not occurred in about 30 seconds a further 100-150mg may be given. Injection should be given with patients in the recumbent position and care should be taken to see none of this solution is injected outside the vein, as it may cause tissue nacrosis. For longer procedures repeated or continuous administration may be used. It may be administered by rectum as a basal anesthetic in a dose of 40mg per kg body weight, with a maximum of 2g dissolved in about 30ml of water for injection.

Preparation:

	%	mg/ml	Diluent
Thiopen 500mg	2.5	25 mg/ml	20 ml
	5.0	50 mg/ml	10 ml
Thiopen 1g	2.5	25 mg/ml	40 ml
	5.0	50 mg/ml	20 ml

Use in pregnancy and lactation

Moderate doses of Thiopen® injection do not usually cause fetal depression when used in pregnancy. Small amounts of Thiopen® may appear in the milk of nursing mothers following administration of large doses.

Precautions

Thiopental sodium for injection should be administered with caution to patients with preexisting hypotension or in conditions where the hypnotic effect may be prolonged or intensified, such as in the presence of liver disease and renal disease.

Thiopen® injection should be used with caution in shock and dehydration, severe anemia, hyperkalaemia, toxaemia, myasthenia gravis, oedema and other metabolic disorders or in severe hepatic and renal disease.

Reduced doses are required in elderly. Difficulty may be experienced in producing anesthesia with the unusual doses in patients accustomed to taking alcohol or some drugs; additional anesthetic agents may be needed. Care should be taken when anesthetizing the patients being treated with phenothiazine neuroleptics since there may be increased hypotension. Reduced doses may be required to patients receiving sulphafurazole.

Warning

Care should be taken in administering Thiopental sodium to patients with advanced cardiac disease, increased intracranial pressure, asthma, myasthenia gravis and endocrine insufficiency (pituitary, thyroid, adrenal, and pancreas).

Side effects

Hypersensitivity reactions to barbituates, including Thiopental sodium have been reported.

Adverse reactions include respiratory depression, myocardial depression, cardiac arrhythmias, prolonged somnolence and recovery, sneezing, coughing, bronchospasm, laryngospasm and shivering. Anaphylactoid reactions to Thiopen® have been reported. Symptoms e.g. urticaria, bronchospasm, vasodilation and oedema should be managed by conventional means.

Rarely immune haemolytic anaemia with renal failure and radial nerve palsy has been reported.

Contraindications

Thiopental sodium for injection is contraindicated in patients with severe respiratory embarrassment, hypersensitivity to barbiturates status asthmaticus, variegate or acute intermittent porphyria, and inflammatory conditions of the mouth, jaw, and neck and in the absence of suitable veins for intravenous administration.

Thiopental sodium for injection is also relatively contraindicated in severe cardiovascular disease, hypotension or shock, and conditions in which the hypnotic effect may be prolonged or potentiated, i.e. excessive premedication, Addison's disease, hepatic or renal dysfunction, myxedema, increased blood urea, severe anemia and myasthenia gravis.

Drug interactions

The following medicine interactions have been reported with Thiopen® and these are Probenecid, Diazoxide, Opoid analgesics, Aminophylline, Midazolam, Sulphisoxazole and Zimelidine.

Pharmaceutical precautions

Thiopen® should be stored below 30°C in a cool dry place and should not freeze. Keep it out of reach of children.

Presentation

Thiopen® is sterile powder of Thiopen Na for infection. It is prepared by dissolving Thiopental Sodium for injection in the requisite amount of water for injection.

Each Thiopen 500 vial contains: Thiopental Sodium Na BP 500mg powder for injection

Each Thiopen 1 vial contains: Thiopental Sodium BP 1g powder for injection

Packaging quantities

Thiopen® 500mg lV dry powder for injection: Each carton contains 1 vial of Thiopen® 500mg powder for injection & 1 ampoule of 10ml water for injection.

Thiopen® 1 g IV dry powder injection: Each carton contains 1 vial of Thiopen® 1gm powder for injection & 2 ampoules of 10ml water for injection.

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