markedly delay recovery.

In **anaesthesia**, the dosage of Thiopentone varies greatly according to the state of the patient and the nature of other drugs being used concurrently (see under Precautions above and Interactions above for further details). Thiopental is usually given intravenously as the sodium salt as a 2.5% solution but a 5% solution is occasionally used. UK licensed product information states that a typical dose for inducing anaesthesia is 100 to 150 mg injected over 10 to 15 seconds, repeated after 30 to 60 seconds according to response. It also recommends that the total dosage used should not exceed 500 mg; in pregnant patients the total maximum dose is 250 mg. In some other countries, it is recommended that induction begin with a test dose of 25 to 75 mg; thereafter, a dose of 50 to 75 mg may be given at intervals of 20 to 40 seconds according to response. Once anaesthesia has been established, additional doses of 25 to 50 mg may be given as necessary. When thiopental is used as the sole anaesthetic, anaesthesia can be maintained by repeat doses as needed or by continuous intravenous infusion of a 0.2 or 0.4% solution.

ADMINISTRATION IN CHILDREN.

For the *induction of anaesthesia* in children, UK licensed product information recommends that thiopentone sodium is given by slow intravenous injection (over 10 to 15 seconds) in a dose of 2 to 7 mg/kg; the dose may be repeated after 1 minute. In the treatment of prolonged *status epilepticus* (see below), the *BNFC* recommends an initial dose of up to 2 mg/kg in neonates or up to 4 mg/kg in children aged 1 month and over, given as a slow intravenous injection; for all patients, this should then be followed by a continuous intravenous infusion of up to 8 mg/kg per hour, adjusted according to response. Intravenous injections are normally given as a 2.5% solution; the *BNFC* recommends that intravenous infusions are given as a 0.25% solution.

PREPARING THE SOLUTION FOR INJECTION:

For the 5% solution for injection, the contents of one Thiopental Sodium for Injection IP 500 mg vial are dissolved in 10 ml water for injection IP or 0.9% sodium chloride solution IP.

Any solution of this medicine with a visible precipitate should not be administered. The solutions are used immediately after preparation. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

PREGNANCY

There is only a limited amount of data from the use of thiopentone in pregnant women. Studies in animals have shown reproductive toxicity. In an epidemiological study in man (exposure during the first four weeks of pregnancy), no teratogenic effects could be detected. New-born babies, whose mothers had been exposed to Thiopentone, showed signs and symptoms of withdrawal. Thiopental crosses the placental barrier. Therefore, a general anaesthesia with Thiopental should be in pregnant women only if clearly indicated and after a careful risk-benefit assessment. When given during labour, new-borns should be observed for a depressive effect on breathing.

BREAST FEEDING

Thiopentone sodium for injection IP is excreted in the breast milk. The concentrations in the blood of nursing infants may be higher than in the mother because of the immature metabolic function. Thiopental is detected in the breast milk up to 36 hours after the injection. During this time period, breastfeeding should be avoided.

OVERDOSAGE

The typical symptom of an overdose is a rapid drop in blood pressure, which can lead to shock. Pulmonary oedema may develop as a result of an insufficient pump function of the heart. A drop in blood pressure may also be the result of allergic reaction; but it is usually occurring in combination with allergic skin reactions.

Overdose may cause persistent respiratory insufficiency or respiratory arrest, which may be life threatening after cessation of artificial respiration. There is a rapid drop in body temperature. Treatment is symptomatic and should be performed under intensive-care conditions: To maintain respiratory function, aspiration of the respiratory tract, intubation and patient ventilation are generally required. Infusion therapy with plasma volume expanders is indicated as a measure against the drop in blood pressure and for shock prophylaxis. Dopamine (2 to 5 µg/kg/min) or norepinephrine (noradrenaline 0.1 to 0.2 µg/kg/min) may be added on the direction of physician to the solution for infusion. Body temperature must be normalised.

Storage: - **Store below 30 °C protect from light.**

Improper Storage may deteriorate the product

Medicine: - **Keep out of reach of children.**

Dosage: - As directed by the Anaesthesiologist

Presentation: - Each pack contain Thiopentone for Injection IP 500 mg in a 20 ml clear glass vial & 10 vial in a outer.

Manufactured by:
AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA
Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhiwandi, Mumbai - 421302
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For the use only of a Registered Medical Practitioner or a hospital or a laboratory

℞ Thiopentone for Injection IP

AMERICAN **Thiopton** Injection **500 mg**

FOR SLOW IV USE ONLY

Composition:-

Each Vial Contains:-

Thiopentone Sodium IP (Sterile) 500 mg

DESCRIPTION

Thiopentone for injection IP is a thiobarbiturate, the sulfur analogue of sodium pentobarbital. The drug is prepared as a sterile powder and after reconstitution with an appropriate diluent, is administered by the intravenous route.

PHARMACOLOGY

PHARMACOKINETICS

Thiopentone is highly lipid soluble and when it is given intravenously as the sodium salt; concentrations sufficient to produce unconsciousness are achieved in the brain within 30 seconds. Onset of action occurs within 8 to 10 minutes when Thiopentone sodium is given rectally but absorption may be unpredictable if a suspension rather than a solution is used. Recovery from anaesthesia is also rapid due to redistribution to other tissues, particularly fat. About 80% of Thiopentone may be bound to plasma proteins, although reports show a wide range of figures. Thiopental is metabolised almost entirely in the liver, but as it is only released slowly from lipid stores this occurs at a very slow rate. It is mostly metabolised to inactive metabolites but a small amount is desulfurated to pentobarbital. Repeated or continuous use can lead to accumulation of thiopental in fatty tissue and this can result in prolonged anaesthesia and respiratory and cardiovascular depression. Elimination of thiopental after bolus injection can be described by a triexponential curve. The terminal elimination half-life has been reported to be 10 to 12 hours in adults and about 6 hours in children. However, values of 26 to 28 hours have been reported in obese patients and pregnant patients at term. Thiopental readily diffuses across the placenta and is distributed into breast milk.

ADVERSE REACTIONS

Excitatory phenomena such as **coughing, hiccuping, sneezing**, and **muscle twitching or jerking may** occur with any of the barbiturate anaesthetics, particularly during induction, but they occur more frequently with methohexital than with thiopental. Cough, sneezing, and laryngeal spasm or bronchospasm may also occur during induction. The intravenous injection of concentrated solutions of thiopental sodium such as 5% may result in thrombophlebitis. Extravasation of barbiturate anaesthetics may cause tissue necrosis. Intra-arterial injection causes severe arterial spasm with burning pain and may cause prolonged blanching of the forearm and hand and gangrene of digits. Hypersensitivity reactions have been reported. Barbiturate anaesthetics can cause respiratory depression. They depress cardiac output and often cause an initial fall in blood pressure, and over dosage may result in circulatory failure. Arrhythmias may occur. Postoperative vomiting is infrequent but shivering may occur and there may be persistent drowsiness, confusion, and amnesia. Headache has also been reported.

WARNINGS

Keep resuscitative and endotracheal in tubation equipment and oxygen readily available. Maintain patency of the airway at all times.

This drug should be administered only by persons qualified in the use of intravenous anaesthetics.

INTERACTIONS

Difficulty may be experienced in producing anaesthesia with the usual dose of barbiturate anaesthetics in patients accustomed to taking alcohol or other CNS depressants; additional anaesthetics may be necessary.

Patients being treated with phenothiazine antipsychotics may experience increased hypotension. Some phenothiazines, especially promethazine, may also increase the incidence of excitatory phenomena produced by barbiturate anaesthetics; cyclizine may possibly have a similar effect. Opioid analgesics can potentiate the respiratory depressant effect of barbiturate anaesthetics and the dose of the anaesthesia. Reduced doses of thiopental may be required in patients receivingsulfafurazole.

USES AND ADMINISTRATION

Thiopentone is a short-acting barbiturate anaesthetic. It is given intravenously, usually for the induction of general anaesthesia, but may be used as the sole anaesthetic to maintain anaesthesia for short procedures with minimal painful stimuli. It is also used in anaesthesia as a supplement to other anaesthetics and as a hypnotic in balanced anaesthesia. Thiopental sodium may also be used intravenously in the control of refractory tonic-clonic status epilepticus and in neurosurgical patients to reduce increased in tracranial pressure. It has also been given rectally for basal anaesthesia or basal narcosis.

Thiopentone does not usually produce excitation and induction of anaesthesia is usually smooth. It has poor muscle relaxant properties and a muscle relaxant must be given before in tubation is attempted. Thiopental also has poor analgesic properties and small doses may even lower the pain threshold. Recovery from moderate doses usually occurs within 10 to 30 minutes, but the patient may remain sleepy or confused for several hours. Large doses, repeated smaller doses, or continuous use may