THIOPENTAL INJECTION BP

Presentation: Vials of Thiopental Sodium BP

It is supplied in vials of 0.5 g for extemporaneous preparation of 2.5 % solutions, and in vials of 1.0 g for extemporaneous preparation of 5.0 % solution.

Uses: Administered intravenously THIOPENTAL INJECTION BP produces general anaesthesia of short duration. THIOPENTAL INJECTION BP is indicated for the induction of general anaesthesia; for general anaesthesia of short duration with or without the addition of a muscle relaxant; for the control of convulsive states. It is administered rectally for the induction of basal anaesthesia.

Other information: Although bound to plasma proteins it rapidly crosses the bloodbrain barrier and reaches maximum concentration in the brain within 30 seconds of injection. It is slowly metabolised by the liver. Only a small proportion of the active drug is excreted in the urine.

Dosage and administration: THIOPENTAL INJECTION BP is administrated usually as a 2.5 % solution, but a 5 % solution is sometimes used. A 2.5 % solution is advised for all elderly and bad-risk patients. The injection may be given through any superficial vein.

Definite dosage cannot be stated for every case. The response of each patient must be observed and the dose regulated according to the onset of unconsciousness.
Fractional administration is advised rather than the single-dose method, as this gives close control and greater flexibility of the anaesthetic and helps to prevent overdosage.

Most patients will require not more than 0.5 g otherwise recovery will be prolonged and possibly complicated. The patient should in all cases be pre-medicated with atropine and if necessary with an analgesic or tranquiliser, although the latter will increase the recovery time. If chlorpromazine or promethazine are used for premedication the amount of THIOPENTAL INJECTION BP required for induction should be reduced.

Solutions are prepared by adding Water for Injections (BP).

For induction: Inject 2 - 3 ml of the 5 % solution or twice this volume of the 2.5 % solution in 10 - 15 seconds, then pause for 30 seconds to 1 minute to observe the effect of the drug, depending on the state of the patient's circulation. Usually there is loss of consciousness and some relaxation. A further quantity of the solution may then be given if indicated, otherwise anaesthesia should be maintained by an appropriate inhalation agent.

For minor operations: Induction is as described above with additional quantities of the anaesthetic solution being given as required to maintain anaesthesia at a level adequate to obtain pain reflexes. The level of anaesthesia is best judged by the depth of respiration; surgical anaesthesia is usually present when respiration is depressed. It cannot be too strongly emphasised that the airway must be kept open with the patient breathing an adequate concentration of oxygen. In these circumstances the depressed respiration is not dangerous and the patient should remain a good colour with the skin warm and dry.

Intravenous anaesthesia is not recommended for the maintenance of unconsciousness in lengthy procedures, so that for these, after induction, it should always be supplemented by the chosen inhalation agent.

Children: THIOPENTAL INJECTION BP is suitable for use in children as well as adults. The dosage is 2 - 7 mg/kg intravenously.

Contra-indications, warnings, etc.:

Use in pregnancy: There is epidemiological and clinical evidence of the safety of barbiturates in pregnancy including thiopental. This drug readily crosses the placenta and appears in human milk. Dosage in the pregnant female should not exceed 250 mg.

Contra-indications: A history of acute intermittent porphyria is an absolute contraindication to any barbiturate. Special care is required in patients with the following conditions: hypovolaemia; severe haemorrhage; burns; dehydration; severe anaemia; cardiovascular disease; status asthmaticus; severe liver disease; myasthenia gravis and muscular dystrophies; adrenocortical insufficiency even when controlled by cortisone; cachexia and severe toxaemia; raised intracranial pressure; raised blood urea; raised plasma potassium; metabolic disorders, e.g. thyrotoxicosis, myxoedema, diabetes.

Precautions: Reduced doses are required in the elderly and in patients heavily premedicated with narcotics and other central depressants. On the other hand, those addicted to drugs are difficult subject to anaesthetise with normal thiopental dosage and it is advised that supplementary analgesic agents and relaxants be given as necessary.

The jaw drops rapidly after starting the injection and must be supported, since it is imperative to keep the airway open. The patient should always be in an recumbent position to avoid cerebral ischaemia.

If THIOPENTAL INJECTION BP is used in dental work a mouth prop is inserted before injection is commenced. The throat must be properly packed to prevent access of blood, etc. to the larynx and the dose employed should not exceed 0.25 g otherwise recovery will be delayed. Facilities for intubation and administration of oxygen under positive pressure must always be available.

To prevent accidental intra-arterial injection the site of administration must be palpated carefully and after insertion of the needle a little blood should be drawn into the syringe to observe its colour. Intra-arterial injection produces severe arterial spasm with intense burning pain in the hand and fingers. The patient can sometimes warn the anaesthetist of this before loosing consciousness. In the event of such accident, inject procaine hydrochloride directly into the artery and perform a stellate ganglion block. Early anticoagulant therapy is advisable.

Adverse effects: Coughing, sneezing or laryngeal spasm may occur during induction. Extravasation causes pain and possible tissue necrosis. Thrombophlebitis may result from the use of 5% solution. Skin rashes, fever, arthralgia and weakness are rare side-affects. Allergic reactions and hypersensitivity have been documented.

Toxicity and treatment of overdosage: Respiratory depression during thiopental anaesthesia must be treated by artificial ventilation with oxygen, as should cardiac arrythmia associated with anoxia or hypercarbia. A fall in blood pressure is often noted initially, while overdose may lead to circulatory failure.

Apnoea or serious respiratory depression must be treated by controlled respiration with oxygen. Cardiovascular collapse requires immediate lowering of the head of the table; if the blood pressure falls to rise a pressor agent such as mephentermine or a plasma expander should be given. If the heart stops immediate massage should be given.

Pharmaceutical precautions: Aqueous solutions of thiopental sodium are strongly alkaline; a 2.5 % solution has a pH about 10.5. The solution is incompatible with acids, acidic salts and oxidising agents. Solutions decompose on standing giving cloudiness, precipitation or crystallisation; any such solution must not be used.

Solutions should be freshly prepared and used immediately. Any portion of the contents remaining should be discarded.

Store below 25 °C.

Date of issue: January 2000

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TAC3P200-11