

For the use of Registered Medical Practitioner or Hospital use or Laboratory use only

Diprivan® Injection 1%

Composition: Each ml contains propofol 10 mg, soyabean oil, purified egg phosphatide, glycerol, disodium edetate, sodium hydroxide.

Description: Propofol (2, 6-diisopropylphenol) is a short-acting general anaesthetic agent with a rapid onset of action of approximately 30 seconds. In general, falls in mean arterial blood pressure and slight changes in heart rate are observed when propofol is administered for induction and maintenance of anaesthesia. However, the haemodynamic parameters normally remain relatively stable during maintenance. Propofol reduces cerebral blood flow, intracranial pressure and cerebral metabolism. The reduction in intracranial pressure is greater in patients with an elevated baseline intracranial pressure. Recovery from anaesthesia is usually rapid and clear headed with a low incidence of headache and post-operative nausea and vomiting.

Indications: Propofol is a short-acting intravenous anaesthetic agent suitable for induction and maintenance of general anaesthesia, sedation of ventilated adult patients receiving intensive care and for conscious sedation for surgical and diagnostic procedures.

Contraindications: Patients with a known allergy to propofol. For the sedation of children under the age of 3 years with serious viral respiratory tract infections receiving intensive care. For the sedation of children of all ages with croup or epiglottitis receiving intensive care.

Warnings and precautions: Propofol should be given by those trained in anaesthesia (or, where appropriate, doctors trained in the care of patients in Intensive Care). Propofol lacks vagolytic activity and has been associated with reports of bradycardia (occasionally profound) and also asystole. When Propofol is administered to an epileptic patient, there may be a risk of convulsion. Appropriate care should be applied in patients with disorders of fat metabolism and in other conditions where lipid emulsions must be used cautiously. It is recommended that blood lipid levels should be monitored if propofol is administered to patients thought to be at particular risk of fat overload. Propofol should not be used in pregnancy as it crosses the placenta and may be associated with neonatal depression. It should not be used for obstetric anaesthesia.

Adverse effects: During induction of anaesthesia, hypotension and transient apnoea may occur depending on the dose and use of premedicants and other agents. During the recovery phase, nausea, vomiting and headache occur in only a small proportion of patients. Epileptiform movements, including convulsions and opisthotonus, have been reported rarely during induction, maintenance and recovery. Rarely, clinical features of anaphylaxis, which may include angioedema bronchospasm, erythema and hypotension, occur following Propofol administration.

Dosage and administration: *Induction of General Anaesthesia:* 1.5 to 2.5 mg/kg of propofol. In patients of ASA Grades 3 and 4, lower rates of administration should be used (approximately 20 mg every 10 seconds). *Maintenance of general anaesthesia:* Continuous Infusion: The required rate of administration varies in the region of 4 to 12 mg/kg/h usually to maintain satisfactory anaesthesia. Repeat Bolus Injections: Increments of 25 mg to 50 mg may be given according to clinical need. *Sedation during intensive care:* The infusion rate in the region of 0.3 to 4.0 mg/kg/h should achieve satisfactory sedation. *Conscious sedation for surgical and diagnostic procedures:* 0.5 to 1 mg/kg over 1 to 5 minutes to initiate sedation. For maintenance most patients will require 1.5 to 4.5 mg/kg/h. In addition to the infusion, bolus administration of 10 to 20 mg may be used if a rapid increase in the depth of sedation is required. In patients in ASA grades 3 and 4 the rate of administration and dosage may need to be reduced.

Presentation: DIPRIVAN® Injection, 1% glass ampoules (20ml) (box of 5)

For further information please contact:

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