℞ MCT-PROFOL™

PROPOFOL WITH MCT-LCT IP 1%

20 ml/50 ml

Abridged Prescribing Information:

MCT-PROFOL™

Presentation: Each mL contains:Propofol Ph. Eur 10 mg, Soyabean refined oil Ph. Eur 50 mg , Medium chain triglycerides Ph. Eur 50 mg , Egg lecithin IH 12 mg , Glycerin Ph. Eur 22.5 mg , Sodium oleate IH 0.40 mg , Water for Injection Ph. Eur q.s. to 1 mL, Excipient(s) with known effect, Soyabean refined oil Ph. Eur Dosage and administration: supplementary analgesic agents are generally required in addition to Propofol 1%. Propofol 1% can be used for infusion undiluted from glass containers or diluted with 5% Dextrose (Intravenous Infusion BP) only. Dilutions, which must not exceed 1 in 5 (2 mg propofol per mL) should be prepared aseptically immediately before administration and must be used within 6 hours of preparation.It is recommended that, when using diluted Propofol 1%, the volume of 5% Dextrose removed from the infusion bag during the dilution process is totally replaced in volume by Propofol 1% emulsion.The dilution may be used with a variety of infusion control techniques, but a giving set used alone will not avoid the risk of accidental uncontrolled infusion of large volumes of diluted Propofol 1%. A burette, drop counter or volumetric pump must be included in the infusion line. The risk of uncontrolled infusion must be taken into account when deciding the maximum amount of Propofol 1% in the burette.When Propofol 1% is used undiluted to maintain anaesthesia, it is recommended that equipment such as syringe pumps or volumetric infusion pumps should always be used to control infusion rates. Propofol 1% may be administered via a Y-piece close to the injection site into infusions of the following: Dextrose 5% Intravenous Infusion B.P. Sodium Chloride 0.9% Intravenous Infusion B.P. Dextrose 4% with Sodium Chloride 0.18% Intravenous Infusion B.P. Mix 20 parts of Propofol 1% with up to 1 part of either 0.5% or 1% lidocaine hydrochloride injection. Induction and Maintenance of General Anaesthesia. Adult: an initial target of 4 microgram/mL is recommended in premedicated patients and in unpremedicated patients an initial target of 6 microgram/mL is advised. Induction time with these targets is generally within the range of 60–120 seconds. Higher targets will allow more rapid induction of anaesthesia but may be associated with more pronounced haemodynamic and respiratory depression. A lower initial target concentration should be used in patients over the age of about 55 years and in patients of ASA grades 3 and 4. The target concentration can then be increased in steps of 0.5–1.0 microgram/mL at intervals of 1 minute to achieve a gradual induction of anaesthesia. Supplementary analgesia will generally be required and the extent to which target concentrations for maintenance of anaesthesia can be reduced will be influenced by the amount of concomitant analgesia administered. Target propofol concentrations in the region of 3–6 microgram/mL usually maintain satisfactory anaesthesia. The predicted propofol concentration on waking is generally in the region of 1.0–2.0 microgram/mL and will be influenced by the amount of analgesia given during maintenance. Contraindications: Hypersensitivity to the active substance or to any of the excipients (Soyabean refined oil Ph. Eur, Medium chain triglycerides Ph. Eur, Egg lecithin IH, Glycerin Ph. Eur, Sodium oleate IH, Water for Injection Ph. Eur). Should not be used in patients who are hypersensitive to peanut or soya. Should not be used in patients of 16 years of age or younger for sedation in Intensive care. Warnings & precautions: Patients should be constantly monitored and facilities for maintenance of a patient airway, artificial ventilation, oxygen enrichment and other resuscitative facilities should be readily available at all times. Propofol 1% should not be administered by the person conducting the diagnostic or surgical procedure. As with other general anaesthetics, the administration of Propofol 1% without airway care may result in fatal respiratory complications. When Propofol 1% is administered for consclous sedation, for surgical and diagnostic procedures, patients should be continually monitored for early signs of hypotension, airway obstruction and oxygen desaturation. As with other sedative agents, when Propofol 1% is used for sedation during operative procedures, involuntary patient movements may occur. During procedures requiring immobility these movements may be hazardous to the operative site. An adequate period is needed prior to discharge of the patient to ensure full recovery after use of Propofol 1%. Very rarely the use of Propofol 1% may be associated with the development of a period of postoperative unconsciousness, which may be accompanied by an increase in muscle tone. This may or may not be preceded by a period of wakefulness. Although recovery is spontaneous, appropriate care of an unconscious patient should be administered. Propofol 1% induced impairment is not generally detectable beyond 12 hours. The effects of Propofol 1%, the procedure, concomitant medications, the age and the condition of the patient should be considered when advising patients on: The advisability of being accompanied on leaving the place of administration. The timing of recommencement of skilled or hazardous tasks such as driving. The use of other agents that may sedate (Eg. benzodiazepines, opiates, alcohol.) As with other intravenous anaesthetic agents, caution should be applied in patients with cardiac, respiratory, renal or hepatic impairment or in hypovolaemic or debilitated patients. Propofol 1% clearance is blood flow dependent, therefore, concomitant medication that reduces cardiac output will also reduce Propofol 1% clearance. Propofol 1% lacks vagolytic activity and has been associated with reports of bradycardia (occasionally profound) and also asystole. The intravenous administration of an anticholinergic agent before induction, or during maintenance of anaesthesia should be considered, especially in situations where vagal tone is likely to predominate, or when Propofol 1% is used in conjunction with other agents likely to cause a bradycardia. As with other intravenous anaesthetic and sedative agents, patients should be instructed to avoid alcohol before and for at least 8 hours after administration of Propofol 1%. During bolus administration for operative procedures, extreme caution should be exercised in patients with acute pulmonary insufficiency or respiratory depression. Concomitant use of central nervous system depressants e.g., alcohol, general anaesthetics, narcotic analgesics will result in accentuation of their sedative effects. When Propofol 1% is combined with centrally depressant drugs administered parenterally, severe respiratory and cardiovascular depression may occur. It is recommended that Propofol 1% is administered following the analgesic and the dose should be carefully titrated to the patient's response. During induction of anaesthesia, hypotension and transient apnoea may occur depending on the dose and use of premedicants and other agents. Occasionally, hypotension may require use of intravenous fluids and reduction of the rate of administration of Propofol 1% during the period of anaesthetic maintenance. When Propofol 1% 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. Use is not recommended with electroconvulsive treatment. As with other anaesthetics, sexual disinhibition may occur during recovery. The benefits and risks of the proposed procedure should be considered prior to proceeding with repeated or prolonged use (>3 hours) of propofol in young children (<3 years) and in pregnant women. Paediatric population The use of Propofol is not recommended in newborn infants. Propofol must not be used in patients of 16 years of age or younger for sedation for intensive care. Advisory statements concerning Intensive Care Unit management Use of propofol emulsion infusions for ICU sedation has been associated with a constellation of metabolic derangements and organ system failures that may result in death. Reports have been received of combinations of the following: Metabolic acidosis, Rhabdomyolysis, Hyperkalaemia, Hepatomegaly, Renal failure, Hyperlipidaemia, Cardiac arrhythmia, Brugada-type ECG (elevated ST-segment and coved T-wave) and rapidly progressive Cardiac failure usually unresponsive to inotropic supportive treatment. Combinations of these events have been referred to as the Propofol Infusion Syndrome. These events were mostly seen in patients with serious head injuries and children with respiratory tract infections who received dosages in excess of those advised in adults for sedation in the intensive care unit. The following appear to be the major risk factors for the development of these events: decreased oxygen delivery to tissues; serious neurological injury and/or sepsis; high dosages of one or more of the following pharmacological agents - vasoconstrictors, steroids, inotropes and/or Propofol 1% (usually at dose rates greater than 4mg/kg/h for more than 48 hours). Prescribers should be alert to these events in patients with the above risk factors and immediately discontinue propofol - when the above signs develop. All sedative and therapeutic agents used in the intensive care unit (ICU), should be titrated to maintain optimal oxygen delivery and haemodynamic parameters. Patients with raised intra-cranial pressure (ICP) should be given appropriate treatment to support the cerebral perfusion pressure during these treatment modifications. Treating physicians are reminded if possible not to exceed the dosage of 4 mg/kg/h. 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. Administration of propofol should be adjusted appropriately if the monitoring indicates that fat is being inadequately cleared from the body. If the patient is receiving other intravenous lipid concurrently, a reduction in quantity should be made in order to take account of the amount of lipid infused. Additional Precautions Caution should be taken when treating patients with mitochondrial disease. These patients may be susceptible to exacerbations of their disorder when undergoing anaesthesia, surgery and ICU care. Maintenance of normothermia, provision of carbohydrates and good hydration are recommended for such patients. The early presentations of mitochondrial disease exacerbation and of the 'propofol infusion syndrome' may be similar. The need for supplemental zinc should be considered during prolonged administration of Propofol 1%, particularly in patients who are predisposed to zinc deficiency, such as those with burns, diarrhoea and/or major sepsis. When Propofol 1% is to be aspirated, it must be drawn aseptically into a sterile syringe or giving set immediately after breaking the vial seal. Administration must commence without delay. Asepsis must be maintained for both Propofol 1% and infusion equipment throughout the infusion period. Any infusion fluids added to the Propofol 1% line must be administered close to the cannula site. Propofol 1% must not be administered via a microbiological filter. A single infusion of propofol must not exceed 12 hours. At the end of the procedure or at 12 hours, whichever is the sooner, both the reservoir of propofol and the infusion line must be discarded and replaced as appropriate. Pregnancy Propofol 1% should not be given to pregnant women except when absolutely necessary. Propofol 1% can, however, be used during an induced abortion. Obstetrics Propofol 1% crosses the placenta and can cause neonatal depression. It should not be used for obstetric anaesthesia unless clearly necessary. Breast-feeding: Women should not breast-feed for 24 hours after administration of Propofol 1%. Milk produced during this period should be discarded. Symptoms and treatment of overdosage: Accidental overdosage is likely to cause cardiorespiratory depression. Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression would require lowering of the patient's head and, if severe, use of plasma expanders and pressor agents. Drug Interaction: Propofol 1% has been used in association with spinal and epidural anaesthesia and with commonly used premedicants, neuromuscular blocking drugs, inhalational agents and analgesic agents. Lower doses of Propofol 1% may be required where general anaesthesia is used as an adjunct to regional anaesthetic techniques. Profound hypotension has been reported following anaesthetic with propofol in patients treated with rifampicin. The concurrent administration of other CNS depressants such as pre-medication drugs, inhalation agents, analgesic agents may add to the sedative, anaesthetic and cardiorespiratory depressant effects of Propofol 1%. Aneed for lower propofol doses has been observed in patients taking valproate. When used concomitantly, a dose reduction of propofol may be considered. Storage: Store below 30°C. Do not freeze. Keep out of the reach and sight of children. Amneal Healthcare Private Limited Gujarat, INDIA.

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