Pr **Diprivan® 1%**
propofol

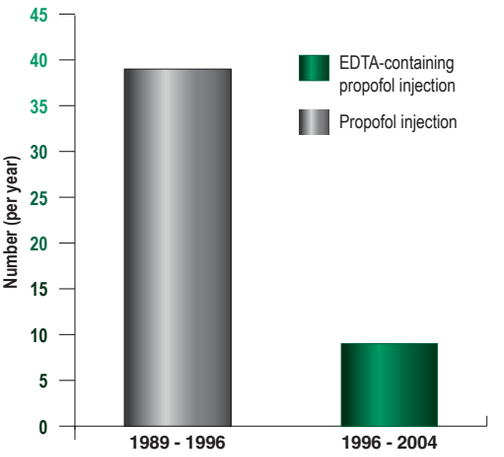
The original and only propofol with EDTA[1*]

Microbial contamination of anaesthetic agents has been identified as one of the risk factors for healthcare-associated infection [2,3]

The propofol with EDTA antimicrobial formulation effectively reduces post-operative infection rate following propofol use [2]

The number of reported cases of post-operative infections and fever following propofol use (average per year) [2]

from
39 to **9**
cases per year [2]



Between 1989 and 1996 in the US, before the propofol with EDTA formulation was introduced, the annual incidence of propofol-related infection and fever cases was an average of 39 cases per year [2]

The annual incidence of infection and fever were greatly reduced from 1996 to 2004 following the introduction of the propofol EDTA antimicrobial formulation to an average incidence of only 9 cases per year [2]

*As an antimicrobial ion chelator, disodium ethylenediaminetetraacetate (EDTA) causes a loss of control of osmotic pressure gradients in microbial cells, resulting in the rupture of the cell membrane.[3] Clinical trials have demonstrated antimicrobial efficacy and safety in human subjects. [2,3] The propofol with EDTA (disodium ethylenediaminetetraacetate) antimicrobial formulation effectively reduces the post-operative infection rate following propofol use. [2]

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The original propofol with EDTA formulation can help you to reduce the risk of microbial contamination.[2]

Diprivan® 1%
propofol

The propofol with EDTA antimicrobial formulation effectively reduces post-operative infection rate following propofol use[2]

Indications and clinical use:
Adults (>18 years of age): DIPRIVAN® 1% (propofol) is indicated for:
- Induction and maintenance of general anaesthesia
- Conscious sedation for surgical and diagnostic procedures
- Sedation during intensive care

DIPRIVAN® 1% is a short-acting intravenous (i.v.) general anaesthetic agent, that can be used for both induction and maintenance of anaesthesia as part of a balanced anaesthesia technique, including total i.v. anaesthesia (TIVA), for inpatient and outpatient surgery. DIPRIVAN® 1%, when administered i.v. as directed, can be used to initiate and maintain sedation in conjunction with local/ regional anaesthesia in adult patients undergoing surgical procedures. DIPRIVAN® 1% may also be used for sedation during diagnostic procedures in adults. DIPRIVAN® 1% should only be administered to intubated, mechanically ventilated, adult patients in the Intensive Care Unit (ICU) to provide continuous sedation and control of stress responses. In this setting, DIPRIVAN® 1% should be administered only by or under the supervision of persons trained in general anaesthesia or critical care medicine.
Pediatrics (≥ 3 years of age): DIPRIVAN® 1% is only indicated for anaesthesia in children 3 years of age and older.
Pediatrics (≤ 18 years of age): DIPRIVAN® 1% is not recommended for sedation or during surgical/diagnostic procedures in children under the age of 18, as safety and efficacy have not been established ihn this patient population.
Geriatrics (> 65 years of age): Elderly patients should be given reduced doses of propofol, commensurate with their age and physical condition.

Contraindications:
DIPRIVAN® 1%(propofol) is contraindicated:
- In patients who are hypersensitive or allergic to this drug, lipid emulsions or to any other ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- for the sedation of children 18 years or younger receiving intensive care
- when sedation or general anaesthesia are contraindicated

Most serious warnings and precautions:
Administration: Strict aseptic techniques must always be maintained during handling as DIPRIVAN® 1% is a single-use parenteral product, for use in an individual patient, and contains no antimicrobial preservatives. The vehicle is capable of supporting rapid growth of microorganism. Failure to follow aseptic handling procedures may result in microbial contamination causing fever/ infection/sepsis, which could lead to life-threatening illness. For general anaesthesia or sedation for surgical/diagnostic procedures, DIPRIVAN® 1% should be administered only by persons trained in the administration of general anaesthesia and not involved in the conduct of surgical/diagnostic procedures. Patients should be continuously monitored and facilities for maintenance of a patent airway, artificial ventilation, and oxygen enrichment and circulatory resuscitation must be immediately available. For sedation of intubated, mechanically ventilated, adult patients in the ICU, DIPRIVAN® 1% should be administered only by persons trained in general anaesthesia or critical care medicine. As with other general anaesthetics, the administration of DIPRIVAN® 1% without airway care may result in fatal respiratory complications. Extreme care should be used in administering DIPRIVAN® 1% in elderly, debilitated or other ASA III or IV patients. In the elderly, debilitated and ASA III or IV patients, rapid (single or repeated) bolus administration should not be used during general anaesthesia or sedation in order to minimize undesirable cardiorespiratory depression including hypotension, apnea, airway obstruction and/or oxygen desaturation

Propofol Infusion Syndrome (PRIS): Use of DIPRIVAN® 1% Injectable Emulsion infusions for both adult and pediatric ICU sedation has been associated with a constellation of metabolic derangements and organ system failures, referred to as Propofol Infusion Syndrome, that have resulted in death. The syndrome is characterized by severe metabolic acidosis, hyperkalaemia, lipemia, rhabdomyolysis, hepatomegaly, cardiac and renal failure. The syndrome is most often associated with prolonged, high-dose infusions (> 5 mg/kg/h for > 48h) but has also been reported following large-dose, short-term infusions during surgical anaesthesia. 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.

Other relevant warnings and precautions:
General: Extreme care should be used in administering DIPRIVAN® 1% in patients with impaired left ventricular function or who are hypotensive, hypovolemic or in shock. DIPRIVAN® 1% lacks vagolytic activity and has been associated with reports of bradycardia, and asystole. DIPRIVAN® 1% should not be co-administered through the same i.v. catheter with blood or plasma and the neuromuscular blocking agents, atracurium and mivacurium should not be given through the same i.v. line as DIPRIVAN® 1% without prior flushing. The administration of DIPRIVAN® 1% should be initiated as a continuous infusion and changes in the rate of administration made slowly (>5 min) in order to minimize hypotension and avoid acute overdosage. Since DIPRIVAN® 1% is formulated in an oil-water emulsion, patients should be monitored for lipemia. Administration of DIPRIVAN® 1% should be adjusted if fat is being inadequately cleared from the body. A reduction in the quantity of concurrently administered lipids is indicated to compensate for the amount of lipid infused as part of the DIPRIVAN® 1% formulation; 1.0 mL of DIPRIVAN® 1% contains approximately 0.1 g of fat (1.1 kcal).In adults and children, attention should be paid to minimize pain on administration of propofol. Transient local pain during i.v. injection may be reduced by prior injection of i.v. lidocaine (1.0 mL of a 1% solution).
Cardiovascular: significant hypotension and/or cardiovascular depression, during cardiac anaesthesia slower rates of administration should be utilized in premedicated patients, geriatric patients, patients with recent fluid shift, or patients who are hemodynamically unstable.
Other: Patients receiving DIPRIVAN® 1% should not drive or operate heavy machinery, it should not be used for ICU sedation in patients who have severe lipidemia or severely disordered fat metabolism, and should be given with caution in conditions of impaired lipid metabolism as in renal insufficiency, uncompensated diabetes mellitus, pancreatitis, impaired liver function, hypothyroidism (if hypertriglyceridemic) and sepsis. The need for supplemental zinc should be considered during prolonged administration of DIPRIVAN® 1%, particularly in patients who are predisposed to zinc deficiency, such as those with burns, diarrhoea and/or major sepsis. The use of DIPRIVAN® 1% has been associated with both fatal and life threatening anaphylactic and anaphylactoid reactions. When using DIPRIVAN® 1% in patients with increased intracranial pressure (ICP) or impaired cerebral circulation, significant decreases in mean arterial pressure should be avoided because of the resultant decreases in cerebral perfusion pressure. Care should be taken when administering DIPRIVAN® 1% to patients with hepatic insufficiency, epilepsy, patients undergoing surgery, patients with renal failure, and special populations. DIPRIVAN® 1% should not be used during pregnancy unless absolutely necessary and should not be used in obstetrics including Caesarean section deliveries. DIPRIVAN® 1% is not recommended for use in breast-feeding women, in children less than 3 years of age, and for sedation or during surgical/diagnostic procedures in children under the age of 18. The dosage of DIPRIVAN® 1% should be reduced in elderly patients.

For more information:
Please consult the Product Monograph at www.aspenpharma.ca/download/1502/ for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling Aspen Medical Information at 1-844-330-1213.

1. Government of Canada, H. (2019, March 19). Search results summary. Retrieved September 14, 2020, from https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
2. Jansson JR, Fukada T, Ozaki M, Kimura S. Propofol EDTA and reduced incidence of infection. Anaesth Intensive Care. 2006;34:362–368. *3. Zorrilla-Vaca A, Arevalo JJ, Escandón-Vargas K, et al. Infectious Disease Risk Associated with Contaminated Propofol Anesthesia, 1989–2014(1). Emerg Infect Dis. 2016;22(6):981–992.* *4. DIPRIVAN® 1% Product Monograph. Aspen Pharmacare Canada. May 29, 2019.*

0620641012547 DIPRIVAN® 1% propofol injection (10 mg/mL) 20 mL
0620641010796 DIPRIVAN® 1% propofol injection (10 mg/mL) 50 mL
0620641010802 DIPRIVAN® 1% propofol injection (10 mg/mL) 100 mL

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