NAME OF THE MEDICINAL PRODUCT

Propofol-Lipuro 5 mg/ml emulsion for injection or infusion
Propofol-Lipuro 10 mg/ml emulsion for injection or infusion
Propofol-Lipuro 20 mg/ml emulsion for injection or infusion

COMPOSITION

The emulsion for injection or infusion contains:

	Propofol 5 mg/ml	**Propofol 10 mg/ml**	**Propofol 20 mg/ml**
1 ml	5 mg propofol	10 mg propofol	20 mg propofol
in 1 ampoule of 10 ml	-	100 mg propofol	-
in 1 ampoule or vial of 20 ml	100 mg propofol	200 mg propofol	-
in 1 vial of 50 ml	-	500 mg propofol	1000 mg propofol
in 1 vial or of 100 ml	-	1000 mg propofol	-

Excipients with known effect:
1 ml of emulsion for injection or infusion contains
Soya-bean oil (refined) 50 mg

Excipients:
Soya-bean oil (refined), medium-chain triglycerides, glycerol, egg phospholipids for injection, sodium oleate, water for injections.

THERAPEUTIC INDICATIONS

Propofol-Lipuro is a short-acting intravenous general anaesthetic indicated for

Indication	**Propofol 5 mg/ml**	**Propofol 10 mg/ml**	**Propofol 20 mg/ml**
Induction of general anaesthesia	adults and children > 1 month	adults and children > 1 month	adults and children > 3 years
Maintenance of general anaesthesia	-	adults and children > 1 month	adults and children > 3 years
Sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia	in adults only[1]	adults and children > 1 month	adults and children > 3 years
Induction of sedation for diagnostic and surgical procedures	adults and children > 1 month	-	-
Sedation of ventilated patients in the intensive care unit	-	> 16 years of age	> 16 years of age

[1]only short term sedation

CONTRAINDICATIONS

Hypersensitivity to the active substance, soya, peanut or to any of the excipients listed.

Propofol-Lipuro 5 mg/ml is contraindicated for maintenance of general anaesthesia; for maintenance of sedation for diagnostic and surgical procedures in children; for sedation for intensive care. Safety and efficacy for these indications have not been demonstrated.

Propofol-Lipuro 10 mg/ml and 20 mg/ml must not be used in patients of 16 years of age or younger for sedation for intensive care. Safety and efficacy for these age groups have not been demonstrated.

UNDESIRABLE EFFECTS

Induction and maintenance of anaesthesia or sedation with propofol is generally smooth with minimal evidence of excitation. The most commonly reported ADRs are pharmacologically predictable side effects of an anaesthetic/sedative agent, such as hypotension. The nature, severity and incidence of adverse events observed in patients receiving propofol may be related to the condition of the recipients and the operative or therapeutic procedures being undertaken.

Undesirable effects are listed according to their frequencies as follows:

Very common:	(≥ 1/10)
Common:	(≥ 1/100 to < 1/10)
Uncommon:	(≥ 1/1000 to < 1/100)
Rare:	(≥ 1/10000 to < 1/1000)
Very rare:	(<1/10000)
Not known:	(cannot be estimated from the available data)

System Organ Class	Frequency	Undesirable Effects
Immune system disorders:	Very rare (<1/10 000)	Anaphylaxis up to anaphylactic shock – may include angioedema, bronchospasm, erythema and hypotension
Metabolism and Nutritional disorders:	Frequency not known (9)	Metabolic acidosis (5), hyperkalaemia (5), hyperlipidaemia (5)
Psychiatric disorders:	Very rare (<1/10 000)	Sexual disinhibition
	Frequency not known (9)	Euphoric mood, drug abuse and drug dependence (8)
Nervous system disorders:	Common (≥1/100, <1/10)	Headache during recovery phase
	Rare (≥1/10 000, <1/1000)	Epileptiform movements, including convulsions and opisthotonus during induction, maintenance and recovery

	Very rare (<1/10 000)	Postoperative unconsciousness
	Frequency not known (9)	Involuntary movements
Cardiac disorders:	Common (≥1/100, <1/10)	Bradycardia (1)
	Very rare (<1/10 000)	Pulmonary oedema
	Frequency not known (9)	Cardiac arrhythmia (5) cardiac arrest, cardiac failure (5), (7)
Vascular disorders:	Common (≥1/100, <1/10)	Hypotension (2)
Respiratory, thoracic and mediastinal disorders:	Common (≥1/100, <1/10)	Transient apnoea during induction
	Frequency not known (9)	Respiratory depression (dose-dependent)
Gastrointestinal disorders:	Common (≥1/100, <1/10)	Nausea and vomiting during recovery phase
	Very rare (<1/10 000)	Pancreatitis
Hepatobiliary disorders:	Frequency not known (9)	Hepatomegaly (5)
Musculoskeletal and connective tissue disorders:	Frequency not known (9)	Rhabdomyolysis (3), (5)
Reproductive system and breast disorders:	Frequency not known (9)	Priapism
Renal and urinary disorders:	Very rare (<1/10 000)	Discolouration of urine following prolonged administration
	Frequency not known (9)	Renal failure (5)
General disorders and administration site conditions:	Very common (≥1/10)	Local pain on induction (4)
	Uncommon (≥1/1000, <1/100)	Injection site thrombosis and injection site phlebitis
	Very rare (<1/10 000)	Tissue necrosis (10) following accidental extravascular administration (11)
	Frequency not known (9)	Local pain, swelling, and inflammation following accidental extravascular administration (11)

Investigations:	Frequency not known (9)	Brugada type ECG (5), (6)
Injury, poisoning and procedural complications:	Very rare (<1/10 000)	Postoperative fever

(1) Serious bradycardias are rare. There have been isolated reports of progression to asystole.

(2) Occasionally, hypotension may require use of intravenous fluids and reduction of the administration rate of propofol.

(3) Very rare reports of rhabdomyolysis have been received where propofol has been given at doses greater than 4 mg/kg/hr for ICU sedation.

(4) May be minimised by using the larger veins of the forearm and antecubital fossa. With Propofol-Lipuro local pain can also be minimised by the co-administration of lidocaine.

(5) Combinations of these events, reported as “Propofol infusion syndrome”, may be seen in seriously ill patients who often have multiple risk factors for the development of the events.

(6) Brugada-type ECG - elevated ST-segment and coved T-wave in ECG.

(7) Rapidly progressive cardiac failure (in some cases with fatal outcome) in adults. The cardiac failure in such cases was usually unresponsive to inotropic supportive treatment.

(8) Abuse of and drug dependence on propofol, predominantly by health care professionals.

(9) Not known as it cannot be estimated from the available clinical trial data.

(10) Necrosis has been reported where tissue viability has been impaired.

(11) Treatment is symptomatic and may include immobilisation and, if possible, elevation of affected limb, cooling, close observation, consultation of surgeon if necessary.

WARNINGS

Keep out of the sight and reach of children.

NOTE

Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

B. Braun Melsungen AG, 34212 Melsungen, Germany, 03/2022