Directions for Use

B. Braun Melsungen AG, 34209 Melsungen, Germany

Propofol–®Lipuro 20 mg/ml

emulsion for injection or infusion

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml emulsion for injection or infusion contains

Propofol	20 mg
One vial of 50 ml contains	1000 mg propofol

Excipients with known effect

1 ml emulsion for injection or infusion contains
Soya-bean oil, refined 50 mg
Sodium 0.03 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection or infusion
White milky oil-in-water emulsion

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Propofol-Lipuro 20 mg/ml is a short-acting intravenous general anaesthetic indicated for

- induction and maintenance of general anaesthesia in adults and children > 3 years
- sedation of ventilated patients >16 years of age in the intensive care unit
- sedation for diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia in adults and children > 3 years

4.2 Posology and method of administration

General instructions

Propofol-Lipuro 20 mg/ml should be given in hospitals or adequately equipped day therapy units by physicians trained in anaesthesia or in the care of patients in intensive care. Circulatory and respiratory functions should be constantly monitored (e.g. ECG, pulse-oxymeter) and facilities for maintenance of patent airways, artificial ventilation, and other resuscitation facilities should be immediately available at all times. For sedation during surgical or diagnostic procedures Propofol-Lipuro 20 mg/ml should not be given by the same person that carries out the surgical or diagnostic procedure.

Propofol is contraindicated in patients of 16 years of age or younger for sedation for intensive care (see section 4.3). Safety and efficacy for these age groups have not been demonstrated.

Supplementary analgesic medicinal products are generally required in addition to Propofol-Lipuro 20 mg/ml.

Posology

Propofol-Lipuro 20 mg/ml is given intravenously. The dosage is adjusted individually according to the patient's response.

- *General anaesthesia in adults*

Induction of general anaesthesia:

For induction of anaesthesia Propofol-Lipuro 20 mg/ml should be titrated (20 – 40 mg propofol every 10 seconds) against the patient's response until the clinical signs show the onset of anaesthesia. Most adult patients younger than 55 years are likely to require 1.5 to 2.5 mg of propofol per kg body weight.
In patients over this age and in patients of ASA grades III and IV, especially those with impaired cardiac function, the dosage requirements will be less and the total dose of Propofol- Lipuro 20 mg/ml may be reduced to a minimum of 1 mg/kg body weight. In these patients lower rates of administration should be applied (approximately 1 ml corresponding to 20 mg of propofol every 10 seconds).

Maintenance of general anaesthesia:

Anaesthesia is maintained by administering Propofol-Lipuro 20 mg/ml by continuous infusion. The dosage requirements usually are in the range of 4 – 12 mg/kg body weight/h.
In elderly patients, in patients of poor general condition, in patients of ASA grade III and IV and in hypovolaemic patients the dosage may have to be reduced further depending on the severity of the patient´s condition and on the performed anaesthetic technique.

- *General anaesthesia in children over 3 years*

Induction of anaesthesia:

For induction of anaesthesia Propofol-Lipuro 20 mg/ml should be slowly titrated against the patient's response until the clinical signs show the onset of anaesthesia. The dosage should be adjusted according to age and/or body weight.
Most patients over 8 years of age require approximately 2.5 mg/kg body weight of propofol for induction of anaesthesia. In younger children, especially between the age of 1 month and 3 years, the dose requirements may be higher (2.5 – 4 mg/kg body weight).

Maintenance of general anaesthesia:

Anaesthesia can be maintained by administering Propofol Lipuro 20 mg/ml by infusion to maintain the depth of anaesthesia required. The required rate of administration varies considerably between patients but rates in the region of 9 – 15 mg/kg/h usually achieve satisfactory anaesthesia.

For ASA III and IV patients lower doses are recommended (see also section 4.4)

- *Sedation of ventilated patients in the intensive care unit*

For sedation during intensive care, it is advised that Propofol-Lipuro 20 mg/ml should be administered by continuous infusion. The infusion rate should be determined by the desired depth of sedation. In most patients sufficient sedation can be obtained with a dosage of 0.3 – 4.0 mg of propofol per kg body weight per hour (see section 4.4).

Propofol is not indicated for sedation of patients of 16 years or younger in intensive care (see section 4.3). Administration of propofol by Target Controlled Infusion (TCI) system is not advised for sedation in the intensive care unit.

- *Sedation for diagnostic and surgical procedures in adults*

To provide sedation during surgical and diagnostic procedures, doses and administration rates should be adjusted according to the clinical response. Most patients will require 0.5 – 1 mg of propofol per kg body weight over 1 to 5 minutes for onset of sedation. Maintenance of sedation may be accomplished by titrating Propofol-Lipuro 20 mg/ml infusion to the desired level of sedation. Most patients will require 1.5 – 4.5 mg of propofol per kg body weight/h.
In patients older than 55 years and in patients of ASA grade III and IV lower doses of Propofol-Lipuro 20 mg/ml may be required and the rate of administration may need to be reduced.

According to required dose, alternatively Propofol 1% (10 mg/ml) may be used.

- *Sedation for diagnostic and surgical procedures in children over 3 years*

Doses and administration rates should be adjusted according to the required depth of sedation and the clinical response. Most paediatric patients require 1 – 2 mg/kg body weight of propofol for onset of sedation. Maintenance of sedation may be accomplished by titrating of propofol infusion to the desired level of sedation. Most patients require 1.5 – 9 mg/kg/h of propofol.

In ASA III and IV patients lower doses may be required.

Method and duration of administration

- *Method of administration*

Intravenous use

Propofol-Lipuro 20 mg/ml is administered undiluted intravenously by injection or continuous infusion. Containers should be shaken before use.

Before use, the surface of the rubber stopper of the vial should be cleaned with medicinal alcohol (spray or swabs). After use, tapped containers must be discarded.

Propofol-Lipuro 20 mg/ml contains no antimicrobial preservatives and supports growth of microorganisms. Therefore, Propofol-Lipuro 20 mg/ml is to be drawn up aseptically into a sterile syringe or an infusion set immediately after breaking the vial seal. Administration must commence without delay. Asepsis must be maintained for both Propofol-Lipuro 20 mg/ml and the infusion equipment throughout the infusion period.

Any medicinal products or fluids added to a running Propofol-Lipuro 20 mg/ml infusion must be administered close to the cannula site. If infusion sets with filters are to be used, these must be lipid-permeable.

The contents of one vial of Propofol-Lipuro 20 mg/ml and any syringe containing Propofol-Lipuro 20 mg/ml are for **single use** in **one** patient. Any portion of the contents remaining after use must be discarded.

For administration of Propofol-Lipuro 20 mg/ml by continuous infusion, it is recommended that burettes, drop counters, syringe pumps or volumetric infusion pumps should always be used to control the infusion rates. Any portion of Propofol-Lipuro 20 mg/ml remaining after the end of infusion or after replacement of the infusion system must be discarded. As established for the parenteral administration of all kinds of fat emulsions, the duration of continuous infusion of Propofol-Lipuro 20 mg/ml from **one** infusion system must not exceed 12 hours. The infusion line and the reservoir of Propofol-Lipuro 20 mg/ml must be discarded and replaced after 12 hours at the latest.

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

In order to reduce pain on initial injection of Propofol-Lipuro 20 mg/ml for induction of general anaesthesia, lidocaine may be injected immediately prior to the injection of Propofol-Lipuro 20 mg/ml.

Before giving the muscle relaxants atracurium or mivacurium subsequent to Propofol-Lipuro 20 mg/ml through the same intravenous line, the line should be rinsed prior to administration.

Propofol may also be used by Target Controlled Infusion. Due to the different algorithms available on the market for dosage recommendations please refer to the instructions for use leaflet of the device manufacturer.

- *Duration of administration*

Propofol-Lipuro 20 mg/ml can be administered for a maximum period of 7 days.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Propofol-Lipuro 20 mg/ml contains soya-bean oil and should not be used in patients who are hypersensitive to peanut or soya.

Propofol-Lipuro 20 mg/ml must not be used in patients of 16 years of age or younger for sedation for intensive care (see section 4.4).

4.4 Special warnings and precautions for use

Propofol should be given by those trained in anaesthesia (or, where appropriate, doctors trained in the care of patients in Intensive Care).

Patients should be constantly monitored and facilities for maintenance of a patent airway, artificial ventilation, oxygen enrichment and other resuscitative facilities should be readily available at all times. Propofol should not be administered by the person conducting the diagnostic or surgical procedure.

The abuse of and dependence on propofol, predominantly by health care professionals, have been reported. As with other general anaesthetics, the administration of propofol without airway care may result in fatal respiratory complications.

When propofol is administered for conscious 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 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. Very rarely the use of propofol may be associated with the development of a period of post-operative 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 induced impairment is not generally detectable beyond 12 hours. The effects of propofol, 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 (e.g. 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 (see also section 4.2).

Propofol clearance is blood flow dependent, therefore, concomitant medication that reduces cardiac output will also reduce propofol clearance.

Propofol 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 is used in conjunction with other agents likely to cause bradycardia.

When propofol is administered to an epileptic patient, there may be a risk of convulsion. Before anaesthesia of an epileptic patient, it should be checked that the patient has received the antiepileptic treatment.

Appropriate care should be applied in patients with disorders of fat metabolism and in other conditions where lipid emulsions must be used cautiously.

Paediatric population

The use of propofol is not recommended in newborn infants as this patient population has not been fully investigated. Pharmacokinetic data (see section 5.2) indicate that clearance is considerably reduced in neonates and has a very high inter-individual variability. Relative overdose could occur on administering doses recommended for older children and result in severe cardiovascular depression.

Propofol must not be used in patients of 16 years of age or younger for sedation for intensive care as the safety and efficacy of propofol for sedation in this age group have not been demonstrated (see section 4.3).

Propofol-Lipuro 20 mg/ml is not recommended for use in children < 3 years of age due to difficulty in titrating small volumes.

Advisory statements concerning Intensive Care Unit management

Use of propofol for ICU sedation has been associated with a constellation of metabolic disturbances 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 (usually at dose rates greater than 4 mg/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 as part of the propofol formulation; 1.0 ml of Propofol-Lipuro 20 mg/ml contains 0.1 g of fat.

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.

Propofol-Lipuro 20 mg/ml contains no antimicrobial preservatives and supports growth of micro-organisms.

When propofol is to be aspirated, it must be drawn aseptically into a sterile syringe or giving set immediately breaking the vial seal. Administration must commence without delay. Asepsis must be maintained for both propofol and infusion equipment throughout the infusion period. Any infusion fluids added to the propofol line must be administered close to the cannula site. If infusion sets with filters are to be used, these must be lipid-permeable.

Propofol and any syringe containing propofol are for single use in an individual patient. In accordance with established guidelines for other lipid emulsions, a single

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2 Seiten

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Propofol-Lipuro 20 mg/ml
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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.

Special warnings/precautions regarding excipients
This medicine contains less than 1 mmol sodium (23 mg) in 100 ml, that is to say essentially 'sodium free'.

4.5 Interaction with other medicinal products and other forms of interaction

Propofol has been used in association with spinal and epidural anaesthesia and with commonly used premedicants, neuromuscular blocking drugs, inhalational agents and analgesic agents; no pharmacological incompatibility has been encountered. Lower doses of propofol may be required where general anaesthesia or sedation is used as an adjunct to regional anaesthetic techniques.

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. Profound hypotension has been reported following anaesthetic induction with propofol in patients treated with rifampicin.

A need for lower propofol doses has been observed in patients taking valproate. When used concomitantly, a dose reduction of propofol may be considered.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of propofol during pregnancy has not been established. Studies in animals have shown reproductive toxicity (see section 5.3).
Propofol should not be given to pregnant women except when absolutely necessary. Propofol crosses the placenta and can cause neonatal depression. Propofol can, however, be used during an induced abortion.

Breast-feeding

Studies of breast-feeding mothers showed that small quantities of propofol are excreted in human milk. Women should therefore not breastfeed for 24 hours after administration of propofol. Milk produced during this period should be discarded.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Patients should be advised that performance at skilled tasks, such as driving and operating machinery, may be impaired for some time after use of propofol.

Propofol induced impairment is not generally detectable beyond 12 hours (please see section 4.4).

4.8 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. These effects depend on the propofol dose administered but also on the type of premedication and other concomitant medication. 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.

Table of Adverse Drug Reactions
Undesirable effects are listed according to their frequencies as follows:
Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from the available data)

System Organ Class	Frequency	Undesirable Effects
Immune system disorders:	Very rare	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:	Frequency not known (9)	Euphoric mood, drug abuse and drug dependence (8)
Nervous system disorders:	Common	Headache during recovery phase
	Rare	Epileptiform movements, including convulsions and opisthotonus during induction, maintenance and recovery
	Very rare	Postoperative unconsciousness
	Frequency not known (9)	Involuntary movements
Cardiac disorders:	Common	Bradycardia (1)
	Very rare	Pulmonary oedema
	Frequency not known (9)	Cardiac arrhythmia (5), cardiac failure (5), (7)
Vascular disorders:	Common	Hypotension (2)
Respiratory, thoracic and mediastinal disorders:	Common	Transient apnoea during induction
	Frequency not known (9)	Respiratory depression (dose-dependent)
Gastrointestinal disorders:	Common	Nausea and vomiting during recovery phase
	Very rare	Pancreatitis
Hepatobiliary disorders	Frequency not known (9)	Hepatomegaly (5)
Musculoskeletal and connective tissue disorders:	Frequency not known (9)	Rhabdomyolysis (3), (5)
Renal and urinary disorders	Very rare	Discolouration of urine following prolonged administration
	Frequency not known (9)	Renal failure (5)
Reproductive system and breast	Very rare	Sexual disinhibition
General disorders and administration site conditions:	Very common	Local pain on induction (4)
	Uncommon	Injection site thrombosis and injection site phlebitis
	Very rare	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	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 20 mg/ml 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, see section 4.4.
(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.

4.9 Overdose

Symptoms

Accidental overdosage is likely to cause cardiorespiratory depression.

Treatment

Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression may require lowering of the patient's head and, if severe, administering plasma expanders and pressor agents.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other general anaesthetics, ATC-code N01AX10.

Mechanism of action, pharmacodynamic effect

After intravenous injection of Propofol-Lipuro 20 mg/ml, onset of the hypnotic effect is rapid. Depending on the rate of injection, the time to induction of anaesthesia is between 30 and 40 seconds. The duration of action after a single bolus administration is short due to the rapid metabolism and excretion (4 – 6 minutes).

With the recommended dosage schedule, clinically relevant accumulation of propofol after repeated bolus injection or after infusion has not been observed.
Patients recover consciousness rapidly.

Bradycardia and hypotension occasionally occur during induction of anaesthesia probably due to the lack of vagolytic activity. The cardio-circulatory situation usually normalises during maintenance of anaesthesia.

The formulation of propofol in a mixed medium- and long-chain triglyceride emulsion leads to lower concentrations of free medicinal product in the aqueous phase compared to pure long-chain triglyceride emulsions. This difference may explain the reduced pain frequency and intensity observed with Propofol-Lipuro formulations in comparative clinical studies, due to the very low concentration of free propofol.

Paediatric population

Limited studies on the duration of propofol based anaesthesia in children indicate safety and efficacy is unchanged up to duration of 4 hours. Literature evidence of use in children documents use for prolonged procedures without changes in safety or efficacy.

5.2 Pharmacokinetic properties

Absorption

After intravenous administration about 98 % of propofol is bound to plasma protein.

Distribution

After intravenous bolus administration the initial blood level of propofol declines rapidly due to rapid distribution into different compartments (α-phase). The distribution half-life has been calculated as 2 – 4 minutes.

During elimination the decline of blood levels is slower. The elimination half-life during the ß-phase is in the range of 30 to 60 minutes. Subsequently a third deep compartment becomes apparent, representing the redistribution of propofol from weakly perfused tissue.

The central volume of distribution is in the range of 0.2 – 0.79 l/kg body weight, the steady-state volume of distribution in the range of 1.8 – 5.3 l/kg body weight.

Biotransformation

Propofol is mainly metabolized in the liver to form glucuronides of propofol and glucuronides and sulphate conjugates of its corresponding quinol. All metabolites are inactive.

Elimination

Propofol is rapidly cleared from the body (total clearance approx. 2 l/min). Clearance occurs by metabolism, mainly in the liver, where it is blood flow dependent. Clearance is higher in paediatric patients compared with adults. About 88% of an administered dose is excreted in the form of metabolites in urine. Only 0.3% is excreted unchanged in the urine.

Paediatric population

After a single dose of 3 mg/kg intravenously, propofol clearance/kg body weight increased with age as follows: Median clearance was considerably lower in neonates < 1 month old (n = 25) (20 ml/kg/min) compared to older children (n = 36, age range 4 months – 7 years). Additionally inter-individual variability was considerable in neonates (range 3.7 – 78 ml/kg/min). Due to this limited trial data that indicates a large variability, no dose recommendations can be given for this age group.

Median propofol clearance in older aged children after a single 3 mg/kg bolus was 37.5 ml/min/kg (4 – 24 months) (n = 8), 38.7 ml/min/kg (11 – 43 months) (n = 6), 48 ml/min/kg (1 – 3 years) (n = 12), 28.2 ml/min/kg (4 – 7 years) (n = 10) as compared with 23.6 ml/min/kg in adults (n = 6).

5.3 Preclinical safety data

Preclinical data reveal no specific hazard for humans based on conventional studies on repeated dose toxicity or genotoxicity. Carcinogenicity studies have not been conducted.

Published studies in animals (including primates) at doses resulting in light to moderate anaesthesia demonstrate that the use of anaesthetic agents during the period of rapid brain growth or synaptogenesis results in cell loss in the developing brain that can be associated with prolonged cognitive deficiencies. The clinical significance of these nonclinical findings is not known.

In local tolerance studies, intramuscular injection resulted in tissue damage around the injection site.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soya-bean oil, refined,
Medium-chain triglycerides,
Glycerol,
Egg phospholipids for injection,
Sodium oleate,
Water for injections.

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

Unopened:

2 years

After first opening:
To be used immediately.

6.4 Special precautions for storage

Do not store above 25 °C.
Do not freeze.

6.5 Nature and contents of container

The product is supplied in

- vials of colourless glass (type II Ph. Eur.) sealed with bromobutyl rubber closure and aluminium caps, containing 50 ml of emulsion. It is available in packs of 1 x 50 ml, 10 x 50 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

Containers should be shaken before use.

For single use only. Any portion of contents remaining after first use must be discarded, see sections 4.2 and 4.4.

If two layers can be seen after shaking, the medicinal product should not be used.

Propofol-Lipuro 20 mg/ml must not be mixed with other solutions for injection or infusion. However, co-administration of Propofol-Lipuro 20 mg/ml together with glucose 50 mg/ml (5% w/v) solution or sodium chloride 9 mg/ml (0.9% w/v) solution via a Y-connector close to the injection site is possible.

7. REVISION DATE

August 2019

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B. Braun Melsungen AG
34209 Melsungen, Germany