Professional Information for Medicines for Human Use

SCHEDULING STATUS

S5

1. NAME OF THE MEDICINE

B Braun Propofol 1 % (10 mg/ml) (Emulsion for intravenous injection or infusion)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

B Braun Propofol 1 % (10 mg/ml) (Emulsion for intravenous injection or infusion)

Each 1 ml of emulsion contains propofol 10 mg

3. PHARMACEUTICAL FORM

Emulsion for intravenous injection or infusion

A white, milky oil-in-water emulsion.

CLINICAL PARTICULARS

4.1. Therapeutic indications

a) The induction and maintenance of general anaesthesia, as part of a balanced anaesthetic technique in patients over the age of three years.

b) Sedation of ventilated adult patients receiving intensive care, for a period of up to 72 hours.

c) Conscious sedation for surgical and diagnostic procedures in adults provided that there are adequate facilities for monitoring of haemodynamic and oxygenation parameters and if administered by a qualified anaesthetist.

4.2. Posology and method of administration

Posology

Supplementary analgesic agents are required in addition to B Braun Propofol 1 % (10 mg/ml), where analgesia is required.

B Braun Propofol 1 % (10 mg/ml) has been used in association with spinal and epidural anaesthesia and with commonly used premedication, neuromuscular

blocking agents, inhalation and analgesic agents; no pharmacological incompatibility has been encountered.

Dosage adjustment may be necessary when used together with the above agents, particularly the narcotics (e.g. morphine, pethidine and fentanyl), combination of opioids and sedatives (e.g. benzodiazepines, barbiturates, droperidol, etc.), supplementary analgesic agents (e.g. nitrous oxide or opioids) and the potent inhalational agents (e.g. isoflurane, enflurane and halothane).

Where general anaesthesia with B Braun Propofol 1 % (10 mg/ml) is used simultaneously with a regional anaesthetic technique, lower doses of B Braun Propofol 1 % (10 mg/ml) may be required.

It is recommended that blood lipid levels be monitored routinely should B Braun Propofol 1 % (10 mg/ml) be administered to patients thought to be at particular risk of fat overload. Administration of B Braun Propofol 1 % (10 mg/ml) 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 B Braun Propofol 1 % (10 mg/ml) formulation; 1,0 ml of B Braun Propofol 1 % (10 mg/ml**)** contains 0,1 g of fat.

Patients with hypovolaemia should have fluid-volume deficits corrected prior to administration of B Braun Propofol 1 % (10 mg/ml).

Dosage in adults:

Induction of General Anaesthesia:

In unpremedicated and pre-medicated patients: Most adult patients aged less than 55 years are likely to require 1,5 to 2,5 mg/kg (0,15 - 0,25 ml/kg) of B Braun Propofol 1 % (10 mg/ml), (approximately 4 ml every 10 seconds in an average healthy adult) by slow bolus injection or infusion titrated against the response of the

patient until clinical signs show onset of anaesthesia. The total dose required can be reduced by lower rates of administration (20 - 50 mg/min [2 - 5 ml/min]).

Patients 55 years and older

Over the age of 55 years the requirements will generally be less. In patients of ASA Grades 3 and 4, lower rates of administration should be used (approximately 20 mg (2 ml) every 10 seconds).

Maintenance of General Anaesthesia:

Anaesthesia can be maintained by administering B Braun Propofol 1 % (10 mg/ml) either by continuous infusion or by repeat bolus injections to prevent the clinical signs of light anaesthesia.

Infusion: The average rate of administration varies between patients, but rates in the region of 4 to 12 mg/kg/hr (0,4 - 1,2 ml/kg/hr) usually maintain satisfactory anaesthesia.

Slightly higher rates of administration may be required for 10 to 20 minutes after induction of anaesthesia.

Repeat Bolus Injections: As a guide, increments of 25 mg (2,5 ml) to 50 mg (5,0 ml) may be used.

Sedation during Intensive Care:

To provide sedation for ventilated adult patients undergoing intensive care, it is recommended that B Braun Propofol 1 % (10 mg/ml) be given by continuous infusion, for up to 72 hours. Adjust infusion rate according to the depth of sedation required. Rates of 0,3 - 4,0 mg/kg/hr should achieve satisfactory sedation. Rates above 4,0 mg/kg/hr are not recommended.

Conscious sedation for surgical and diagnostic procedures (see section 4.4):

To provide sedation for surgical and diagnostic procedures rates of administration should be individualised and titrated to clinical response.

Most patients will require 0,5 mg/kg to 1 mg/kg over 1 to 5 minutes to initiate sedation. Maintenance of sedation may be accomplished by titrating B Braun Propofol 1 % (10 mg/ml) infusion to the desired level of sedation - most patients will require 1,5 mg/kg/hr to 4,5 mg/kg/hr. In addition to the infusion, bolus administration of 10 mg 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.

Elderly Patients

In elderly patients the dose requirement for induction of anaesthesia with B Braun Propofol 1 % (10 mg/ml) is reduced. The reduction should take account of the physical status and age of the patient. The reduced dose should be given at a slower rate and titrated against the response. Where B Braun Propofol 1 % (10 mg/ml) is used for maintenance of anaesthesia or sedation the rate of infusion or "target concentration" should also be reduced. Patients of ASA Grades 3 and 4 will require further reductions in dose and dose rate. Rapid bolus administration (single or repeated) should not be used in the elderly as this may lead to cardio-respiratory depression.

Dosage in children:

B Braun Propofol 1 % (10 mg/ml) is not recommended for use in children less than 3 years of age (*refer to section 4.3*).

Induction of Anaesthesia:

When used to induce anaesthesia, it is recommended that B Braun Propofol 1 % (10 mg/ml**)** should be titrated slowly until the clinical signs show the onset of anaesthesia. The dose should be adjusted for age and/or body weight.

Most children over 8 years of age are likely to require approximately 2,5 mg propofol/kg bodyweight for induction of anaesthesia. Under this age the dose requirement may be higher.

The initial dose should be 3 mg propofol/kg body weight. If necessary, additional doses in steps of 1 mg propofol/kg body weight can be administered. Due to lack of clinical experience, lower dosages are recommended for young patients at increased risk (ASA grades III and IV).

Maintenance of General Anaesthesia:

Administer B Braun Propofol 1 % (10 mg/ml) by infusion or repeat bolus injection to maintain the depth of anaesthesia required. The required rate of administration varies considerably between patients. 9 to 15 mg/kg/hr (0,9 - 1,5 ml/kg/hr) usually achieves satisfactory anaesthesia.

Sedation during Intensive Care:

B Braun Propofol 1 % (10 mg/ml) must not be used for sedation in children under 16 yearsof age as safety and efficacy have not been demonstrated. Serious adverse events (including fatalities) have been observed from spontaneous reports of unlicensed use and these events were seen most often in children with respiratory tract infections, given doses in excess of those recommended for adults.

Conscious sedation for surgical and diagnostic procedures:

B Braun Propofol 1 % (10 mg/ml) is not recommended for conscious sedation in children as safety and efficacy have not been demonstrated.

Method of administration

Intravenous use

Infusion of undiluted B Braun Propofol 1 % (10 mg/ml)

When B Braun Propofol 1 % (10 mg/ml) is used undiluted to maintain anaesthesia, it is recommended that equipment such as drop counters, syringe pumps or volumetric infusion pumps should always be used to control infusion rates.

B Braun Propofol 1 % (10 mg/ml) can be used for infusion undiluted in glass infusion bottles or from plastic syringes.

Infusion of B Braun Propofol 1 % (10 mg/ml)

B Braun Propofol 1 % (10 mg/ml) can be diluted with 5 % dextrose intravenous infusion only, in PVC infusion bags or glass infusion bottles. 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. The dilution may be used with a variety of infusion control techniques, but a giving set alone will not avoid the risk of accidental uncontrolled infusion of large volume or diluted B Braun Propofol 1 % (10 mg/ml). 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 B Braun Propofol 1 % (10 mg/ml) in the burette.

It is recommended that, when using diluted B Braun Propofol 1 % (10 mg/ml), the volume of 5 % dextrose removed from the infusion bag during the dilution process is totally replaced in volume by B Braun Propofol 1 % (10 mg/ml) emulsion.
B Braun Propofol 1 % (10 mg/ml) may be administered via a Y-piece close to the injection site, into intravenous infusion of dextrose 5 % or sodium chloride 0,9 %.
B Braun Propofol 1 % (10 mg/ml) may be premixed with alfentanil injection. In order to reduce pain on initial injection, that part of the B Braun Propofol 1 % (10 mg/ml) used for induction may be mixed with lignocaine injection in the ratio of 20 parts B Braun Propofol 1 % (10 mg/ml) with up to 1 part of 1 % lignocaine injection immediately prior to administration.

Incompatibilities:

B Braun Propofol 1 % (10 mg/ml) should not be mixed prior to administration with injections or infusion fluids other than 5 % Dextrose or lignocaine injection or alfentanil injection (see above).

The neuromuscular blocking agents atracurium and mivacurium should not be given through the same intravenous line as B Braun Propofol 1 % (10 mg/ml) without prior flushing.

In-Use Precautions

General Anaesthesia:

In accordance with established guidelines for other lipid emulsions a single infusion of B Braun Propofol 1 % (10 mg/ml) must not exceed 6 hours. The syringe or giving set and any unused portion of B Braun Propofol 1 % (10 mg/ml) or solution containing B Braun Propofol 1 % (10 mg/ml) must be discarded at the end of the surgical procedure, or at 6 hours, whichever is the sooner, and replaced as appropriate.

Intensive Care Sedation:

Administration should commence promptly and must be completed within 12 hours after the vial has been spiked. The tubing and any unused portion of B Braun Propofol 1 % (10 mg/ml) must be discarded after 12 hours. If B Braun Propofol 1 % (10 mg/ml) is transferred to a syringe or other container prior to administration, the handling procedures for General Anaesthesia (above) should be followed and the product should be discarded and administration lines changed after 6 hours.

4.3. Contraindications

B Braun Propofol 1 % (10 mg/ml) is contraindicated in:

- Known hypersensitivity to the active substance propofol or to any of the excipients listed in section 6.1.
- B Braun Propofol 1 % (10 mg/ml) contains soybean oil, and should not be used in patients who are hypersensitive to peanut or soya.
- B Braun Propofol 1 % (10 mg/ml) is not recommended in children under the age of 3 years.
- Appropriate care should be applied in patients with disorders of fat metabolism, patients predisposed to fat embolism and in other conditions where lipid emulsions must be used cautiously.
- Fat metabolism may be disturbed in conditions such as renal insufficiency, uncompensated diabetes mellitus, certain forms of liver insufficiency, metabolic disorders, severe trauma including long-bone and multiple fractures, and sepsis.
- B Braun Propofol 1 % (10 mg/ml) is not recommended in neonates and premature infants.
- B Braun Propofol 1 % (10 mg/ml) must not be used for sedation of patients less than 16 years of age in the Intensive Care Unit.
- B Braun Propofol 1 % (10 mg/ml) must not be used for sedation of children of all ages with group or epiglottitis receiving intensive care.

4.4. Special warnings and precautions for use

Use with caution in patients with an allergy to egg or soya protein.

Respiration will be depressed and must be monitored to ensure adequate gas exchange. Special care should be exercised when used with other respiratory depressants.

A generalised systemic reaction, which may be anaphylactic in nature (including angioedema, bronchospasm, erythema and hypotension), may occur following B Braun Propofol 1 % (10 mg/ml) administration.

When B Braun Propofol 1 % (10 mg/ml) is administered to an epileptic patient, there may be a risk of convulsion.

In debilitated patients, elderly patients, patients with cardiac, respiratory, renal or hepatic impairment or in hypovolaemic or epileptic patients, B Braun Propofol 1 % (10 mg/ml) should be administered with caution and a reduced administration rate. Cardiac, circulatory or pulmonary insufficiency and hypovolaemia should be compensated before administrationof B Braun Propofol 1 % (10 mg/ml). In the elderly, debilitated or ASA Ill or IV patients, rapid single or repealed bolus administration should not be used in order to minimise undesirable cardiorespiratory side effects.

Appropriate care should be applied in patients with disorders of fat metabolism, patients predisposed to fat embolism and in other conditions where lipid emulsions must be used cautiously. Fat metabolism may be disturbed in conditions such as renal insufficiency, uncompensated diabetes, certain forms of liver insufficiency, metabolic disorders, severe trauma including long-bone and multiple fractures, and sepsis.

B Braun Propofol 1 % (10 mg/ml) should not be administered in patients with advanced cardiac failure or other severe myocardial diseases except with extreme caution and intensive monitoring.

Due to a higher dosage in obese patients, the risk of haemodynamic effects on the cardiovascular system should be taken into consideration. Special care should be recognized in patients with a high intracranial pressure and a low mean arterial pressure, as there is a risk of a significant decrease of the intracerebral perfusion pressure.

Advisory statements concerning Intensive Care Unit management

Use of B Braun Propofol 1 % (10 mg/ml) 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 B Braun Propofol 1 % (10 mg/ml) 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.

Use of B Braun Propofol 1 % (10 mg/ml) is not recommended with electroconvulsive therapy.

B Braun Propofol 1 % (10 mg/ml) 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 ventilationand oxygen enrichment and other resuscitative facilities should be readily available at all times.

B Braun Propofol 1 % (10 mg/ml) should not be administered by the person conducting the diagnostic or surgical procedure. An adequate period is needed prior to discharge of the patient to ensure full recovery after general anaesthesia. Very rarely the use of B Braun Propofol 1 % (10 mg/ml) 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.

The pharmacokinetics of propofol may be prolonged in people with chronic hepatic cirrhosisor chronic renal impairment. Recovery times may double as a result. The effects of acute hepatic or renal failure on the pharmacokinetics of propofol have not been studied.

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 B Braun Propofol 1 % (10 mg/ml) is used in conjunction with other agents likely to cause a bradycardia.

The patient should not be allowed to go home unaccompanied and should be instructed to avoid consumption of alcohol.

Lipids should be monitored in ICU treatment after 3 days.

4.5. Interaction with other medicines and other forms of interaction

The neuromuscular blocking agents atracurium and mivacurium should not be given through the same intravenous line as B Braun Propofol 1 % (10 mg/ml) without prior flushing.

Lower doses may be required when general anaesthesia is carried out in conjunction with regional anaesthesia.

Concomitant use of benzodiazepines, parasympatholytic agents or inhalational anaesthetics has been reported to prolong the anaesthesia and to reduce the respiratory rate.

After supplementary pre-medication of opiates, apnoea may occur with increasing frequency and over a prolonged period. Bradycardia and cardiac arrest may occur after treatment with suxamethonium or neostigmine.

When B Braun Propofol 1 % (10 mg/ml) is combined with centrally depressant drugs administered parenterally, severe respiratory and cardiovascular depression may occur. After administration of fentanyl, the blood level of propofol may be temporarily increased.

Leucoencephalopathy has been reported with administration of lipid emulsions such as propofol in patients receiving cyclosporine.

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:

B Braun Propofol 1 % (10 mg/ml) should not be used in pregnancy.

B BraunPropofol 1 % (10 mg/ml) crosses the placenta and may be associated with neonatal depression. It should not be used for obstetric anaesthesia.

B Braun Propofol 1 % (10 mg/ml) has been used, however, during termination of pregnancy in the first trimester.

Lactation:

Studies of breast-feeding mothers showed that small quantities of propofol are excreted in human milk. Safety to the neonate has not been established.

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, might be impaired for some time after general anaesthesia.

4.8. Undesirable effects

Tabulated list of adverse reactions

Undesirable effects are listed according to their frequencies as follows:

System Organ Class	Frequency	Undesirable Effects
Immune system disorders:	Less Frequent	Anaphylaxis – may include angioedema, bronchospasm, erythema and hypotension
Metabolism and nutritional disorders:	Frequency not known (9)	Metabolic acidosis (5), hyperkalaemia (5), hyperlipidaemia (5)
Psychiatric disorders:	Less frequent	Euphoric during recovery, Sexual disinhibition during recovery,
	Frequency not known (9)	Euphoric mood, drug abuse and drug dependence (8)

Nervous system disorders:	Frequent	Excitation. Headache during recovery phase
	Less Frequent	Epileptiform movements, including convulsions and opisthotonus during induction, maintenance and recovery. Postoperative unconsciousness, syncope
	Frequency not known (9)	Involuntary movements
Cardiac disorders:	Frequent	Bradycardia (1)
	Less Frequent	Pulmonary oedema, excitation. Tachycardia, premature ventricular contractions, premature atrial contractions, abnormal ECG and segment depression, thrombosis
	Frequency not known (9)	Cardiac dysrhythmia (5), cardiac failure (5), (7)
Vascular disorders:	Frequent	Hypotension (2), hypertension, flushing
	Less Frequent	Syncope, phlebitis
Respiratory, thoracic and mediastinal disorders:	Frequent	Transient apnoea during induction, hiccup, coughing
	Less Frequent	Pulmonary oedema
	Frequency not known (9)	Respiratory depression (dose-dependent)
Gastrointestinal disorders:	Frequent	Nausea and vomiting during recovery phase
	Less frequent	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	Less frequent	Discolouration of urine following prolonged administration
	Frequency not known (9)	Renal failure (5)
General disorders and administration site conditions:	Frequent	Local pain on induction (4)
	Less frequent	Injection site thrombosis and injection site phlebitis Tissue necrosis (10) following accidental extravascular administration (11)
	Frequency not known (9)	Local pain and swelling, following accidental extravascular administration (11)
Investigations	Frequency not known (9)	Brugada type ECG (5), (6)
Injury, poisoning and procedural complications:	Less frequent	Postoperative fever

(1) Serious bradycardias are less frequent. 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) 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 local pain can also be minimised by the co-administration of lidocaine (lignocaine).

(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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the ‘6.04 Adverse Drug Reactions Reporting Form’. Found under SAHPRA’s publications: https://www/sahpra.org.za/Publications/Index/8.

4.9. Overdose

Symptoms

Accidental overdosage is likely to cause cardio respiratory depression.

Treatment

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 medicines.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A.2.1 Anaesthetics

ATC code: N01AX10

Mechanism of action

Propofol (2,6-di-isopropylphenol) is a short-acting sedative hypnotic with a rapid onset of action of approximately 30 seconds. The mechanism of action is poorly understood.

Falls in mean arterial blood pressure and slight changes in heart rate are observed when propofol is administered for induction and maintenance of anaesthesia.

Bradycardia and hypotension reported during induction of anaesthesia may be caused by a cerebral vagotonic effect or inhibition of sympathetic activity.

Ventilatory depression can occur following administration of propofol. Propofol reduces cerebral blood flow, intracranial pressure and cerebral metabolism.

Recovery from anaesthesia is usually rapid and clear-headed.

Propofol has an anti-emetic effect.

Propofol, at the concentrations likely to occur clinically, does not inhibit the synthesis of adrenocortical hormones.

5.2. Pharmacokinetic properties

Absorption

Propofol is 98 % bound to plasma proteins.

Distribution

The decline in propofol concentrations following a bolus dose, or following the termination of an infusion, can be described by a three compartment open model. The first phase is characterized by a rapid distribution (half-life 2 -4 minutes) followed by rapid elimination (half-life 30 - 60 minutes) and a slower final phase, representative of redistribution of propofol from poorly perfused tissue.

Biotransformation

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

Elimination

Propofol is extensively distributed and rapidly cleared form the body (total body clearance 1,5 - 2 litres/minute). Clearance occurs by metabolic processes, mainly in the liver, to form inactive conjugates of propofol and its corresponding quinol, which are excreted in the urine. Less than 0,3 % of the administered dose is excreted unchanged in urine.

Linearity

The pharmacokinetics is linear over the recommended range of infusion rates of propofol. Under the usual maintenance regimens, significant accumulation of propofol does not occur.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

B Braun Propofol 1 % (10 mg/ml) contains the following excipients: Soya-bean oil, refined; Triglycerides, medium chain; Egg phospholipids for injection; Glycerol; Sodium oleate; Water for injection.

6.2. Incompatibilities

B Braun Propofol 1 % (10 mg/ml) should not be mixed prior to administration with injections or infusion fluids other than 5 % Dextrose or lignocaine injection or alfentanil injection (see section 4.2).

The neuromuscular blocking agents atracurium and mivacurium should not be given through the same intravenous line as B Braun Propofol 1 % (10 mg/ml) without prior flushing.

6.3. Shelf life

Unopened ampoule: 24 months

Opened ampoule: Must be used immediately

6.4. Special precautions for storage

Store at or below 25 °C. Do not freeze.

Keep the product in the outer carton until ready for use to protect from light.

6.5. Nature and contents of container

B Braun Propofol 1 % (10 mg/ml) is packed in:

20 ml colourless Type I glass ampoules

50 ml colourless Type II glass bottles closed with a Type I bromobutyl rubber stopper and an aluminium cap with flip-off polypropylene centre portion.

100 ml colourless Type II glass bottles closed with a Type I bromobutyl rubber stopper and an aluminium cap with flip-off polypropylene centre portion.

Pack sizes:

5 x 20 ml colourless clear glass ampoules in a tray packed into a cardboard carton.

10 x 50 ml colourless glass bottles in a cardboard carton.

10 x 100 ml colourless glass bottles in a cardboard carton.

Not all packs or pack sizes are necessarily marketed.

6.6. Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

Containers should be shaken before use. B Braun Propofol 1 % (10 mg/ml) should be inspected for particulate matter and discolouration before administration. Do not use if there is evidence of separation of the phases of the emulsion.

B Braun Propofol 1 % (10 mg/ml) contains no anti-microbial preservatives and the vehicle supports growth of micro-organisms. When B Braun Propofol 1 % (10 mg/ml) is to be aspirated it must be drawn aseptically into a sterile syringe or giving set immediately after opening the ampoule or breaking the vial seal.Administration must commence without delay. Asepsis must be maintained for both B Braun Propofol 1 % (10 mg/ml) and infusion equipment throughout the infusion period.

Any infusion fluids added to the B Braun Propofol 1 % (10 mg/ml) line must be administered close to the cannula site.

B Braun Propofol 1 % (10 mg/ml) must not be administered via a microbiological filter.

Any container or syringe containing B Braun Propofol 1 % (10 mg/ml) is for single use in a single patient only.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

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