Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Propofol 10mg/ml emulsion for injection or infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml Emulsion for injection or infusion contains 10 mg Propofol.
Excipient: 1 ml Emulsion for injection or infusion contains 100 mg Soya-bean oil.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection or infusion.
White to slight off-white emulsion for injection or infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Propofol 10 mg/ml is a short acting intravenous general anaesthetic for:

- Induction and maintenance of general anaesthesia in adults and children more than 1 month.
- Sedation of ventilated patients more than 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 more than 1 month.

4.2 Posology and method of administration

Supplemental analgesic agents are normally needed during Propofol administration. In addition, please refer to Section 4.4 Special Warnings and Special Precautions for Use, for additional usage information.

General Anaesthesia in Adults

Induction: Propofol 10 mg/ml may be used for induction of anaesthesia as slow bolus injection or infusion. Propofol should be titrated to clinical response, where the patient shows sign of anaesthesia (usually about 20-40 mg every 10 seconds). Most adults under 55 years of age will need 1.5 to 2.5 mg/kg.

Elderly patients usually need lower doses. Patients in ASA class 3 and 4, especially those with impaired cardiac function, the dosage requirements will be less and the total dose may be reduced to a minimum of 1 mg of propofol/kg body. The total dose could be reduced with a slower administration rate (20 to 50 mg/min).

Maintenance: The anaesthesia may be maintained by administration of Propofol either as a continuous infusion or as bolus injections. The administration rate to be used is greatly varying between patients. If anaesthesia is maintained by continuous infusion, doses of 4 to 12 mg/kg/hr should be given. In older patients, in debilitated or hypovolaemic patients and patients of ASA classes 3 and 4 the dose should be reduced as low as 4 mg/kg/hr. At the onset of anaesthesia (during roughly the first 10-20 minutes), some patients may require a slightly higher infusion rate (8-10 mg/kg/h).

If the anaesthesia is maintained through repeated bolus injections doses ranging from 25 mg to 50 mg may be

administered depending on the clinical need. Rapid bolus administration (singly or repeated) should not be used in the elderly as this may lead to cardiopulmonary depression.

Paediatrics (general anaesthesia in children over 1 month old)
Propofol should not to be used in children younger than 1 month.

Induction of anaesthesia: For induction of anaesthesia Propofol must be titrated slowly until clinical signs show the onset of anaesthesia. The dose should be adjusted according to age and/or weight. Most patients over 8 years of age normally need about 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, dose requirements may be higher (2.5 - 4 mg/kg). Due to lack of clinical experience, lower dosages are recommended for young patients at increased risk (ASA classes III or IV).

Maintenance of general anaesthesia: Anaesthesia can be maintained by administering Propofol by infusion or repeated bolus injections to maintain the depth of anaesthesia required. The required rate of administration varies considerably between patients. But rates in the region of 9 to 15 mg/kg/hr usually achieve satisfactory anaesthesia. In younger children, especially between the age of 1 month and 3 years, dose requirements may be higher. Dosage should be adjusted individually and particular attention paid to the need for adequate analgesia (see also Section 4.4 Special warnings and special precautions for use).

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

Sedation of adults during intensive care: Propofol must be given as continuous infusion in ventilated patients. The infusion rate should be adjusted to the desired depth of sedation, usually 0.3 mg to 4.0 mg/kg/hr provides adequate sedation. Prescribers are reminded not to exceed the dosage of 4 mg/kg/hr (See 4.4 Special warnings and precautions for use).

Sedation for diagnostic and surgical procedures in adult patients: 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/kg over 1 to 5 minutes for onset of sedation. Maintenance of sedation may be accomplished by titrating propofol to the desired level of sedation. Most patients will require 1.5-4.5 mg/kg/hr. The infusion may be supplemented by bolus administration of 10-20 mg (1-2 ml Propofol 10 mg/ml) if a rapid increase of the depth of sedation is required. In patients older than 55 years a lower dose may be required. In patients of ASA class III and IV lower doses of Propofol may be required and the rate of administration may need to be reduced.

Sedation for diagnostic and surgical procedures in children over 1 month of age: 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 Propofol infusion to the desired level of sedation. Most patients require 1.5–9 mg/kg/h Propofol. The infusion may be supplemented by bolus administration of up to 1 mg/kg body weight if a rapid increase of depth of sedation is required. In ASA III and IV patients lower doses may be required.

Sedation of paediatric patients: Propofol 10 mg/ml must not be used for sedation for diagnostic and surgical procedures, or during intensive care, in children under 16 years of age (see section 4.3 Contra-indications).

Method of Administration: For intravenous use only.

Propofol may be used for a maximum of 7 days.

Propofol vials and ampoules, and any syringes containing propofol are for single use in an individual patient. In accordance with current guidelines for other lipid emulsion an infusion with propofol should not be given over more than 12 hours. At the end of the procedure (not more than 12 hours), the vial, ampoule or syringe and any remaining amount of propofol or the infusion containing propofol must be discarded.

For undiluted propofol a drop counter, syringe pump or volumetric pump should be used.

Propofol may be administered diluted in 5% Dextrose for Injection in glass or PVC containers. The concentration of propofol must not be below 2 mg/ml, that is 4 parts of dextrose to 1 part of propofol. The dilutions should be prepared aseptically immediately prior to administration and used within 6 hours of preparation. When administering the diluted infusion it is necessary to include a burette, drop counter, or volumetric pump in the infusion line to avoid the risk of accidental uncontrolled infusion of large volumes of diluted propofol. This risk must be taken into account when deciding the maximum dilution in the burette.

To reduce pain at the injection site propofol may be mixed with 1% lidocaine for injection (20:1) immediately before the induction of anaesthesia. The reconstitution must be prepared aseptically.

Via a Y-set at the site of injection propofol may be given together with 5% dextrose injection or sodium chloride/dextrose isotonic injection.

Co-administration techniques	Additive or diluent	Preparation	Precautions
Pre-mixing	5% Dextrose for Injection	Mix 1 part of Propofol 1% with up to 4 parts of Dextrose 5% in either PVC infusion bags or glass infusion bottles, When diluted in PVC bags it is recommended that the bag should be full and that the dilution be prepared by withdrawing a volume of infusion fluid and replacing it with an equal volume of Propofol 1%.	Prepare aseptically immediately before administration. The mixture is stable up to 6 hours.
	1% Lidocaine Hydrochloride Injection	Mix 20 parts Propofol 1% with up to 1 part of 1% Lidocaine Hydrochloride Injection.	Prepare mixture aseptically immediately prior to administration. Use for induction only.
Co-administration via a Y-set connector	Dextrose 5 % for Injection	Co-administer via a Y-set connector.	Place the Y-set connector close to the injection site.
	Sodium Chloride/Dextrose isotonic injection	Co-administer via a Y-set connector.	Place the Y-set connector close to the injection site.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Propofol contains Soya-bean oil. It must not be used in patients who are allergic to peanut or soya.
- Propofol must not be used in patients 16 years of age or younger for sedation in intensive care.

4.4 Special warnings and precautions for use

The use of Propofol is not recommended for 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 high inter-individual variability. Relative overdose could occur on administering doses recommended for older children and result in severe cardiovascular depression.

Special care should be exercised when propofol is used for anaesthesia in infants and children up to 3 years of age, although currently available data do not suggest significant differences in terms of safety compared with children older than 3 years.

Propofol should be administered only in hospitals or adequately equipped day therapy units by physicians trained in the administration of general anaesthesia or management in an intensive care unit. Circulatory and respiratory functions should be constantly monitored (e.g. ECG, pulse oximeter) and facilities for maintenance of patent airways, artificial ventilation, oxygen enrichment and other resuscitation facilities should be immediately available at all times. A suitable time period is necessary before discharge to ensure that the patient has recovered completely after the anaesthesia.

For sedation during surgical or diagnostic procedures Propofol 10 mg/ml should not be given by the same person that carries out the surgical or diagnostic procedure.

The abuse of propofol, predominantly by health care professionals, has 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.

There is a risk of convulsions, when propofol is given to epileptic patients. Before the anaesthesia of an epileptic patient, it should be checked that the patient has received antiepileptic treatment.

Use is not recommended with electroconvulsive therapy. Propofol should be administered with caution to sedate patients undergoing procedures where spontaneous, involuntary movements are undesirable, such as ophthalmic surgery.

An adequate period is needed prior to discharge of the patient to ensure full recovery after use of propofol. In isolated cases there may be phases of post-operative unconsciousness that may be accompanied by an increased muscle tone. This may or may not be preceded by a period of wakefulness. Although consciousness returns spontaneously, unconscious patients should be under careful observation.

Propofol induced impairment is not generally detectable after 12 hours. The effects of propofol, the procedure, concomitant medications, the age and the condition of the patient should be considered when advising the 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. Propofol clearance is blood flow dependent; therefore, concomitant medication that reduces cardiac output will also reduce propofol clearance. If possible, hypovolaemia, cardiac insufficiency, circulatory depression or impaired respiratory functions should be compensated before the administration of propofol.

Propofol should also be administrated carefully in elderly patients.

Propofol has no vagolytic activity and has been associated with reports of bradycardia (sometimes severe) and asystole. In situations where high vagal tone is present or when propofol is given with other substances that may trigger bradycardia, pre-treatment with an anticholinergic agent may be considered before induction or during maintenance of anaesthesia.

Special care should be recognised in patients with impaired fat metabolism or other conditions, where administration of a fat emulsion could be dangerous. If Propofol 10mg/ml is used in patients with a risk for fat overdosage, the serum

lipid levels must be monitored. If signs of incomplete elimination of fat are present, the administration of propofol should be adjusted accordingly. If the patient is being given other intravenous lipid nutrition concomitantly, the amount of that drug should be reduced to take account of the amount of lipid infused as part of the propofol formulation. 1 ml Propofol contains approximately 0.1 g fat.

Lipids should be monitored in ICU treatment after 3 days.

Due to the higher doses usually administered to patients who are grossly overweight, special care should be taken regarding the increased risk of haemodynamic effects.

Special care should be recognised 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.

Dilutions with lidocaine solution must not be used in patients with hereditary acute porphyria.

Advisory statements concerning Intesive Care Unit management

Propofol should not be used during intensive care in children under 16 years of age. The safety and efficacy of propofol for (background) sedation in children younger than 16 years of age have not been demonstrated. Although no causal relationship has been established, serious undesirable effects with (background) sedation in patients younger than 16 years of age (including cases with fatal outcome) have been reported during unlicensed use. In particular, these effects concerned occurrence of metabolic acidosis, rhabdomyolysis, hyperkalaemia, hyperlipidaemia and/or cardiac and multi organ failure (in some cases with fatal outcome). These effects were most frequently seen in children with respiratory tract infections who received dosages in excess of those advised in adults for sedation in the intensive care unit.

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 (in some cases with fatal outcome) in adults. Combinations of these events have been referred to as the “Propofol Infusion Syndrome”.

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 following extended dosing at doses greater than 4 mg/kg/hr).

The patients affected were mainly (but not only) seriously head- injured patients with raised intracranial pressure (ICP). It is therefore recommended that patients with raised ICP should be given an appropriate treatment to support the cerebral perfusion pressure during these treatment modifications.

All sedative and therapeutic agents used in the intensive care unit (ICU), including propofol, should be titrated to maintain optimal oxygen delivery and haemodynamic parameters.

Prescribers are reminded if possible not to exceed the dosage of 4 mg/kg/h which is usually sufficient for sedation of mechanically ventilated patients in the intensive care unit (ICU) situation (treatment durations in excess of 1 day). Prescribers should be alert to these possible undesirable effects and decrease the dosage or switch to an alternative sedative at the first sign of occurrence of symptoms.

Propofol contains egg lecithin as an emulsifier. Following dissolution, lysolecithin, a compound with haemolytic properties in-vitro, is formed. In the clinical situation, even when dissolution is complete, risk of haemolysis will be low when the recommended dosage is applied. Under pathological conditions of low albumin concentration (patients with hepatic and/or renal failure) this risk increases and should be checked for on a regular basis.

Additional precautions

Propofol 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 after opening the ampoule or 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. Propofol must not be administered via a microbiological filter.

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 infusion of propofol must not exceed 12 hours. At the end of the procedure or at 12 hours, whichever is sooner, both the reservoir of propofol and the infusion line must be discarded and replaced as appropriate.

4.5 Interaction with other medicinal products and other forms of interaction

Propofol has been used during spinal and epidural anaesthesia and in combination with commonly used premedications, neuromuscular blocking agents, inhalation agents and analgesics without signs of pharmacological interactions. Some of the medications mentioned may reduce the blood pressure or impair breathing, thus increasing the effects of propofol and prolonging anaesthesia. If opiates (e.g. fentanyl) are administered as premedication apnoea may occur more frequently and be prolonged. Lower doses of propofol could be necessary, when the general anaesthesia is used in connection with a regional anaesthesia.

After suxamethonium and neostigmine bradycardia and cardiac arrest may occur.

Propofol should not be mixed before administration with other solutions for injection or infusion other than with 5% dextrose in glass or PVC containers or with 1% lidocaine in plastic syringes.

After co-administration of lidocaine, the following undesirable effects may occur: giddiness, vomiting, drowsiness, convulsions, bradycardia, cardiac arrhythmia and shock.

4.6 Fertility, pregnancy and lactation

Pregnancy:
The safety of propofol during pregnancy has not been established. Thus, propofol should not be used in pregnant women unless clearly necessary. Propofol crosses the placenta and may be associated with respiratory depression in neonates..
Propofol can, however, be used during an induced abortion.

Breastfeeding:
Studies in breastfeeding women have shown that propofol is excreted in small amounts in the milk. Breast-feeding should be stopped, and the breast milk discarded, for 24 hours after administration of propofol.

4.7 Effects on ability to drive and use machines

After administration of propofol the patient has to be carefully monitored for an appropriate period of time. The patient should be instructed not to drive vehicles, operate machinery or work in potentially dangerous situations. The patient should be escorted when going home and should not drink alcohol. 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 adverse drug reactions are pharmacologically predictable side effects of an anaesthetic/sedative agent, such as hypotension and pain at the injection site. The pain can be reduced by mixing the preparation with lidocaine (see 4.2 Posology and method of administration, 4.5 Interaction with other medicinal products and other forms of interaction). Transient apnoea is common during induction of anaesthesia.

The nature, severity and incidence of adverse events observed in patients receiving propofol may be related to the conditions of the recipients and the operative or therapeutic procedures being undertaken. Adverse drug reactions reported with propofol are presented in the following table in which adverse drug reactions are grouped under the most relevant System Organ Class (SOC) related to the target organ. The adverse reactions are ranked under the following frequency groupings, with most frequent reactions presented first:

- 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).

Table of Adverse Drug Reactions

System Organ Class	Frequency	Undesirable Effects
Immune system disorders	Very rare	Anaphylaxis – may include angioedema, bronchospasm, erythema and hypotension
Metabolism and Nutritional disorder	Frequency not known	Metabolic acidosis (1), hyperkalaemia (1), hyperlipidaemia (1)
Psychiatric disorders	Frequency not known	Euphoric mood, drug abuse(2),
	Very rare	Sexual disinhibition
Nervous system disorders	Common	Headache during the recovery period
	Rare	Epileptiform movements, including convulsions and opisthotonus during induction, maintenance and recovery
	Very rare	Post-operative unconsciousness.
	Frequency not known	Involuntary movements
Cardiac disorders	Common	Bradycardia (3)
	Very rare	Pulmonary oedema
	Frequency not known	Cardiac arrhythmia (1), cardiac failure (1), (4)
Vascular disorders	Common	Hypotension (5)
	Uncommon	Thrombosis and phlebitis Marked hypotension
Respiratory, thoracic and mediastinal disorders	Common	Transient apnoea during induction
Gastrointestinal disorders	Common	Nausea and vomiting during recovery phase,
	Very rare	Pancreatitis
Hepatobiliary disorders	Frequency not known	Hepatomegaly (1)

Musculoskeletal and connective tissue disorders	Frequency not known	Rhabdomyolysis (6), (1)
Renal and urinary disorders	Very rare	Discolouration of urine following prolonged administration
	Frequency not known	Renal failure(1)
General disorders and administration site conditions	Very common	Local pain on induction (7)
Investigations	Frequency not known	Brugada type ECG (1), (8)
Injury, poisoning and procedural complications	Very rare	Post-operative fever

(1) 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.
(2) Drug abuse, predominantly by health care professionals.
(3) Serious bradycardias are rare. There have been isolated reports of progression to asystole.
(4) 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.
(5) Occasionally, hypotension may require use of intravenous fluids and reduction of the administration rate of propofol.
(6) Very rare reports of rhabdomyolysis have been received where propofol has been given at doses greater than 4 mg/kg/hr for ICU sedation.
(7) May be minimised by using the larger veins of the forearm and antecubital fossa. With propofol 1% local pain can also be minimised by the co-administration of lidocaine.
(8) Brugada-type ECG - elevated ST-segment and coved T-wave in ECG.

4.9 Overdose

Overdose causes cardiovascular and respiratory depression. Respiratory depression should be treated by controlled ventilation with pure oxygen.

Cardiovascular depression is treated by putting the patient in Trendelenburg's position and eventual fluid infusion, or treatment with plasma expanders and pressor agents, depending on the patient's condition.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other general anaesthetics
ATC code: N 01 AX 10.

Propofol (2,6 di-isopropyiphenol) is a short-acting anaesthetic agent for use in intravenous anaesthesia with an onset after approx. 30 seconds. The recovery phase is rapid and the patient feels alert within a short period of time. As with other general anaesthetics, the mechanism of action is not clearly known.

In general a drop in blood pressure and bradycardia is observed when Propofol is used for induction and maintenance of anaesthesia. During maintenance of anaesthesia the presence of unintentional hemodynamic changes is low and the haemodynamic parameters are normally reasonably stable.

Even if ventilatory depression may occur during administration of propofol the occurrence and degree are the same as for other agents used for intravenous administration.

The recovery phase is usually rapid and the patient feels alert within a short period of time and with a low presence of post-operative nausea and vomiting.

The clinical concentration of propofol does not inhibit the synthesis of adrenocortical hormones.

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

The decline in propofol concentration following a bolus injection, or termination of infusion, can be described by a 3 compartment open model with a very rapid distribution (half-life 2-4 minutes), rapid elimination (half-life 30- 60 minutes), and a slow final phase representing redistribution of propofol from poorly perfused tissues.

Propofol is extensively distributed and rapidly cleared from the body (total body clearance 1.5 to 2 litres/minute). Clearance occurs by metabolic processes, mainly in the liver where it is blood flow dependent to form inactive conjugates of propofol and its corresponding quinol, which are excreted in the urine. Clearance in children is 50% higher than in adults.

When propofol is used to maintain anaesthesia, blood concentration is increasing asymptomatic to steady state for a given administration rate. The pharmacokinetics arelinear for the infusion rates recommended for propofol.

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.

5.3 Preclinical safety data

Clinical experience with the use of propofol is very well documented. All relevant information regarding safety in connection with administration is addressed in other parts of this Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified egg phosphatides;
Soy-bean oil;
Glycerol;
Sodium hydroxide;
Water for injections.

6.2 Incompatibilities

Propofol should not be mixed before administration with other solutions for injection or infusion other than with 5% Dextrose in glass or PVC containers or with 1% Lidocaine in plastic syringes.

The neuromuscular blocking agents atracurium and mivacurium should not be administered through the same IV line as Propofol without previous wash out.

6.3 Shelf life

3 years. The product shall be used immediately after opening the ampoule or the vial.

Shelf –life after dilution
Chemical and physical in-use stability has been demonstrated for 6 hours at 2 to 8°C.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.
Any unused solution must be discarded immediately after first use.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.
For storage conditions of the diluted medicinal product, see section 6.3.

6.5 Nature and contents of container

20 ml clear, colourless glass ampoules in pack size of 5 ampoules.
20 ml clear, colourless glass ampoules in pack size of 25 ampoules.
20 ml clear, colourless glass vials with rubber stoppers and flip off seals, in pack size of 5 vials.
20 ml clear, colourless glass vials with rubber stoppers and flip off seals, in pack size 25 vials.
50 ml clear, colourless glass vials with rubber stoppers and flip off seals, in pack size of 1 vial.
50 ml clear, colourless glass vials with rubber stoppers and flip off seals, in pack sizes of 20 vials.
100 ml clear, colourless glass vials with rubber stoppers and flip off seals, in pack size of l vial.
100 ml clear, colourless glass vials with rubber stoppers and flip off seals, in pack sizes of 10 vials.
Not all pack sizes may be marketed.

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

Inspect the product visually and discard any product where the visual appearance of the product has changed or if the container is damaged.

Shake well before use. For single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

Propofol 10mg/ml contains no antimicrobial preservatives and the emulsion supports the growth of micro-organisms. When Propofol 10mg/ml is drawn out this should be done aseptically to a syringe immediately after opening the ampoule/vial. The administration should be started without delay. Both Propofol 10mg/ml and the infusion equipment should be aseptically handled throughout the infusion period. Any drugs or fluids added to the Propofol 10mg/ml line must be administered close the cannula site. Propofol 10mg/ml must not be administered through a microbial filter.

7 MARKETING AUTHORISATION HOLDER

Hospira Enterprises B.v.
Randstad 22-11
1316 BN Almere
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA 1250/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

May 2013