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Certification

VERIFIED TRANSLATION OF DOCUMENT & DECLARATION

The undersigned, of the below address, hereby certifies and declares that he/she knows well both the English and Dutch languages, and that the attached is an accurate translation of the document listed below:

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I hereby declare that all statements in the translation made herein of my own knowledge are true and that all statements made in the translation on information and belief are believed to be true. Further, these statements in the translation were made with the knowledge that willful false statements and the like so made are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the United States Code. Signed this 5th day of February, 2015

Signature _____

Name: Robert Endoy

Address: Rochester, MI 48306

Subscribed and sworn to before me, a Notary Public in and for the County of Cook, State of Illinois, on February 5, 2015.

Marigrace Clark

Marigrace Clark, Notary

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Dr. Reddy's Laboratories
v.
Fresenius Kabi USA, LLC
U.S. Patent No. 8,476,010

1. Name of the drug

Propofol 10 mg/ml Fresenius, injectable emulsion

2. Qualitative and quantitative composition

One ml Propofol 10 mg/ml Fresenius, injectable emulsion contains 10 mg Propofol. Each ampoule of 20 ml, injection vial of 50 ml and 100 ml contains respectively 200 mg, 500 mg and 1000 mg Propofol.
For the additives refer to point 6.1.

3. Pharmaceutical form

Injectable emulsion.
Isotonic, white oil-in-water emulsion.

4. Clinical information

4.1 Therapeutic indications

Propofol Fresenius is an intravenous short acting total anesthetic for:

1. Inducing and maintaining total anesthesia.
2. Sedation of ventilated patients in intensive care units.
3. Sedation for diagnostic and surgical procedures, in isolation or in combination with local or regional anesthesia.

4.2 Dosage and method of administering

4.2.1 Special warnings

Propofol Fresenius should only be administered in hospitals or well-equipped medical centers by physicians trained in anesthesia or in the treatment of intensive care patients. Continuous monitoring of the blood circulation and the respiration (ex. ECG, pulse oximeter) is necessary. Equipment for prevention of respiratory tract obstruction, artificial respiration and other reanimation equipment must be immediately available at all times. When used for sedation during surgical or diagnostic procedures, Propofol Fresenius should not be administered by the same person who is performing the surgical or diagnostic procedure. Additional analgesics are usually necessary in combination with Propofol Fresenius.

4.2.2. Recommended dosage and treatment time

Propofol Fresenius is administered intravenously. The dosage is adjusted individually based on the response of the patient.

General anesthesia of adults:

Induction of anesthesia

Propofol must be titrated for the induction of anesthesia (20-40 mg Propofol every 10 seconds), while continuously monitoring the reaction of the patient until clinical signs signal the onset of anesthesia. In general, an adult patient, not older than 55 years, will require 1,5-2.5 mg Propofol per kg body weight.

For older patients and patients with an ASA (American Society of Anesthesiologists) classification III or IV, in particular with deteriorated heart function, the requirement will be less and the total dose of Propofol Fresenius can be reduced to a minimum of 1 mg Propofol/kg body weight. The administration rate must also be reduced with these patients (approximately 20mg (2 ml Propofol 10 mg/ml Fresenius) per 10 seconds).

Maintenance of the anesthesia :

The anesthesia can be maintained by administering Propofol 10 mg/ml as continuous infusion or as repeated bolus injections. If the last mentioned method is applied, dosages from 25 mg (2.5 ml Propofol 10 mg/ml Fresenius) to 50 mg (5 ml Propofol 10 mg/ml Fresenius) must be administered depending on the clinical need.

For maintenance of anesthesia by means of a continuous infusion, the dosage requirement will usually be 4 to 12 mg Propofol/kg body weight/hour. With older patients, patients in poor general condition, patients with ASA classification III or IV and hypovolemic patients the dosage can be further reduced depending on the patient's condition and the applied anesthesia technique.

General anesthesia of children older than one month of age:

Induction of anesthesia:

For the induction of anesthesia Propofol must be slowly titrated while continuously monitoring the reaction of the patient, until clinical signals announce the set in of anesthesia.

The dosage must be adjusted to the age and/or the body weight.

In general, a patient older than 8 years will require for induction 2.5 mg Propofol/kg body weight. Higher dosages may be required for younger children (2.5- 4 mg/kg).

In absence of clinical experience, lower dosages are recommended for younger patients with increased risk (ASA classification III and IV).

Maintenance of the anesthesia:
In general, a satisfactory anesthesia level can be obtained by means of a continuous infusion with a dosage of 9-15 mg Propofol/kg body weight/hour.

In comparison with older children, children under 3 years of age may need a higher dose within the recommended dosage range. The dosage must be adjusted individually and special attention must be paid to adequate analgesia (see also point 4.2.1 Special warnings).

The administration time in children younger than 3 years of age was usually 20 minutes with a maximum duration of 75 minutes. A maximum duration of 60 minutes should therefore not be exceeded, except if there is a specific indication for longer duration such as for instance malign hyperthermia whereby volatile substances must be avoided.

Propofol Fresenius should not be used for induction and maintenance of anesthesia in children younger than 1 month.

Sedation of ventilated patients during intensive care

Administration of a continuous infusion of Propofol Fresenius is recommended for sedation of ventilated patients under intensive care conditions. The infusion rate should be adjusted to the required sedation level. In general, a satisfactory sedation is obtained with a dosage of 0.3 to 4.0 mg Propofol per kg body weight per hour (see 4.4 Special warnings and precautions with use).

Propofol Fresenius should not be used for sedation under intensive care conditions of children under 16 years of age or younger (see 4.3: Contraindications).

It is not recommended to administer Propofol via a TCI system for sedation under intensive care.

Sedation for diagnostic and surgical procedures in adults:

For diagnostic and surgical procedures, the sedation dosage and administration rate must be adapted to the clinical response. As introduction, most patients need 0.5-1 mg Propofol per kg body weight per hour for 1 – 5 minutes.

Maintenance of the sedation is obtained by titration of a Propofol Fresenius infusion until the desired sedation level is obtained. In general, 1.5-4.5 mg Propofol per kg bodyweight per hour will be required.

When using Propofol 10 mg/ml Fresenius, a bolus injection of 10-20 mg Propofol (1-2 ml Propofol 10 mg/ml Fresenius) can be used in addition to the infusion, if a fast increase of the sedation depth is required. With patients older than 55 years of age and patients with ASA classification III or IV, it may be necessary to lower the dosage and administration rate.

Propofol Fresenius should not be used to sedate children 16 years of age or younger during diagnostic or surgical procedures.

4.2.2 **Method of administration and duration**

Method of administration

Propofol 10 mg/ml Fresenius must be administered intravenously as injection or as continuous infusion, either undiluted or diluted with a 5% glucose solution or a 0.9% sodium chloride solution. Solutions in glass bottles and in PVC bags can both be used and must be thoroughly mixed prior to the administration.

It is possible to simultaneously administer Propofol 10 mg/ml Fresenius together with a 5% glucose or a 0.9% sodium chloride infusion via a Y connector near the injection spot.

Prior to use, the neck of the ampoule and the rubber stopper of the injection vial must be disinfected with medicinal alcohol (spray or patches). After use, the leftovers must be destroyed.

Propofol Fresenius does not contain preservatives and promotes the growth of microorganisms. Therefore, after opening of a Propofol Fresenius ampoule or pricking through a vial, the content must be drawn immediately in antiseptic manner in a sterile syringe or infusion system. Administration should take place immediately afterwards. The sterility of the Propofol Fresenius and the infusion system must be maintained during the administration.

Drugs or liquids added to a running Propofol Fresenius infusion must be introduced close to the catheter. Propofol Fresenius should not be administered via infusion systems equipped with microbial filters. The content of one ampoule or one vial of Propofol Fresenius is intended for one time use in one patient. The leftover must be destroyed after use.

Infusion of undiluted Propofol 10 mg/ml Fresenius

When Propofol Fresenius is administered by means of a continuous infusion it is recommended to control the infusion rate by means of a burette, a dropper, a syringe pump or a volumetric infusion pump.

As applicable for parenteral administration of all sorts of fat emulsions, the use of one infusion system for continuous infusion of Propofol Fresenius must be limited to maximum 12 hours. The infusion system and the container must be removed and replaced after maximum 12 hours. Leftovers of Propofol Fresenius that remain at the end of the infusion period or after changing the system must be destroyed.

Infusion of diluted Propofol 10 mg/ml Fresenius

When diluted Propofol Fresenius 10 mg/ml is administered by means of a continuous infusion, it is recommended to control the infusion rate by means of a burette, a dropper, a syringe pump or a volumetric infusion pump, in order to prevent accidental administration of too large doses of diluted Propofol Fresenius.

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