

Factory: 24, Jeyakgongdan 1-gil, Hyangnam-eup,
Hwaseong-si, Gyeonggi-do, Korea
T 82-31-353-4451~3
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# **Summary of Product Characteristics (SmPC)**

#### 1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Freefol-MCT Inj. 1%

## 2. QUALITATIVE AND QUALNTITATIVE COMPOSITION

Each 1mL contains, as active pharmaceutical ingredient, Propofol 10.0mg

For the full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Injection

#### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic indications

- Induction and maintenance of general anesthesia for adults and children of the age over 3 years old
- Sedation of ventilated patients receiving intensive care
- Sedation for surgical and diagnostic procedures

## 4.2. Posology and method of administration

- 1.General anaesthesia
- 1) Induction of general anaesthesia
- (1) Adults aged under 55 years: It is recommended that this drug should be titrated (approximately 4 mL (40 mg) every ten seconds in an average healthy adult) against the response of the patient until the clinical signs show the onset of anaesthesia. Most adult patients aged under 55 years are likely to require this drug at 1.5 to 2.5 mg/kg. The total dose required can be reduced by lower rates of administration (20 to 50mg/min)
- (2) Adults aged over 55 years, frail patients, adult patients with ASA Grades III and IV and patients with cardiac disorders: Dose should be reduced (1~1.5mg per kg of body weight) according to the clinical response and conditions (20mg per 10 seconds) as these people may be unduly sensitive to the effects of this drug. Rapid intravenous injection (bolus) should not be used in adults aged over 55 years, frail patients and adult patients with ASA Grades III and IV as it may increase cardiorespiratory depression such as hypotension, apnea, airway obstruction and oxygen desaturation.
- (3) Pediatrics over 3 years of age: When used to induce anaesthesia in children, it is recommended that this drug is given slowly until the clinical signs show the onset of anaesthesia. The dose should be adjusted for age and/or weight. Most patients over eight years of age are likely to require



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approximately 2.5 mg/kg for induction of anaesthesia. Under this age the requirement may be more. Lower dosage is recommended for children of ASA grades III or IV.

- 2) Maintenance of general anaesthesia
- (1) Adults aged under 55 years: Anaesthesia can be maintained by administering this drug by infusion or repeat bolus injection to maintain the depth of anaesthesia required.
- ① Continuous intravenous injection: The required rate of administration varies considerably between patients but rates in the region of 4 to 12 mg/kg/hour usually achieve satisfactory anaesthesia
- ② Repeated intravenous injection: There is individual difference between patients, but 25~50mg can be increased according to clinical necessity.
- (2) Adults aged over 55 years, frail patients, adult patients with ASA Grades III and IV and patients with cardiac disorders: Generally, anesthesia can be properly maintained at the infusion rate of  $3 \sim 6$  mg/hr per kg of body weight. Rapid intravenous injection (bolus) should not be used in adults aged over 55 years, frail patients and adult patients with ASA Grades III and IV as it may increase cardiorespiratory depression such as hypotension, apnea, airway obstruction and oxygen desaturation.
- (3) Pediatrics over 3 years of age The required rate of administration varies considerably between patients but rates in the region of 9 to 15 mg/kg/hour usually achieve satisfactory anaesthesia. It is

recommended to use lower dose of this drug in patients with ASA Grades III and IV.

#### 2. Sedation during intensive care

#### 1) Adult

When used to provide sedation for ventilated adult patients undergoing intensive care, it is recommended that this drug is given by continuous infusion within 3 days. The infusion rate should be adjusted according to the depth of sedation required but rates in the region of 0.3 to 4.0 mg/kg/hour should achieve satisfactory sedation. Infusion rates greater than 4.0 mg/kg/hour are not recommended. It can be diluted with Dextrose 5% Intravenous Infusion or Intravenous Isotonic

Sodium Chloride Injection (See Cautions on Application or Table "Dilution or Coadministration of propofol")

- 2) Elderly people: the infusion rate should be reduced when using this drug for sedation. The Dose and infusion rate should be reduced more when using in patients with ASA Grades III and IV.
- 3) Pediatrics: This drug is not recommended for sedation in children as safety and efficacy have not been demonstrated.



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<Dilution or Co-administration of Propofol>

Co-administration	Additive or Diluent	Preparation	Precautions
Technique		To I was a second	
Premix	Dextrose 5% Intravenous Infusion or Intravenous Isotonic Sodium Chloride Injection	Mix 1 part of this drug with up to 4 parts of Dextrose 5% Intravenous Infusion or Intravenous Isotonic Sodium Chloride Injection 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 this drug.	Aseptic preparation immediately before administration, The mixture is stable for 6 hours.  After dilution, the final concentration of this drug should not be lower than 2 mg/ml.
	Lidocaine hydrochloride injection (0.5% or 1% without preservatives) Alfentanil injection (500µg/ml).	Mix 20 parts of this drug with up to 1 part of either 0.5% or 1% lidocaine hydrochloride injection.  Mix this drug with alfentanil injection in a ratio of 20:1 to 50:1 v/v.	Prepare mixture aseptically immediately prior to administration. Use for Induction only Prepare mixture aseptically; use within 6 hours of
Co-administration via a Y-piece connector.	Dextrose 5% intravenous infusion	Co-administer via a Y-piece connector.	preparation.  Place the Y-piece connector close to the injection site.
Comission	Intravenous Isotonic Sodium Chloride Injection	As above	As above
	Dextrose 4% with sodium chloride 0.18% intravenous infusion	As above	As above

#### 3. Sedation For Surgical And Diagnostic Procedures:

- 1) Adults aged under 55 years: 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 to 1 mg/kg over 1 to 5 minutes for onset of sedation. Maintenance of sedation may be accomplished by titrating this drug to the desired level of sedation most patients will require 1.5 to 4.5 mg/kg/h. In addition to the infusion, bolus administration of 10 to 20 mg may be used if a rapid increase in the depth of sedation is required.
- 2) Adults aged over 55 years, frail patients, adult patients with ASA Grades III and IV: The dose and infusion rate of this drug should be reduced in 20~30% of adults.
- 3) Pediatrics: This drug is not recommended for sedation in children as safety and efficacy have not been demonstrated.



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#### 4.3. Contraindications

- 1) Patients who have a history of hypersensitivity to this drug or any of its components
- 2) Patients who are hypersensitive to peanut or soya
- 3) This drug is contraindicated for anaesthesia of children 3 years of age or younger and for the sedation of children
- 4) This drug is contraindicated for the sedation of Children
- 5) Pregnant and lactating women or women of childbearing potential

## 4.4. Special warnings and precautions for use

- 1) This drug should be administered only by persons trained in the administration of general anesthesia. Facilities for maintenance of a patent airway, providing artificial ventilation, administering supplemental oxygen, and instituting cardiovascular resuscitation must be immediately available.
- 2) This drug should not be administered by persons involved in the conduct of the surgical/diagnostic procedure.
- 3) For general anesthesia or monitored anesthesia care (MAC) sedation, patients should be continuously monitored for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation. These cardiorespiratory effects are more likely to occur following rapid bolus administration, especially in the elderly, debilitated, or ASA-PS III or IV patients.
- 4) For sedation of intubated, mechanically ventilated patients in the Intensive Care Unit (ICU), this drug should be administered only by persons skilled in the management of critically ill patients and trained in cardiovascular resuscitation and airway management
- 5) Use of this drug for both adult and pediatric ICU sedation has been associated with a constellation of metabolic derangements and organ system failures, referred to as Propofol Infusion Syndrome, that have resulted in death. This syndrome includes metabolic acidosis, hyperkalemia, hyperlipidemia, rhabdomyolysis, hepatomegaly, renal failure, cardiac arrhythmia, and Burgadada ECG (elevated ST-segment and coved T-wave). And acute progressive heart failure that does not respond to inotropic supportive treatment. These adverse events have been reported mainly in patients with severe head injuries or in pediatric patients with airway infections who have been given this drug in excess of the recommended adult dose. The main risk factors for the onset of symptoms are as follows.
- Reduction of oxygen transport in tissues
- Severe nerve damage and / or sepsis
- Administering one or more high doses of vasoconstrictors, steroids, contractile accelerators and / or propofol (more than 4 mg / kg / h for more than 48 hours).

The prescribing physician should warn patients with these risk factors about the symptoms of this syndrome

and should immediately discontinue this drug. If these symptoms develop. Any sedative or therapeutic agent used in the intensive care unit must be optimized for optimal oxygenation and maintenance of hemodynamic factors. When changing treatments, patients with increased intracranial pressure should be given appropriate treatment to maintain cerebral perfusion pressure.

Doctors should avoid giving more than 4 mg / kg / h of dose as much as possible

### 4.5. Interaction with other medicinal products and other forms of interaction

1) This drug has been used in combination with pretreatment, neuromuscular blockers,



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inhalants and analgesics commonly used in connection with spinal anesthesia and epidural anesthesia. No pharmacological incompatibility has been found. When general anesthesia or sedation is used as an adjunct to local anesthesia techniques, low doses of this drug may be necessary. The induction dose requirements of this drug may be reduced in patients with intramuscular or intravenous premedication, particularly with narcotics (e.g. morphine, meperidine and fentanyl, etc.) and combinations of opioids and sedatives (e.g. benzodiazepines, barbiturates, chloral hydrate, droperidol, etc.). These agents may increase the anaesthetic of propofol and may also result in more pronounced decreases in systolic, diastolic and mean arterial pressures and cardiac output, and increase in onset frequency of apnea.

- 2) During maintenance of anaesthesia, the rate of this drug administration should be adjusted according to the desired level of anaesthesia or sedation and may be reduced in the presence of supplemental analysesic agents (e.g. nitrous oxide or opioids).
- 3) The concurrent administration of potent inhalational agents (e.g. isoflurane, enflurane and halothane) during maintenance with propofol has not been extensively evaluated.
- 4) Propofol does not cause a clinically significant change in onset, intensity or duration of action of the commonly used neuromuscular blocking agents (e.g. suxamethonium and nondepolarising muscle relaxants).
- 5) As with other IV anesthetics, alcohol intake should be limited until 8 hours before and after taking this drug.
- 6) If this drug is concurrently used with succinylcholine or neostigmine, brady cardiaor cardiac arrest may occur.
- 7) Leukoencephalopathy has been reported when lipid emulsion such as Propofol was administered to patients receiving Cyclosporin.
- 8) In pediatric patients, administration of fentanyl concomitantly with this drug may result in serious bradycardia.
- 9) Patients receiving rifampicin have been reported to have severe hypotension with induction of general anesthesia.
- 10) Since the need to lower the dose of propofol has been observed in patients taking valproic acid, a decrease in propofol dose may be considered in combination administration.

#### 4.6. Pregnancy and lactation

- 1) Do not administer this drug to pregnant women.
- 2) This drug can cross the placenta and suppress fetus. Therefore, this drug should not be taken for obstetrical anesthesia.
- 3) In nursing mothers, safety for neonate has not been established.

#### 4.7. Effects on ability to drive and use machines

Avoid driving or operating machinery.

#### 4.8. Undesirable effects

Most common adverse reactions are reactions such as hypotension expected with anesthetics Pharmacologically. When characteristics of anesthetics and patients requiring intensive care were considered, although it was reported to be associated with anesthetics and incentive care, there can be casual relationship with exercised operation or Patients' condition. Very often ( $\geq 1/10$ ), often ( $\geq 1/100$ , <1/10), rarely ( $\geq 1/1000$ , <1/100), rarely ( $\geq 1/10000$ )



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Metabolic and Nutritional Disorder   Metabolic and Nutritional Disorder   Metabolic and Nutritional Disorder   Metabolic and Nutritional Disorder   Metabolic acidosis (5), hyperkalaemia (5), hyperlipmia (5)   Chorea, stimulation, derangement, delirium, fatigue, groan, dysorexia   Euphoria, sexual disinhibition   Drug abuse and drug dependency (8)   Headache, exercise, acute spasm, forme tardive spasm, spasm, bucking, muscular reflex and struggle during the period of convalescence   Stromatogenous movement including spasm and opisthotonos during induction, maintenance anesthesia and anesthesia recovery period.   Dizziness and chills and sense of coldness during the period of convalescence   Somnolence, hypertonia, dystonia, paraesthesia, and systomia   Metabolic and poisthotonos during induction, maintenance anesthesia and anesthesia recovery period.   Dizziness and chills and sense of coldness during the period of convalescence   Somnolence, hypertonia, dystonia, paraesthesia, and systomia   Metabolic and poisthotonos during induction, maintenance anesthesia and exercise, acute spasm, forme tardive spasm, spasm, bucking, muscular reflex and struggle during the period of convalescence   Somnolence, hypertonia, dystonia, paraesthesia, and sense of coldness during the period of convalescence   Metabolic and poisthotonos during induction, distribution, dysporal period of convalescence   Metabolic and poisthotonos during induction   Prequently   Unknown (9)   Deep vein (5), cardiac insufficiency (5), (7)   Frequently   Unknown (9)   Deep vein (5), cardiac insufficiency (5), (7)   Frequently   Uncommonly   Human   Premature ventricular contraction, premature atrial contraction, and proposal propos	Classification of Tissues	Frequency	Adverse Event	
Metabolic acidosis (5), hyperkalaemia (5), hyperliftinal Disorder   Rarely   Chorea, stimulation, derangement, delirium, fatigue, groan, dysorexia   Chorea, sexual disinhibition   Chorea, sexual pleasure   Chorea, sexual pleasure   Chorea, sexual pleasure   Chorea, sexual disinhibition   Chorea, sexual disinhibition   Chorea, sexual pleasure, sexual disinhibition   Chorea, sexual disinhibition   Chorea, sexual pleasure, sexual disinhibition   Chorea, sexu	Immune System Disorder	Very rarely	Anaphylaxis- It includes angioedema, bron- chiospasm, erythema and hypotension	
Mental Disorder  Very rarely Very rarely Euphoria, sexual disinhibition Drug abuse and drug dependency (8) Headache, exercise, acute spasm, forme tardive spasm, spasm, bucking, muscular reflex and struggled during the period of convalescence Stromatogenous movement including spasm and opisthotonos during induction, maintenance anesthesia and anesthesia recovery period. Disorder Rarely Unknown (9) Introduction described and anesthesia recovery period. Disorder Prequently Pulmonary angioneurotic edema Unknown (9) Prequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, Cardiac Disorder Prequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, Cardiac Disorder Prequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, Cardiac Disorder Prequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, Cardiac Insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, Cardiac Insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, Cardiac Insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, Cardiac Insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, Cardiac Insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, (5), cardiac insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, (5), cardiac insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, (5), cardiac insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, (5), cardiac insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, (5), cardiac insufficiency (5), (7) Perequently Pulmonary angioneurotic edema Unknown (9) Pep veriod, (5), cardiac insufficiency (6), (7) Pep veriod,		Unknown (9)	Metabolic acidosis (5), hyperkalaemia (5), hyper-	
Unknown (9)  Frequently  Frequ	Mental Disorder	Rarely	Chorea, stimulation, derangement, delirium, fatigue, groan, dysorexia	
Prequently   Headache, exercise, acute spasm, forme tardive spasm, spasm, bucking, muscular reflex and struggle during the period of convalescence   Stromatogenous movement including spasm and opisthotonos during induction, maintenance anesthesia recovery period.   Dizziness and chills and sense of coldness during the period of convalescence   Somnolence, hypertonia, dystonia, paraesthesia, analytosis   Very rarely   Unknown (9)   Involuntary movement   Amblyopia, diplopia and ocular pain   Frequently   Frequently   Frequently   Frequently   Frequently   Pulmonary angioneurotic edema   Unknown (9)   Deep vein (5), cardiac insufficiency (5), (7)   Frequently   Uncommonly   Thrombosis and phlebitis   Premature ventricular contraction, premature atrial contraction, faint, ST segment descent   Unknown (9)   Rarely   Unknown (9)   Respiratory, Thoracic Ductus, Mediastinum Disorder   Frequently   Premature ventricular contraction, premature atrial contraction, faint, ST segment descent   Unknown (9)   Rarely   Uncommonly   Abdominal cramping   Premature ventricular contraction, gyspnea, astigmatism, respiratory failure, throat burning, sneeze, tachypnea, hyperpnea and hypoxia   Unknown (9)   Rarely   Pancreatitis   Uncommonly   Frequently   Pancreatitis   Uncommonly   Filush   Rarely   Pancreatitis   Unknown (9)   Rarely   Pancreatitis   Unknown (9)   Rarely   Pancreatitis   Very rarely   Unknown (9)   Rarely   Unknown (9)   Rarely   Unknown (9)   Rarely   Unknown (9)   Panal insufficiency (5)   Panal and Urinary Disorder   Panal insufficiency (5)   Panal and Urinary Disorder   Panal insufficiency (5)   Panal insufficiency (6)   Pan		Very rarely	Sexual pleasure	
Neurological Disorder  Neurological Disorder  Rarely  Neurological Disorder  Cardiac Disorder  Neurological Disorder  Cardiac Disorder  Neurological Disorder  Rarely  Neurological Disorder  Cardiac Disorder  Neurological Disorder  Rarely  Neurological Disorder  Cardiac Disorder  Neurological Disorder  Neurologi		Linknown (9)		
Neurological Disorder  Neurological Disorder  Rarely  Rarely  Rarely  Rarely  Rarely  Rarely  Rarely  Rarely  Prequently Inconsciousness after surgery  Unknown (9)  Prequently Prequently Prequently Prequently Uncommonly Thrombosis and phyboxis order  Cardiac Disorder  Vascular Disorder  Rarely  Vascular Disorder  Respiratory, Thoracic Ductus, Mediastinum Disorder  Gastrointestina Disorder  Castion and Subcutaneous Tissue  Hepatobiliary Disorder  Misculoskeletal and Connective Tissue Disorder  Rarely  Renal and Urinary Prequently  Rarely  Rarely  Renal and Urinary movement  Rarely  Rarely  Respiratory, Thoracic Ductus, Mediastinum Disorder  Prequently  Rarely  Rubefaction, urticaria  Rarely  Rarely  Rarely  Rarely  Rubefaction, urticaria  Rarely  Rarely  Rarely  Rubefaction, urticaria  Rarely  Rarely  Rarely  Rarely  Rarely  Rarely  Rarely  Rarely  Rubefaction, urticaria  Rarely  Rarely  Rarely  Rarely  Rarely  Rubefaction, urticaria  Rarely  Rubefaction, urticaria  Rarely  Ra		OTIKITOWIT (5)		
Neurological Disorder  Rarely  Dizziness and sense of coldness during the period of convalescence Somnolence, hypertonia, dystonia, paraesthesia, anklylosis Very rarely Unknown (9) Involuntary movement  Eye Disorder  Rarely  Cardiac Disorder  Cardiac Disorder  Vascular Disorder  Rarely Vascular Disorder  Rarely Vascular Disorder  Rarely Vascular Disorder  Rarely Uncommonly Thrombosis and phlebitis Prequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Prequently Unknown (9) Rarely Contraction, faint, ST segment descent Premature ventricular contraction, premature atrial contraction, premature atrial contraction, faint, ST segment descent Prequently Unknown (9) Rarely Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Prequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Prequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Prequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Prequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Prequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Prequently Premature ventricular contraction, premature atrial contraction, distriction, dyspnea, astignatism, respiratory failure, throat burning, sneeze, tachypnea, hyperpinea and hypoxia Unknown (9) Prepative ventraction, discoderation, inspiration, does dependent) Nausea and vomit during the period of convalescence Uncommonly Rarely Prepative ventricular contraction, discoderation, discoderation, uniticaria Prequently Unknown (9) Prepative ventricular contraction, discoderation, melalgia, chest pain, ankylosis in the neck Very rarely Very rarel	Neurological Dis- order	Frequently		
order  Harely  Dizziness and chills and sense of coldness during the period of convalescence Somnolence, hypertonia, dystonia, paraesthesia, ankylosis  Very rarely Unknown (9)  Eye Disorder  Eye Disorder  Amblyopia, diplopia and ocular pain Frequently Frequently Junknown (9) Pulmonary angioneurotic edema Unknown (9) Pulmonary angioneurotic edema Unknown (9) Puepe vein (5), cardiac insufficiency (5), (7) Frequently Hypotension (2), hypertension Uncommonly Thrombosis and phlebitis Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Parenture ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Parenture ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Parenture ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Premature ventricular contraction, formature atrial contraction, faint, ST segment descent Premature ventricular contraction, formature atrial contraction, faint, ST segment descent Premature ventricular contraction, formature atrial faint, septial fain		Rarely	Stromatogenous movement including spasm and opisthotonos during induction, maintenance anesthesia and anesthesia recovery period.	
Skin and Subcutaneous Tissue   Uncommonly   Very rarely   Uncommonly   Very rarely   Unknown (9)   Involuntary movement   Very rarely   Very			the period of convalescence	
Eye Disorder  Rarely Amblyopia, diplopia and ocular pain Frequently Frequent pulse during brachycardia (1) and induction Very rarely Unknown (9) Pep vein (5), cardiac insufficiency (5), (7) Frequently Unknown (9) Pep vein (5), cardiac insufficiency (5), (7) Frequently Uncommonly Thrombosis and phlebitis  Rarely Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Temporary apnea, cough and hiccup during induction Temporary apnea, cough and hiccup during induction Temporary apnea, cough and hiccup during induction Uncommonly Frequently Unknown (9) Frequently Unknown (9) Frequently Uncommonly Frequently Uncommonly Abdominal cramping Rarely Very rarely Pancreatitis Uncommonly Flush Rarely Rubefaction, urticaria  Hepatobiliary Disorder Musculoskeletal and Connective Tissue Disorder Renal and Urinary Disorder Renal Disorder Reselv Renal Disorder Renal Disorder Reselv Renal Reselv Renal Disorder Reselv Resel			Somnolence, hypertonia, dystonia, paraesthesia, ankylosis	
Eye Disorder Cardiac Disorder Very rarely Unknown (9) Cardiac Disorder Very rarely Unknown (9) Cardiac Disorder Cardiac Disorder Very rarely Vascular Disorder Cardiac Disorder Cardiac Disorder Very rarely Vascular Disorder Cardiac Disorder Cardia (1) Cardiac Institution Cardia Disorder Cardia Disorder Cardiac Disorder Cardiac Disorder Cardiac Disorder Cardiac Disorder Cardia Disorder Car		, ,		
Cardiac Disorder    Frequently   Frequent pulse during brachycardia (1) and induction		Unknown (9)		
Cardiac Disorder  Very rarely Unknown (9) Deep vein (5), cardiac insufficiency (5), (7)  Frequently Hypotension (2), hypertension Uncommonly Thrombosis and phlebitis  Rarely Premature ventricular contraction, premature atrial contraction, premature atrial contraction, premature atrial contraction, premature ventricular contraction, premature atrial contraction, premature atrial contraction, premature atrial contraction, premature ventricular contraction, premature atrial contraction, premature ventricular contraction, premature atrial contraction, premature ventricular contraction, descondant premature ventricular contraction, premature ventricular contraction, premature ventricular contraction, premature v	Eye Disorder			
Vascular Disorder  Vascular Disorder  Vascular Disorder  Respiratory, Thoracic Ductus, Mediastinum Disorder  Gastrointestinal Disorder  Skin and Subcutaneous Tissue  Hepatobiliary Disorder  Musculoskeletal and Connective Tissue Disorder  Rarely  Rarely  Rarely  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently  Prespiratory failure, throat burning, sneeze, tachypnea, hyperpana and hypoxia  Unknown (9)  Respiratory failure, throat burning, sneeze, tachypnea, hyperpana and hypoxia  Unknown (9)  Respiratory failure, throat burning, sneeze, tachypnea, hyperpana and hypoxia  Unknown (9)  Frequently  Nausea and vomit during the period of convalescence  Hyperialosis, thirst and aerophagia  Wery rarely  Rarely  Rarely  Rarely  Rarely  Rarely  Nuscle soreness  Unknown (9)  Rarely  Schuria  Rarely  Very rarely  Discoloration of urine after long-term administration  Topalgia during induction (4)  Uncommonly Huncomnonly Huncomnonly Heat, irritability, other pain, cold sense, insensibility  President Hyperial Contraction, discoloration, melalgia, chest pain, ankylosis in the neck  Amination  Discorder  Unknown (9)  Topalgia and edema according to administr		Frequently		
Vascular Disorder    Vascular Disorder   Vascular Disorder   Rarely   Thrombosis and phlebitis	Cardiac Disorder			
Vascular Disorder  Rarely Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently Temporary apnea, cough and hiccup during induction  Paraly Upper airway obstruction, dyspnea, astigmatism, respiratory failure, throat burning, sneeze, tachypnea, hyperpnea and hypoxia  Unknown (9) Respiratory depression (dose dependent)  Frequently Nausea and vomit during the period of convalescence Uncommonly Abdominal cramping  Rarely Hypersialosis, thirst and aerophagia  Very rarely Pancreatitis  Uncommonly Flush  Rarely Rubefaction, urticaria  Hepatobiliary Disorder  Musculoskeletal and Connective Tissue Disorder  Renal and Urinary Disorder  Rarely Unknown (9) Renal insufficiency (5)  Farely Unknown (9) Renal insufficiency (5)  Farely Tinnitus  Very frequently Topalgia during induction (4)  Uncommonly Heat, irritability, other pain, cold sense, insensibility  Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Necrosis of skin tissues according to administration other than the blood vessel (10)  Unknown (9) Brugada type ECG(5), (6)		Unknown (9)	1 7: 7	
Rarely Premature ventricular contraction, premature atrial contraction, faint, ST segment descent Frequently Temporary apnea, cough and hiccup during induction Temporary and hypoxia Temporary apnea and hypoxia Temporary apnea and hypoxia Temporary apnea, cough and hypoxia Temporary apnea and hypoxia Temporary apnea and hypoxia Temporary apnea and hypoxia Tempor		Frequently		
Rarely Premature ventricular contraction, premature atrial contraction, faint, ST segment descent  Frequently Temporary apnea, cough and hiccup during induction  Rarely Upper airway obstruction, dyspnea, astigmatism, respiratory failure, throat burning, sneeze, tachypnea, hyperpnea and hypoxia  Unknown (9) Respiratory depression (dose dependent)  Frequently Nausea and vomit during the period of convalescence  Uncommonly Abdominal cramping  Rarely Hypersialosis, thirst and aerophagia  Very rarely Pancreatitis  Uncommonly Flush  Rarely Rubefaction, urticaria  Hepatobiliary Disorder  Musculoskeletal and Connective Tissue Disorder  Renal and Urinary Disorder  Renal and Urinary Disorder  General Disorder  General Disorder  General Disorder and Administration  Parely Uncommonly Heat, irritability, other pain, cold sense, insensibility  Very rarely Very rarely other than the blood vessel (10)  Unknown (9) Topalgia and edema according to administration other than the blood vessel  Unknown (9) Brugada type ECG(5), (6)	Vascular Disorder	Uncommonly		
Respiratory, Thoracic Ductus, Mediastinum Disorder  Gastrointestinal Disorder  Gastrointestinal Disorder  Skin and Subcutaneous Tissue  Hepatobiliary Disorder  Musculoskeletal and Connective Tissue Disorder  Rarely Muscle soreness  Henal and Urinary Disorder  General Disorder  General Disorder  General Disorder  General Disorder  General Disorder  Rarely Very rarely Uncommonly Earand Administration Part Disorder  Laboratory Examination  Rarely Uncommonly Flush  Rarely Muscle soreness  Unknown (9) Repairatory depression (dose dependent)  Nausea and vomit during the period of convalescence  Uncommonly Abdominal cramping  Hypersialosis, thirst and aerophagia  Pancreatitis  Uncommonly Flush  Rarely Rubefaction, urticaria  Unknown (9) Liver hypertrophy (5)  Muscle soreness  Unknown (9) Rhabdomyolysis (3), (5)  Rarely Unknown (9) Renal insufficiency (5)  Ear and Labyrinthine Disorder  General Disorder  Wery frequently Uncommonly Heat, irritability, other pain, cold sense, insensibility  Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Necrosis of skin tissues according to administration other than the blood vessel (10)  Unknown (9) Brugada type ECG(5), (6)	vasculai bisordei	Rarely	Premature ventricular contraction, premature atrial contraction, faint, ST segment descent	
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Skin and Subcutaneous Tissue  Rarely Hepatobiliary Disorder  Musculoskeletal and Connective Tissue Disorder  Renal and Urinary Disorder  Barely  Rarely Muscle soreness Unknown (9)  Rarely Muscle soreness Unknown (9)  Rarely Unknown (9)  Rarely Unknown (9)  Rarely Ischuria  Penal and Urinary Disorder  Rarely Very rarely Unknown (9)  Renal insufficiency (5)  Farely Unknown (9)  Rarely Tinnitus  Very frequently Uncommonly Heat, irritability, other pain, cold sense, insensibility Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck Very rarely Unknown (9)  Unknown (9)  Unknown (9)  Topalgia and edema according to administration other than the blood vessel  Laboratory Examination  Damage, Toxic, Pro-  Very rarely Very rarely Pursois effer surgery	Gastrointestinal	Uncommonly	Abdominal cramping	
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Rarely Rubefaction, urticaria  Hepatobiliary Disorder  Musculoskeletal and Connective Tissue Disorder  Renal and Urinary Disorder  Renal and Urinary Disorder  Renal Labyrinthine Disorder  General Disorder  General Disorder  General Disorder  General Disorder  General Disorder  General Disorder  Laboratory Examination  Damage, Toxic, Pro-  Damage, Toxic, Pro-  Muscle soreness  Muscle soreness  Muscle soreness  Muscle soreness  Invertigation, urticaria  Rubefaction, urticaria  Rubefaction, urticaria  Rubefaction, urticaria  Rubefaction, urticaria  Rubefaction, urticaria  Invertigation, urticaria  Rarely  Liver hyppertrophy (5)  Muscle soreness  Unknown (9)  Rhabdomyolysis (3), (5)  Rarely  Discoloration of urine after long-term administration  of urine after long-term administration  of urine after long-term administration  Topalgia during induction (4)  Uncommonly  Heat, irritability, other pain, cold sense, insensibility  Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Very rarely  Very rarely  Necrosis of skin tissues according to administration other than the blood vessel (10)  Unknown (9)  Topalgia and edema according to administration other than the blood vessel  Laboratory Examination  Damage, Toxic, Pro-		Very rarely	Pancreatitis	
Rarely Rubefaction, urticaria  Hepatobiliary Disorder  Musculoskeletal and Connective Tissue Disorder  Renal and Urinary Disorder  Renal and Urinary Disorder  Renal Labyrinthine Disorder  General Disorder  General Disorder  General Disorder  General Disorder  General Disorder  General Disorder  Laboratory Examination  Damage, Toxic, Pro-  Damage, Toxic, Pro-  Muscle soreness  Muscle soreness  Muscle soreness  Muscle soreness  Invertigation, urticaria  Rubefaction, urticaria  Rubefaction, urticaria  Rubefaction, urticaria  Rubefaction, urticaria  Rubefaction, urticaria  Invertigation, urticaria  Rarely  Liver hyppertrophy (5)  Muscle soreness  Unknown (9)  Rhabdomyolysis (3), (5)  Rarely  Discoloration of urine after long-term administration  of urine after long-term administration  of urine after long-term administration  Topalgia during induction (4)  Uncommonly  Heat, irritability, other pain, cold sense, insensibility  Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Very rarely  Very rarely  Necrosis of skin tissues according to administration other than the blood vessel (10)  Unknown (9)  Topalgia and edema according to administration other than the blood vessel  Laboratory Examination  Damage, Toxic, Pro-	Skin and Subcu- taneous Tissue	Uncommonly	Flush	
Hepatobiliary Disorder  Musculoskeletal and Connective Tissue Disorder  Renal and Urinary Disorder  Ear and Labyrinthine Disorder  General Disorder  General Disorder  General Disorder  General Disorder  General Disorder  General Disorder  Laboratory Examination  Laboratory Examination  Damage, Toxic, Pro-  Muscle soreness  Muscle soreness  Muscle soreness  Muscle soreness  Inknown (9)  Muscle soreness  Inknown (9)  Rarely  Muscle soreness  Inknown (9)  Rarely  Discoloration of urine after long-term administration  Inknown (9)  Rarely  Topalgia during induction (4)  Uncommonly  Heat, irritability, other pain, cold sense, insensibility  Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Necrosis of skin tissues according to administration other than the blood vessel (10)  Unknown (9)  Topalgia and edema according to administration other than the blood vessel  Unknown (9)  Brugada type ECG(5), (6)		,	Rubefaction, urticaria	
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and Connective Tissue Disorder  Renal and Urinary Disorder  Renal Labyrinthine Disorder  General Disorder and Administration Part Disorder  Laboratory Examination  Laboratory Examination  Laboratory Examination  Disorder  Unknown (9)  Rarely Discoloration of urine after long-term administration further after long-term administration further and start long place of the properties of units and start longer and st		` '	***	
Renal and Urinary Disorder  Rarely   Ischuria   Very rarely   Discoloration of urine after long-term administration   Unknown (9)   Renal insufficiency (5)    Ear and Labyrinthine Disorder   Rarely   Topalgia during induction (4)   Uncommonly   Heat, irritability, other pain, cold sense, insensibility   Rarely   Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck   Very rarely   Very rarely   Unknown (9)   Topalgia and edema according to administration other than the blood vessel (10)    Laboratory Examination   Unknown (9)   Brugada type ECG(5), (6)    Damage, Toxic, Pro-				
Renal and Urinary Disorder  Very rarely Unknown (9) Renal insufficiency (5)  Ear and Labyrinthine Disorder  General Disorder  General Disorder Administration Part Disorder  Laboratory Examination  Laboratory Examination  Damage, Toxic, Pro-  Very rarely Discoloration of urine after long-term administration  Topalgia during induction (4)  Heat, irritability, other pain, cold sense, insensibility  Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Necrosis of skin tissues according to administration other than the blood vessel (10)  Topalgia and edema according to administration other than the blood vessel  Unknown (9) Brugada type ECG(5), (6)		- (-/		
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Ear and Labyrinthine Disorder  Rarely  Very frequently Topalgia during induction (4) Uncommonly Heat, irritability, other pain, cold sense, insensibility  Rarely Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Very rarely Very rarely Very rarely Unknown (9)  Laboratory Examination  Damage, Toxic, Pro- Very rarely  Renal insufficiency (5)  Tinnitus  Topalgia during induction (4) Heat, irritability, other pain, cold sense, insensibility Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Necrosis of skin tissues according to administration other than the blood vessel  Unknown (9)  Brugada type ECG(5), (6)				
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General Disorder and Administration Part Disorder  Uncommonly Heat, irritability, other pain, cold sense, insensibility  Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Very rarely Necrosis of skin tissues according to administration other than the blood vessel (10)  Unknown (9) Topalgia and edema according to administration other than the blood vessel  Laboratory Examination  Damage, Toxic, Pro-	Ear and Labyrinthine Disorder	Rarely	Tinnitus	
General Disorder and Administration Part Disorder  Unknown (9)  Harely Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck  Necrosis of skin tissues according to administration other than the blood vessel (10)  Topalgia and edema according to administration other than the blood vessel  Unknown (9)  Brugada type ECG(5), (6)  Damage, Toxic, Pro-				
and Administration Part Disorder  Very rarely  Necrosis of skin tissues according to administration other than the blood vessel (10)  Unknown (9)  Topalgia and edema according to administration other than the blood vessel  Unknown (9)  Brugada type ECG(5), (6)  Damage, Toxic, Pro-		Uncommonly		
tion Part Disorder  Very rarely  Very rarely  Very rarely  Unknown (9)  Laboratory Examination  Damage, Toxic, Pro-  Very rarely  Very rarely  Necrosis of skin tissues according to administration other than the blood vessel (10)  Topalgia and edema according to administration other than the blood vessel  Brugada type ECG(5), (6)	and Administra-	Rarely	Phlebitis, rash, itchiness, rubefaction, discoloration, melalgia, chest pain, ankylosis in the neck	
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amination Officiowii (9) Brugada type ECG(9), (0)  Damage, Toxic, Pro-		Unknown (9)	Topalgia and edema according to administration other than the blood vessel	
Damage, Toxic, Procedural Complication Very rarely Pyrexia after surgery	amination	Unknown (9)	Brugada type ECG(5), (6)	
	Damage, Toxic, Pro- cedural Complication	Very rarely	Pyrexia after surgery	



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- 1) Cases of serious bradycardia are rare. There have been reports of cases of asystole.
- 2) Occasionally, the use of intravenous administration fluids and decrease in the rate of administration of this drug may be required due to hypotension.
- 3) When this drug is administered in exceeded capacity of 4 mg/hr per kg for sedation at the intensive care unit, a very rare case of rhabdomyolysis may occur.
- 4) It may be minimized when injected into the thick veins of the forearm and the cubital. The pain in the site of injection may be minimized through co-administration of lidocaine.
- 5) The complex manifestation of the relevant condition reported as "propofol intravenous infusion syndrome" may be observed in critical patients with risk factors.
- 6) Brugada type ECG: Elevated ST-segment and coved T-wave
- 7) Rapidly developing cardiac insufficiency in adults (Sometimes may be fatal). In this case, cardiac insufficiency usually does not respond to inotropic supportive care.
- 8) Abuse and dependence of this drug are usually seen in health care workers.
- 9) The frequency was marked as 'unknown' cause it could not be measured from the valid clinical trial materials.
- 10) Necrosis was reported in the case of damage in the viability of the tissue.

Reporting of suspected adverse reactions: It is important to report any suspected adverse reactions that occur after the approval of this drug. This allows to continuously check the benefit/risk balance of this drug. Health care workers report suspected adverse events through the National Reporting System. As a result of analyzing the report on domestic harmful drug cases (1989  $\sim$  first half of 2013), the following cases showed statistically significant harmful cases compared to harmful cases reported in other drugs. However, this does not mean that the casual relationship between the relevant component and the following harmful cases have been proven.

11) Psychoneural: Drug abuse

12) Cardiac: Cyanosis

13) Other: Death (Includes cases of death due to drug abuse)

## 4.9. Overdose

- 1) Accidental overdosage is likely to cause cardiorespiratory depression. Respiratory depression can be treated by artificial ventilation with oxygen.
- 2) Cardiovascular depression would require lowering of the patient's head and, if severe, use of plasma expanders and pressor agents.

#### 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

ATC code: PROPOFOL / N01AX10

The product contains propofol as an active ingredient and it is dependent upon the therapeutic blood propofol concentrations. Steady-state propofol blood concentrations are generally proportional to infusion rates. Undesirable side effects, such as cardiorespiratory depression, are likely to occur at higher blood concentrations which result from bolus dosing or rapid increases in infusion rates. An adequate interval (3 to 5 minutes) must be allowed between dose adjustments in order to assess clinical effects.



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## 5.2. Pharmacokinetic properties

Not applicable.

## 5.3. Preclinical safety data

Not applicable

### 6. PHARMACEUTICAL PARTICULARS

## 6.1. List of excipients

Refined soybean oil
Medium chain triglycerides
Purified egg yolk lecithin
Oleic acid
Sodium hydroxide
Glycerin
Disodium edetate hydrate

## **6.2** Incompatibilities

Water for Injection

Not applicable

#### 6.3 Shelf life

36 months

## 6.4 Special precautions for storage

Store in a hermetic container ( $2 \sim 25$ °C). It shall not be frozen.

#### 6.5 Nature and contents of container

12mL, 15mL, 20mL/vial X 5 or 10 vials/Box 50mL/vial X 1 vial/Box

## 6.6 Instructions for use/handling

No special requirements.

## 7. Marketing authorisation holder

Daewon Pharm. Co., Ltd.

24 Jeyakgongdan 1-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea

## 8. Marketing authorisation number(s)

No. 19

## 9. Date of first authorisation/renewal of the authorization

Dec. 23, 2014 / Sep. 18, 2018

## 10. Date of revision of the text

Apr. 24, 2020