

הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך: 6.3.17

שם תכשיר באנגלית ומספר רישום: Propofol 1% MCT Fresenius

156-46-34397-00, 156-46-34397-01, 156-46-34397-02

שם בעל הרישום: Cure Medical & Technical Supply

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

פרק בעלון	טקסט נוכחי	טקסט חדש
4. CLINICAL PARTICULARS 4.2 Posology and method of administration 4.4 Special warnings and precautions for use		<p>Administration of Propofol 1% MCT Fresenius by a Target Controlled Infusion system is restricted to induction and maintenance of general anaesthesia in adults. It is not recommended for use in ICU sedation or sedation for surgical and diagnostic procedures.</p> <p>Delayed epileptiform attacks may occur even in non-epileptic patients, the delay periods ranging from a few hours to several days.</p>

Cardiac, circulatory or pulmonary insufficiency and hypovolaemia should be compensated before administration of propofol.

Propofol should not be administered in patients with advanced cardiac failure or other severe myocardial disease except with extreme caution and intensive monitoring.

Due to a higher dosage in patients with severe overweight the risk of haemodynamic effects on the cardiovascular system should be taken into consideration.

Before anaesthesia of an epileptic patient, it should be checked that the patient has received the antiepileptic treatment.

Patients with a high intracranial pressure

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.

Due to the limited data available, the use of target controlled infusion (TCI) in the paediatric population below 2 years of age cannot be recommended.

Pain on the injection site

To reduce pain on the injection site during induction of anaesthesia with Propofol 1% MCT Fresenius, lidocaine can be injected prior to the propofol emulsion (see section 4.2).

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

<p>Profound hypotension has been reported following anaesthetic induction with propofol in patients treated with rifampicin.</p> <p>After administration of Propofol 1% MCT Fresenius, the patient should be kept under observation for an appropriate period of time. The patient should be instructed not to drive, operate machinery, or work in potentially hazardous situations. The patient should not be allowed to go home unaccompanied, and should be instructed to avoid consumption of alcohol.</p> <p>See Table 1</p>	<p>See Table 2</p>	<p>4.5 Interaction with other medicinal products and other forms of interaction</p> <p>4.7 Effects on ability to drive and use machines</p> <p>4.8 Undesirable effects</p>
<p>Due to the limited data available, the use of target controlled infusion (TCI) in the paediatric population below 2 years of age cannot be recommended.</p>		<p>5. PHARMACOLOGICAL PROPERTIES</p> <p>5.2 Pharmacokinetic properties</p>

מצ"ב העלון, שבו מסומנות החמרות המבוקשות על רקע צהוב.

שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

Table 1

System Organ Class	Frequency	Undesirable Effects
Immune system disorders:	Very rare (<1/10 000)	Anaphylaxis – may include angioedema, bronchospasm, erythema and hypotension

Metabolism and Nutritional disorder:	Frequency not known ⁽⁹⁾	Metabolic acidosis ⁽⁵⁾ , hyperkalaemia ⁽⁵⁾ , hyperlipidaemia ⁽⁵⁾
Psychiatric disorders:	Frequency not known ⁽⁹⁾	Euphoric mood, sexual disinhibition. Drug abuse and drug dependence ⁽⁸⁾
Nervous system disorders:	Common (>1/100, <1/10)	Headache during recovery phase
	Rare (>1/10 000, <1/1000)	Epileptiform movements, including convulsions and opisthotonus during induction, maintenance and recovery.
	Very rare (<1/10 000)	Postoperative unconsciousness
	Frequency not known ⁽⁹⁾	Involuntary movements
Cardiac disorders:	Common (>1/100, <1/10)	Bradycardia ⁽¹⁾
	Very rare (<1/10 000)	Pulmonary oedema
	Frequency not known ⁽⁹⁾	Cardiac arrhythmia ⁽⁵⁾ , cardiac failure ^{(5), (7)}
Vascular disorders:	Common (>1/100, <1/10)	Hypotension ⁽²⁾

	Uncommon ($>1/1000$, $<1/100$)	Thrombosis and phlebitis
Respiratory, thoracic and mediastinal disorders:	Common ($>1/100$, $<1/10$)	Transient apnoea,
	Frequency not known ⁽⁹⁾	Respiratory depression (dose dependant)
Gastrointestinal disorders:	Common ($>1/100$, $<1/10$)	Nausea and vomiting during recovery phase
	Very rare ($<1/10\ 000$)	Pancreatitis
Hepatobiliary disorders	Frequency not known ⁽⁹⁾	Hepatomegaly ⁽⁵⁾
Musculoskeletal and connective tissue disorders:	Frequency not known ⁽⁹⁾	Rhabdomyolysis ^{(3), (5)}
Renal and urinary disorders	Very rare ($<1/10\ 000$)	Discolouration of urine following prolonged administration
	Frequency not known ⁽⁹⁾	Renal failure ⁽⁵⁾
General disorders and administration site conditions:	Very common ($>1/10$)	Local pain on induction ⁽⁴⁾
	Very rare ($<1/10\ 000$)	Tissue necrosis ⁽¹⁰⁾ following accidental extravascular administration

	Frequency not known ⁽⁹⁾	Local pain, swelling, following accidental extravascular administration
<i>Investigations</i>	Frequency not known ⁽⁹⁾	Brugada type ECG ^{(5), (6)}
<i>Injury, poisoning and procedural complications:</i>	Very rare ($<1/10\ 000$)	Postoperative fever

Table 2

System Organ Class	Frequency	Undesirable Effects
<i>Immune disorders:</i> system	Very rare ($<1/10\ 000$)	Anaphylaxis – may include angioedema, bronchospasm, erythema and hypotension
<i>Metabolism and Nutritional disorder:</i>	Frequency not known ⁽⁹⁾	Metabolic acidosis ⁽⁵⁾ , hyperkalaemia ⁽⁵⁾ , hyperlipidaemia ⁽⁵⁾
<i>Psychiatric disorders:</i>	Frequency not known ⁽⁹⁾	Euphoric mood, sexual disinhibition. Drug abuse and drug dependence ⁽⁸⁾
<i>Nervous disorders:</i> system	Common ($>1/100$, $<1/10$)	Headache during recovery phase
	Rare ($>1/10\ 000$, $<1/1000$)	Epileptiform movements, including convulsions and opisthotonus during induction, maintenance and recovery.
	Very rare ($<1/10\ 000$)	Postoperative unconsciousness
	Frequency not known ⁽⁹⁾	Involuntary movements

Cardiac disorders:	Common (>1/100, <1/10)	Bradycardia ⁽¹⁾
	Very rare (<1/10 000)	Pulmonary oedema
	Frequency not known ⁽⁹⁾	Cardiac arrhythmia ⁽⁵⁾ , cardiac failure ^{(5), (7)}
Vascular disorders:	Common (>1/100, <1/10)	Hypotension ⁽²⁾
	Uncommon (>1/1000, <1/100)	Thrombosis and phlebitis
Respiratory, thoracic and mediastinal disorders:	Common (>1/100, <1/10)	Transient apnoea, during induction
	Frequency not known ⁽⁹⁾	Respiratory depression (dose dependant)
Gastrointestinal disorders:	Common (>1/100, <1/10)	Nausea and vomiting during recovery phase
	Very rare (<1/10 000)	Pancreatitis
Hepatobiliary disorders	Frequency not known ⁽⁹⁾	Hepatomegaly ⁽⁵⁾
Musculoskeletal and connective tissue disorders:	Frequency not known ⁽⁹⁾	Rhabdomyolysis ^{(3), (5)}
Renal and urinary disorders	Very rare (<1/10 000)	Discolouration of urine following prolonged administration
	Frequency not known ⁽⁹⁾	Renal failure ⁽⁵⁾
General disorders and administration site conditions:	Very common (>1/10)	Local pain on induction ⁽⁴⁾

	Very rare ($<1/10\,000$)	Tissue necrosis ⁽¹⁰⁾ following accidental extravascular administration
	Frequency not known ⁽⁹⁾	Local pain, swelling, following accidental extravascular administration
<i>Investigations</i>	Frequency not known ⁽⁹⁾	Brugada type ECG ^{(5), (6)}
<i>Injury, poisoning and procedural complications:</i>	Very rare ($<1/10\,000$)	Postoperative fever

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