הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך: 3.3.17

שם תכשיר באנגלית ומספר רישום: Propofol 1% Fresenius 1g100 ml emulsion for injection or infusion
121-62-30136-00, 121-62-30136-01, 121-62-30136-02

שם בעל הרישום: Cure Medical & Technical Supply

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
4. CLINICAL PARTICULARS **4.4 Special warnings and precautions for use**		Delayed epileptiform attacks may occur even in non-epileptic patients, the delay period ranging from a few hours to several days. 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. Concomitant use of benzodiazepines, parasympatholytic agents or inhalational anaesthetics has been reported to prolong the anaesthesia and to reduce the respiratory rate. After additional premedication with opioids, the sedative effects of propofol may be intensified and prolonged, and there may be a higher incidence and longer duration of apnoea. It should be taken into consideration that concomitant use of propofol and medicinal products for premedication, inhalation agents or analgesic agents may potentiate anaesthesia and cardiovascular side effects. Concomitant use of central nervous system depressants (e.g. alcohol, general anaesthetics, narcotic analgesics) will result in intensification of their sedative effects. When Propofol 1% Fresenius is combined with centrally depressant drugs administered		**4.5 Interaction with other medicinal products and other forms of interaction**

parenterally, severe respiratory and cardiovascular depression may occur. After administration of fentanyl, the blood level of propofol may be temporarily increased with an increase in the rate of apnoea. Bradycardia and cardiac arrest may occur after treatment with suxamethonium or neostigmine. Leucoencephalopathy has been reported with administration of lipid emulsions as used for Propofol 1% Fresenius in patients receiving cyclosporine. High doses (more than 2.5 mg propofol/kg bodyweight for induction or 6 mg propofol/kg bodyweight/h for maintenance of anaesthesia) should be avoided. After administration of Propofol 1%, 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. See Table 1	See Table 2	**4.6 Fertility, Pregnancy and lactation** **4.7 Effects on ability to drive and use machines** **4.8 Undesirable effects**

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

Table 1

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

Table 2

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