הודעה על החמרה (מידע בטיחות) בעלון לצרכן

תאריך: 29.11.2016

שם תכשיר באנגלית ומספר הרישום:

Ondansetron – Fresenius Reg. No. 148-94-33550-00

שם בעל הרישום: תרימה, תוצרי רפואה ישראליים מעברות בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
Paediatric population ***PONV in children aged ≥ 1 month and adolescents*** For prevention of PONV in paediatric patients having surgery performed under general anaesthesia, a single dose of ONDANSETRON – FRESENIUS may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg either prior to, at or after induction of anaesthesia. For the treatment of PONV after surgery in paediatric patients having surgery performed under general anaesthesia, a single dose of ONDANSETRON – FRESENIUS may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg. There are no data from clinical trials -on the use of Ondansetron in the treatment of PONV in children below 2 years of age.	***Paediatric population*** ***PONV in children aged ≥ 1 month and adolescents*** For prevention of PONV in paediatric patients having surgery performed under general anaesthesia, a single dose of ONDANSETRON – FRESENIUS may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg either prior to, at or after induction of anaesthesia. For the treatment of PONV after surgery in paediatric patients having surgery performed under general anaesthesia, a single dose of ONDANSETRON – FRESENIUS may be administered by slow intravenous injection (not less than 30 seconds) at a dose of 0.1mg/kg up to a maximum of 4mg. There are no data on the use of Ondansetron in the treatment of PONV in children below 2 years of age.	**Posology and Method of Administration**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il).		**Undesirable Effects**
Paediatric population Pediatric cases consistent with serotonin syndrome have been reported after inadvertent oral overdoses of ondansetron (exceeding estimated ingestion of 4 mg/kg) in infants and children aged 12 months to 2 years. Reported symptoms included somnolence, agitation, tachycardia, tachypnea, hypertension, flushing, mydriasis, diaphoresis, myoclonic movements, horizontal nystagmus, hyperreflexia, and seizure. Patients required supportive care, including intubation in some cases, with complete recovery without sequelae within 1 to 2 days	Paediatric population Pediatric cases consistent with serotonin syndrome have been reported after inadvertent oral overdoses of ondansetron (exceeding estimated ingestion of 5 mg/kg) in young children. Reported symptoms included somnolence, agitation, tachycardia, tachypnea, hypertension, flushing, mydriasis, diaphoresis, myoclonic movements, horizontal nystagmus, hyperreflexia, and seizure. Patients required supportive care, including intubation in some cases, with complete recovery without sequelae within 1 to 2 days	**Overdose**

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.

הועבר בדואר אלקטרוני בתאריך 29.11.16.

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