

הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך 30/01/2017

שם התכשיר באנגלית ומספר הרישום

Marcaine 0.5% (046 89 23721 01)

שם בעל הרישום Tec-O-Pharm-Libra Ltd

טופס זה מיועד לפרוט החמרות בלבד!

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
Retrobulbar and peribulbar injections with local anaesthetic agents may involve some risk of persistent ocular muscle dysfunction.	Retro- and peribulbar injections with local anaesthetics may involve some risk of persistent ocular muscle dysfunction.	
<p>There have been post-marketing reports of chondrolysis in patients who have received continuous intra-articular infusion of local anaesthetics postoperatively. The majority of the cases reported involved chondrolysis in the shoulder joint. It has not been possible to establish a clear causal link due to several contributory factors. There is also inconsistency in the scientific literature regarding the mechanism of action. Continuous intra-articular infusion is not an approved indication for Marcaine.</p> <p>Paediatric population The safety and efficacy of Marcaine in children aged < 1 year has not been established. Only limited data are available.</p> <p>Use of bupivacaine for intra-articular block in children aged 1 to 12 years has not been documented.</p> <p>Use of bupivacaine for major nerve block in children aged 1 to 12 years has not been documented.</p> <p>For epidural anaesthesia, children should be administered gradually increasing</p>		

doses proportional to their age and weight, since thoracic epidural anaesthesia in particular can result in severe hypotonia and decreased respiratory function.		
Paediatric population Side effects in children are similar to those in adults, but early signs of local anaesthetic toxicity in children may be difficult to detect in cases where the blockade is given under sedation or general anaesthesia.		Undesirable effects
If circulatory shock occurs ... intravenous fluids vasopressors, inotropes and/or lipid emulsions should be considered. Administer IV fluids ... (initially 0.05 µg/kg/min...)	If circulatory depression occurs, give intravenous fluids, dobutamine and if necessary noradrenaline (initially 5 µg/kg/minute,	
Solution without preservatives should be used straight after the packaging has been opened.	Solution without preservative must be used as soon as possible after the container has been opened.	Shelf-life