

הודעה על עדכון עלון לרופא**ROCURIM***(Rocuronium bromide 10 mg/ml)***חברת אוניפארם סחר בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר**

בפירוט שלהלן כלולים העדכונים המהותיים בלבד. עדכונים שאינם מהותיים, אינם כלולים בהודעה זו. למידע מלא, יש לעיין בעלון. תוספת המידע מסומנת בצבע כחול, החמרה מודגשת בצבע צהוב והסרות המידע מופיעות בקו חוצה.

ההתוויה המאושרת:

Rocurim is indicated in adult and paediatric patients (from term neonates to adolescents [0 to <18 years]) as an adjunct to general anaesthesia to facilitate tracheal intubation during routine sequence induction and to provide skeletal muscle relaxation during surgery. In adults, **Rocurim** is also indicated to facilitate tracheal intubation during rapid sequence induction and as an adjunct in the intensive care unit (ICU) to facilitate intubation and mechanical ventilation.

עדכונים מהותיים בעלון לרופא:**4.2 Posology and method of administration**Posology

..Consequently, adjustments with **Rocurim** should be made by administering smaller maintenance doses at less frequent intervals or by using lower infusion rates of **Rocurim** during long-lasting procedures (longer than 1 hour) under inhalational anaesthesia (see section 4.5).

Risk of Medication Errors: Accidental administration of neuromuscular blocking agents may result in serious adverse events, including fatal outcomes.....

5.1 Pharmacodynamic propertiesPaediatric population

Mean onset time in toddlers and children at an intubation dose of 0.6 mg/kg is slightly shorter than in adults. Comparison within paediatric age groups showed that the mean onset time in neonates and adolescents (1.0 min.) is slightly longer than in infants, toddlers and children (0.4, 0.6 and 0.8 min., respectively). The duration of relaxation and the time to recovery tend to be shorter in children compared to infants and adults. Comparing within paediatric age groups demonstrated that mean time to reappearance of T3 was prolonged in neonates and infants (56.7 and 60.7 min., respectively) when compared to toddlers, children and adolescents (45.4, 37.6 and 42.9 min., respectively).

Mean (SD) time to onset and clinical duration following 0.6 mg/kg rocuronium initial intubating dose* during sevoflurane/nitrous oxide and isoflurane/nitrous oxide (maintenance) anaesthesia (Paediatric patients) PP group

	Time to maximum block ** (min)	Time to reappearance of T3 ** (min)
Neonates (0-27 days) n=10	0.98 (0.62)	56.69 (37.04) n=9
Infants (28 days-2 months) n=11	0.44 (0.19) n=10	60.71 (16.52)
Toddler (3 months-23 months) n=28	0.59 (0.27)	(12.94) 45.46 n=27
Children (2-11 years) n=34	0.84 (0.29)	37.58 (11.82)
Adolescents (12-17 years) n=31	0.98 (0.38)	42.90 n=30

* Dose of rocuronium administered within 5 seconds.

** Calculated from the end of administration of the rocuronium intubating dose

5.2 Pharmacokinetic properties

Paediatric population

Pharmacokinetics of rocuronium bromide in paediatric patients (n=146) with ages ranging from 0 to 17 years were evaluated using a population analysis of the pooled pharmacokinetic datasets from two clinical trials under sevoflurane (induction) and isoflurane/nitrous oxide (maintenance) anesthesia. All pharmacokinetic parameters were found to be linearly proportional to body weight illustrated by a similar clearance (l.hr⁻¹.kg⁻¹). The volume of distribution (l.kg⁻¹) and elimination half-life (h) decrease with age (years). The pharmacokinetic parameters of typical paediatrics within each age group are summarized below:

Estimated PK parameters (Mean [SD]) of rocuronium bromide in typical paediatric patients during sevoflurane and nitrous oxide (induction) and isoflurane/nitrous oxide (maintenance anaesthesia)

PK Parameters	Patient age range				
	Term newborn infants (0-27 days)	Infants (28 days to 2 months)	Toddlers (3-23 months)	Children (2-11 years)	Adolescents (12-17 years)
CL (L/kg/hr)	0.31 (0.07)	0.30 (0.08)	0.33 (0.10)	0.35 (0.09)	0.29 (0.14)
Volume of distribution (L/kg)	0.42 (0.06)	0.31 (0.03)	0.23 (0.03)	0.18 (0.02)	0.18 (0.01)
t _{1/2β} (hr)	1.1 (0.2)	0.9 (0.3)	0.8 (0.2)	0.7 (0.2)	0.8 (0.3)

בעלון לרופא היו עדכונים נוספים שאינם מהותיים ואינם נכללים בהודעה זו. העלון לרופא מפורסם במאגר התרופות שבאתר האינטרנט של משרד הבריאות www.health.co.il וניתן לקבלו מודפס ע"י פניה לבעל הרישום.

לדיווח על תופעות לוואי בשימוש בתכשירנו, ניתן לפנות טלפוניית **03-6135050**, בפקס **03-6135151** או אנא השאירו פרטי זיהוי מלאים על מנת שנוכל ליצור קשר בדואר האלקטרוני: safety_first@unipharm.co.il: להשלמת פרטים במידת הצורך.