

04-2022

Ropivacaine Fresenius 2 mg /ml solution for Injection

רופיוקאין פרזניוס 2 מג'/מלי תמיסה להזרקה

Solution for injection
Epidural ,Perineural

Ropivacaine Fresenius 2 mg /ml solution for Infusion

רופיוקאין פרזניוס 2 מג'/מלי תמיסה ל עירוי

Solution for Infusion
Epidural ,Perineural

חומר פעיל:

Ropivacaine Hydrochloride 2 mg /ml

רופא/ה, רוקח/ת נכבד/ה,

- חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשירים:

Ropivacaine Fresenius 2 mg /ml solution for Injection , Ropivacaine Fresenius 2 mg /ml solution for Infusion

- עלון התכשירים עודכן ב 04-2022
- בהודעה זו כלולים שינויי בטיחות מהותיים שמופיעים **בכחול** -טקסט חדש מופיע **בכחול** , טקסט שהוסר מופיע **באדום** עם **קו-חוצה** , טקסט שעובר מקום מופיע **בירוק**

להלן נוסח ההתוויות המאושרות לתכשיר:

Acute pain management:

In adults and adolescents above 12 years of age for:

- Continuous epidural infusion or intermittent bolus administration during postoperative or labour pain.
- Field blocks.

Peripheral nerve block via continuous infusion or intermittent bolus injections, e.g: postoperative pain management.

העדכונים נעשו בסעיפים הבאים:

4.4 Special warnings and precautions for use

Cardiovascular

Epidural and intrathecal anaesthesia may lead to hypotension and bradycardia .Hypotension should be treated promptly with a vasopressor intravenously , and with adequate vascular filling.

4.8 Undesirable effects

Table of adverse reactions

The following frequencies are used for the description of the occurrence of adverse reactions: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$) and not known (cannot be estimated from the available data)

System Organ class	Frequency	Undesirable effects
Nervous system disorders	Not known	Dyskinesia
General Disorders and Administration Site Conditions	common	chills

6.3 Shelf -life

Ropivacaine Fresenius 2 mg /ml solution for infusion /injection

Shelf life after first opening:

From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C.

6.4 Special precautions for storage

Ropivacaine Fresenius 2 mg/ml solution for infusion

Store below 30 25 °C.

Ropivacaine Fresenius 2 mg/ml solution for injection

Store below 30 °C.

6.6 Special precautions for disposal and other handling

Ropivacaine Fresenius 2 mg/ml solution for infusion

The solution for infusion is preservative free and is intended for single use only .Discard any unused solution .

~~From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C.~~

Ropivacaine solution for infusion in plastic infusion bag is chemically and physically compatible with the following drugs:

Concentration of Ropivacaine Fresenius: 1-2 mg/ml	
Additive	Concentration*
Fentanyl citrate	1.0 - 10.0 microgram/ml
Sufentanil citrate	0.4 - 4.0 microgram/ml
Morphine sulfate	20.0 - 100 microgram/ml
Clonidine hydrochloride	5.0 - 50 microgram/ml

* The concentration ranges stated in the table are wider than those used in clinical practice. Epidural infusions of Ropivacaine Fresenius/sufentanil citrate, Ropivacaine Fresenius/morphine sulphate and Ropivacaine Fresenius/clonidine hydrochloride have not been evaluated in clinical studies.

The mixtures are chemically and physically stable for 30 days at 20-30 ° C. ~~From a microbiological point of view, the mixtures should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C.~~

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות ו ניתן לקבל מודפס על ידי פניה לבעל הרישום: ניאופרם ישראל (1996) בע"מ, בניין ניאופרם, רח' השילוח 6, ת.ד. 7063, פתח תקווה 4917001. טלפון: 03-9373737, פקס: 03-9373770.

בברכה

עוז וולך, רוקח ממונה.