BioAvenir

12/2021

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלונים של התכשירים :

Remifentanil BioAvenir 1 mg

רמיפנטניל ביואבניר 1 מ"ג

Remifentanil BioAvenir 2 mg

רמיפנטניל ביואבניר 2 מ"ג

Remifentanil BioAvenir 5 mg

רמיפנטניל ביואבניר 5 מ"ג

צורת מינון:

POWDER FOR SOLUTION FOR INJECTION

המרכיב הפעיל:

REMIFENTANIL (AS HYDROCHLORIDE)

<u>עדכונים מהותיים בעלון לצרכן במתכונת עלון לרופא:</u>

<u>התוויה העדכנית :</u>

Remifentanil Bioavenir is indicated as an analgesic agent for use during induction and/or maintenance of general anaesthesia under close supervision .
Remifentanil Bioavenir is indicated for provision of analgesia and sedation in mechanically ventilated intensive care patients 18 years of age and over.

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3. PHARMACEUTICAL FORM

…

WARNING: RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death [see section 4.4 and 4.5] Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation

…

4.2. Posology and method of administration

(…)

Anaesthesia in spontaneously breathing anaesthetised patients with a secured airway (e.g. laryngeal mask anaesthesia): (…)

Remifentanil should not be used as an analgesic in procedures where patients remain conscious or do not receive any airway support during the procedure. (…)

Establishment of alternative analgesia prior to discontinuation of Remifentanil:
Due to the very rapid offset of action of remifentanil, no residual opioid activity will be present within 5 to 10 minutes after discontinuation.
Prior to discontinuation of Remifentanil, patients must be given alternative analgesic and sedative agents to prevent hyperalgesia and associated haemodynamic changes. These agents must be given at a sufficient time in advance to allow the therapeutic effects of these agents to become established. The range of options for analgesia includes long acting oral, intravenous, or regional analgesics controlled by the nurse or the patient. These techniques should always be titrated to individual patient needs as the infusion of Remifentanil is reduced. It is recommended that the choice of agent(s), the dose, and the time of administration are planned prior to discontinuation of Remifentanil

Guidelines for discontinuation of Remifentanil: Due to the very rapid offset of action of Remifentanil, hypertension, shivering and aches have been reported in cardiac patients immediately following discontinuation of Remifentanil (see section 4.8). To minimise the risk of these occurring, adequate alternative analgesia must be established (as described above), before the Remifentanil infusion is discontinued by reducing the infusion rate by 25% decrements in at least 10 min intervals until the infusion is discontinued (…)

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(…)

When other opioids agents are administered as part of the regimen for transition to alternative analgesia, the patient must be carefully monitored. The benefit of providing adequate analgesia must always be balanced against the potential risk of respiratory depression

(…)

There is a potential for the development of tolerance with time during prolonged administration of mu-opioid agonists.

(…)

Pediatric intensive care patients

The use of remifentanil in intensive care patients under the age of 18 years is not recommended as there are no data available in this patient population.

4.4. Warnings and special precautions for use

(…)

Rapid offset of action /Transition to alternative analgesia

Due to the very rapid offset of action of Remifentanil, no residual opioid activity will be present within 5 to 10 minutes after the discontinuation of Remifentanil. For those patients undergoing surgical procedures where post-operative pain is anticipated, analgesics should be administered prior to discontinuation of Remifentanil. The possibility of tolerance, hyperalgesia and associated haemodynamic changes should be considered when used in Intensive Care Unit. Prior to discontinuation of Remifentanil, patients must be given alternative analgesic and sedative agents. Sufficient time must be allowed to reach the therapeutic effect of the longer acting analgesic. The choice of agent(s), the dose and the time of administration should be planned in advance and individually tailored to be appropriate for the patient's surgical procedure and the level of post-operative care anticipated. When other opioid agents are administered as part of the regimen for transition to alternative analgesia, the benefit of providing adequate post-operative analgesia must always be balanced against the potential risk of respiratory depression with these agents.

<u>Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs</u>

Concomitant use of Remifentanil and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedative medicines should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe Remifentanil concomitantly with sedative medicines, the lowest effective dose should be .used, and the duration of treatment should be as short as possible

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The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their .caregivers to be aware of these symptoms (see section 4.5)

(…)

Discontinuation of Treatment

Symptoms following withdrawal of Remifentanil including tachycardia, hypertension and agitation have been reported infrequently upon abrupt cessation, particularly after prolonged administration of more than 3 days.

Where reported, re-introduction and tapering of the infusion has been beneficial. The use of Remifentanil in mechanically ventilated intensive care patients is not recommended for duration of treatment greater than 3 days.

(…)

Inadvertent administration

A sufficient amount of Remifentanil may be present in the dead space of the IV line and/or cannula to cause respiratory depression, apnoea and/or muscle rigidity if the line is flushed with IV fluids or other drugs. This may be avoided by administering Remifentanil into a fast flowing IV line or via a dedicated IV line which is removed when Remifentanil is discontinued.

(…)

4.5. Interaction with other medicinal products and other forms of interaction

Sedative medicines such as benzodiazepines or related drugs

The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited (see section 4.4).

4.6. Fertility, pregnancy and lactation

Breast-feeding

It is not known whether remifentanil is excreted in human milk. However, because fentanyl analogues are excreted in human milk and remifentanil-related material was found in rat milk after dosing with remifentanil, nursing mothers should be advised to discontinue breast feeding for 24 hours following administration of remifentanil (...)

4.7. Effects on the ability to drive and to use machinery

After anaesthesia with remifentanil the patient should not drive or operate machinery. The physician should decide when these activities may be resumed. It is advisable that the patient is accompanied when returning home and that alcoholic drink is avoided.

This medicine can impair cognitive function and can affect a patient’s ability to drive safely.

When prescribing this medicine, patients should be told:

· The medicine is likely to affect your ability to drive

· Do not drive until you know how the medicine affects you

· It is an offence to drive while under the influence of this medicine · (…)

4.8. Adverse effects
(…)
Nervous system disorders
Not known: Convulsions
Cardiac disorders
Not known: Atrioventricular block
General disorders and disturbance of the administration site
Not known: Drug tolerance
Psychiatric disorders
Not known: Drug dependence

Discontinuation of treatment
Symptoms following withdrawal of remifentanil including tachycardia, hypertension and agitation have been reported infrequently upon abrupt cessation, particularly after prolonged administration of more than 3 days (*see section 4.4)*

6.3. Shelf life
(…)
Chemical and physical stability after reconstitution and dilution- see in the updated leaflet
(…)
6.6. Special precautions for disposal
(…)
Reconstitution diluent and Dilution fluid – see in the updated leaflet
(…)

לתשומת לב - בהודעה זו מצוינים שינויים מהותיים והחמרות. בעלון בוצעו שינויים נוספים.
יש לעיין בעלון המצורף לאריזה (ולהודעה זו) לפני השימוש בתכשירים .

העלון לצרכן במתכונת עלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לבעל הרישום ביואבניר בע"מ , דוד המלך 1 הרצליה פיתוח או בטלפון 09-9544129.

בכבוד רב,

שרית קיראי-קוצ'וק

רוקחת ממונה