רופא/ה רוקח/ת נכבד/ה,

חברת ביואבניר מבקשת ליידע אתכם על עדכון העלון לרופא של התכשירים:

REMIFENTANIL BIOAVENIR 1 MG / רמיפנטניל ביואבניר 1 מ"ג

(Remifentanil 1 mg)

REMIFENTANIL BIOAVENIR 2 MG / רמיפנטניל ביואבניר 2 מ"ג

(Remifentanil 2 mg)

REMIFENTANIL BIOAVENIR 5 MG / רמיפנטניל ביואבניר 5 מ"ג

(Remifentanil 5 mg)

POWDER FOR SOLUTION FOR INJECTION

<u>התוויה הרשומה לתכשיר בישראל :</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.

<u>מהות העדכון:</u>

עדכוני בטיחות ועדכוני נוסח בהתאם לעלוני האסמכתא וכן התאמה לפורמט העלונים הנדרש לפי הנחיות משרד הבריאות.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://israeldrugs.health.gov.il

עלון לרופא

1. NAME OF THE MEDICINAL PRODUCT

Remifentanil BioAvenir 1 mg powder for solution for injection
Remifentanil BioAvenir 2 mg powder for solution for injection
Remifentanil BioAvenir 5 mg powder for solution for injection

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4.4 Special warnings and precautions for use

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Discontinuation of Treatment and withdrawal syndrome

Repeated administration at short term intervals for prolonged periods may result in the development of withdrawal syndrome after cessation of therapy.
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.

… **Drug abuse**

Tolerance and opioid use disorder (abuse and dependence)
Tolerance, physical and psychological dependence, and opioid use disorder (OUD) may develop upon repeated administration of opioids. Abuse or intentional misuse of opioids may result in overdose and/or death. The risk of developing OUD is increased in patients with a personal or a family history (parents or siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g. major depression, anxiety and personality disorders).

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4.5 Interaction with other medicinal products and other forms of interaction

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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*). The concomitant use of opioids and gabapentinoids (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and death.

Co-administration of remifentanil with a serotonergic agent, such as Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) or Monoamine Oxidase Inhibitors (MAOIs) may increase the risk of serotonin syndrome, a potentially life-threatening condition. Caution should be exercised with concomitant use of MAOIs. Irreversible MAOIs should be discontinued at least 2 weeks prior to remifentanil use.

Co-admin

The cardiovascular effects of Remifentanil (hypotension and bradycardia) may be exacerbated in patients receiving concomitant cardiac depressant drugs, such as beta-blockers and calcium channel blocking agents.

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4.6 Fertility, pregnancy and lactation

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Labour and delivery

The safety profile of remifentanil during labour or delivery has not been demonstrated. There are insufficient data to recommend remifentanil for use during labour and Caesarean section. Remifentanil crosses the placental barrier and fentanyl analogues can cause respiratory depression in the child. In case remifentanil is administered nevertheless, the patient and the neonate must be monitored for signs of excess sedation or respiratory depression (see section 4.4).

.8 Undesirable effects

System Organ Class	Frequency	Adverse reactions
Psychiatric disorders	Not known	Drug dependence, withdrawal syndrome
Cardiac Disorders	Common	Bradycardia
	Rare	Asystole/cardiac arrest, usually preceded by bradycardia, has been reported in patients receiving remifentanil in conjunction with other anaesthetic agents
	Not known	Atrioventricular block, arrhythmia
Respiratory, Thoracic and Mediastinal Disorders	Common	Acute respiratory depression, apnoea, cough
	Uncommon	Hypoxia

BioAvenir

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