



פברואר 2019

רופא/ה רוקח/ת נכבד/ה,

משרד הבריאות אישר את העדכונים הבאים בעלון התכשירים :

Ultiva 5mg
אולטיוה 5 מ"ג

Ultiva 2mg
אולטיוה 2 מ"ג

Ultiva 1mg
אולטיוה 1 מ"ג

חומר פעיל:

Remifentanil (as hydrochloride) 1mg/vial, 2mg/vial, 5mg/vial

התוויה כפי שאושרה בתעודת הרישום:

Ultiva is indicated as an analgesic agent for use during induction and/or maintenance of general anaesthesia under close supervision .

Ultiva is indicated for provision of analgesia and sedation in mechanically ventilated intensive care patients 18 years of age and over.

ברצוננו להודיע שעלון התכשירים הנדונים עודכן בסעיפים המפורטים מטה.
בהודעה זו מצוינים ומסומנים ברקע צהוב רק שינויים אשר מהווים החמרה או שינוי מהותי.
בעלון בוצעו שינויים נוספים שאינם מהווים החמרה .

העלון לרופא הועבר לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
<http://www.health.gov.il> וניתן לקבלו מודפס ע"י פניה לחברת פריגו ישראל,
בטלפון: 03-5773700.

בברכה,
פריגו ישראל סוכנויות בע"מ

3. PHARMACEUTICAL FORM

Lyophilised powder for reconstitution for solution ~~for intravenous~~ for intravenous (IV) administration.

Ultiva is a sterile, non-pyrogenic ~~endotoxin-free~~, preservative-free, white to off white, Lyophilised powder, to be reconstituted before use.

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.

4.4 Special warnings and precautions for use

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Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs

Concomitant use of Ultiva 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 Ultiva concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.

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).

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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).

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