הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 05.2013)

תאריך: 10.2015
שם תכשיר באנגלית ומספר הרישום: Ultiva 1 mg 108-33-29193-22, Ultiva 2 mg 108-34-29194-22, Ultiva 5 mg 108-35-29195-22
שם בעל הרישום : GlaxoSmithKline (ISRAEL) Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
Ultiva should be administered only in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function, and by persons specifically trained in the use of anaesthetic drugs and the recognition and management of the expected adverse effects of potent opioids, including respiratory and cardiac resuscitation. Such training must include the establishment and maintenance of a patent airway and assisted ventilation. The use of Ultiva in mechanically ventilated intensive care patients is not recommended for a duration of treatment greater than 3 days. **Patients with a known hypersensitivity to opioids of a different class may exhibit a hypersensitivity reaction following administration of Ultiva. Caution should be exercised before using Ultiva in these patients.**	**Ultiva should be administered only in a setting fully equipped for the monitoring and support of respiratory and cardiovascular function, and by persons specifically trained in the use of anaesthetic drugs and the recognition and management of the expected adverse effects of potent opioids, including respiratory and cardiac resuscitation. Such training must include the establishment and maintenance of a patent airway and assisted ventilation. The use of Ultiva in mechanically ventilated intensive care patients is not recommended for a duration of treatment greater than 3 days.**	**Special Warnings and Special Precautions for Use**

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק.