

הודעה על החמרה (מידע בטיחות) בעלון לרופא

(משדכן 05.2013)

תאריך: 05/07/2017

שם תכשיר באנגלית ומספר הרישום:

Ketalar Injection 10 mg/ml: 110-91-21856

Ketalar Injection 50 mg/ml: 110-99-21857

שם בעל הרישום: פייזר פי אף אי פרמצבטיקה בע"מ

פרוט ההחמרות בלבד !

ההחמרות המבוקשות

| טקסט חדש | טקסט נוכחי | פרק בעלון |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <p><u>Drug Abuse and Dependence</u> Ketalar has been reported as being a drug of abuse. Reports suggest that ketamine produces a variety of symptoms including, but not limited to, flashbacks, hallucinations, dysphoria, anxiety, insomnia, or disorientation. Cases of cystitis including haemorrhagic cystitis and cases of hepatotoxicity have also been reported. If used on a daily basis for a few weeks, dependence and tolerance may develop, particularly in individuals with a history of drug abuse and dependence. Therefore the use of Ketalar should be closely supervised and it should be prescribed and administered with caution.</p> | <p><u>Drug Abuse and Dependence</u> Ketalar has been reported as being a drug of abuse. Reports suggest that ketamine produces a variety of symptoms including, but not limited to, flashbacks, hallucinations, dysphoria, anxiety, insomnia, or disorientation. Cases of cystitis including haemorrhagic cystitis have also been reported. If used on a daily basis for a few weeks, dependence and tolerance may develop, particularly in individuals with a history of drug abuse and dependence. Therefore the use of Ketalar should be closely supervised and it should be prescribed and administered with caution.</p> | <p>Special warnings and precautions for use</p> |
| <p>Hepatobiliary disorders: Not Known: Liver function test abnormal, Drug-induced liver injury** ** Extended period use (>3 days) or drug abuse</p> | <p>Hepatobiliary disorders: Not Known: Liver function test abnormal</p> | <p>Undesirable effects</p> |

.....