



אוגוסט 2025

KETAMINE PROP Harm 10MG/ML

קטמין פרופארם 10 מ"ג/מ"ל

חומר פעיל: KETAMINE (AS HYDROCHLORIDE) 10MG/ML

SOLUTION FOR INJECTION / INFUSION : צורת מינון:

I.M , I.V: צורת המתן:

עדכונים בעלון לרופא

ברצוננו להודיע שהעלון עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד(תוספות / שינויים מסומנים באדום והחמרות/מידע חדש על רקע צהוב):

3. PHARMACUTICLA FORM

Solution for Injection or Infusion

Clear, colourless to slightly coloured, practically free from particles.

4. CLINICAL PARTICULARS

4.4 Special warnings and precautions for use

Long-Term Use

Ketamine is not indicated nor recommended for long-term use.

Cases of cystitis, including haemorrhagic cystitis, acute kidney injury, hydronephrosis, and ureteral disorders have been reported in patients being given ketamine on a long term basis, especially in the setting of ketamine abuse. (These adverse reactions develop in patients receiving long-term ketamine treatment after a time ranging from 1 month to several years). ~~Ketamine is not indicated nor recommended for long term use.~~

Hepatotoxicity such as mixed liver injury, cholestatic liver injury and biliary dilation has also been reported in patients with extended use (> 3 days). See section 4.8.