יוני 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

הנדון:
SPRAVATO®
ספראבטו™

חברת יאנסן ישראל בע"מ (J-C Health Care Ltd.) מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון התעדכן במאי 2024.

פרטי העדכון העיקריים מופיעים בהמשך *(טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן כטקסט ~~כחול עם קו חוצה~~, טקסט המהווה החמרה מודגש ברקע צהוב)*,אך קיימים עדכונים נוספים.

ההתוויות המאושרות לתכשיר בישראל:

Spravato, in combination with a SSRI or SNRI, is indicated for adults with treatment-resistant Major Depressive Disorder, who have not responded to at least two different treatments with antidepressants in the current moderate to severe depressive episode.

Spravato, co-administered with oral antidepressant therapy, is indicated in adults with a moderate to severe episode of Major Depressive Disorder, as acute short-term treatment, for the rapid reduction of depressive symptoms, which according to clinical judgement constitute a psychiatric emergency.

Limitations of Use: The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato.

מרכיב פעיל: Esketamine (as hydrochloride) 28mg

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug.

כמו כן, מצורף לפרסום זה וניתן לקבל העתק מודפס שלהם באמצעות פנייה לבעל הרישום:

ג'יי-סי הלת' קר בע"מ - יאנסן ישראל , קיבוץ שפיים, 6099000, טל': 09-9591111.

בברכה,
ויקטוריה גוטלויבר-הדדי
רוקחת ממונה
ג'יי-סי הלת' קר בע"מ

העדכונים בעלון לרופא הינם:

4.4 Special warnings and precautions for use

Respiratory depression

Respiratory depression may occur at high doses following rapid intravenous injection of esketamine or ketamine when used for anaesthesia. ~~No case of respiratory depression was observed in clinical trials with esketamine nasal spray (Spravato);~~ ~~r~~Rare cases of deep sedation have been reported. Concomitant use of Spravato with CNS depressants may increase the risk for sedation (see section 4.5). During post-marketing use, rare cases of respiratory depression have been observed. The majority of these cases have been reported with concomitant use of CNS depressants and/or in patients with comorbidities such as obesity, anxiety, cardiovascular and respiratory conditions. These events were transient in nature and resolved after verbal/tactile stimulation or supplemental oxygen. Close monitoring is required for sedation and respiratory depression.

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Severe hepatic impairment

Due to expected increase in exposure and lack of clinical experience, Spravato is not recommended in patients with Child-Pugh class C (severe) hepatic impairment.
Hepatotoxicity has been reported with chronic ketamine use, therefore, the potential for such an effect due to long-term use of Spravato cannot be excluded. In a long-term clinical trial with patients treated for a mean total duration of exposure of 42.9 months (up to 79 months), no evidence of hepatotoxicity was observed.

4.8 Undesirable effects

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Long-term safety

Long-term safety was assessed in a Phase 3, multicentre, open-label extension study (TRD3008) in 1 148 adult patients with treatment-resistant Major Depressive Disorder representing 3 777 patient-years of exposure. Patients were treated with esketamine for a mean total duration of exposure of 42.9 months (up to 79 months) with 63% and 28% of patients receiving treatment at least 3 years and 5 years, respectively. The safety profile of esketamine was consistent with the known safety profile observed in the pivotal clinical trials. No new safety concerns were identified.

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Description of selected adverse reactions

Cognitive and memory impairment

Cognitive and memory impairment have been reported with long-term ketamine use or drug abuse. These effects did not increase over time and were reversible after discontinuing ketamine. In long-term clinical trials, including a clinical trial with patients treated for a mean total duration of exposure of 42.9 months (up to 79 months), the effect of esketamine nasal spray on cognitive functioning was evaluated over time and performance remained stable.

Urinary tract symptoms

Cases of interstitial cystitis have been reported with daily and long-term ketamine use at high doses. In clinical studies with esketamine, there were no cases of interstitial cystitis, however a higher rate of lower urinary tract symptoms was observed (pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) in esketamine-treated patients compared with placebo-treated patients. In a long-term clinical trial with patients treated for a mean total duration of exposure of 42.9 months (up to 79 months), no cases of interstitial cystitis were observed.