J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

יולי 2023

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: Haldol Ampoules Solution for Injection

בעל הרישום J-C Health Care Ltd. מבקש להודיעכם כי העלון לרופא במתכונת עלון לצרכן של התכשיר שבנדון התעדכן ביוני 2023.

פרטי העדכון העיקריים מופיעים בהמשך *(טקסט שנוסף מסומן ב**אדום**, טקסט שהושמט מסומן כטקסט ~~כחול עם קו חוצה~~, טקסט שמיקומו בעלון שונה מסומן בירוק)* ,אך קיימים עדכונים נוספים.

ההתוויה המעודכנת והמאושרת בישראל:

HALDOL solution for injection is indicated in adult patients for:

- Rapid control of severe acute psychomotor agitation associated with psychotic disorder or manic episodes of bipolar I disorder when oral therapy is not appropriate.
- Acute treatment of delirium in patient suffering from severe agitation that may harm the patient, when non-pharmacological treatments have failed.
- Treatment of mild to moderate chorea in Huntington's disease, when other medicinal products are ineffective or not tolerated, and oral therapy is not appropriate.
- Single or combination prophylaxis in patients at moderate to high risk of postoperative nausea and vomiting, when other medicinal products are ineffective or not tolerated.
- Combination treatment of postoperative nausea and vomiting when other medicinal products are ineffective or not tolerated.

מרכיב פעיל:
Haloperidol

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug.

כמו כן, מצורפים לפרסום זה וניתן לקבל העתק מודפס שלהם באמצעות פנייה לבעל הרישום: יאנסן ישראל בע"מ , קיבוץ שפיים, 6099000, טל': 09-9591111.

בברכה,
יהב ורדי
רוקחת ממונה

J-C Health Care Ltd.

J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

בהודעה זו כלולים העדכונים המהותיים בלבד. **עיקרי העדכון נוגעים לאישור משרד הבריאות התוויה ומשטר מינון** חדשים, להלן העדכונים:

עלון לרופא במתכונת עלון לצרכן

בנוסף לעדכון ההתוויה בוצעו תיקוני ניסוח בהתאם לעלון מדינת רפרנס.

עיקרי העדכונים:

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

HALDOL solution for injection is indicated in adult patients for:

- Rapid control of severe acute psychomotor agitation associated with psychotic disorder or manic episodes of bipolar I disorder when oral therapy is not appropriate.
- Acute treatment of delirium in patient suffering from severe agitation that may harm the patient, when non-pharmacological treatments have failed.
- Treatment of mild to moderate chorea in Huntington's disease, when other medicinal products are ineffective or not tolerated, and oral therapy is not appropriate.
- Single or combination prophylaxis in patients at moderate to high risk of postoperative nausea and vomiting, when other medicinal products are ineffective or not tolerated.
- Combination treatment of postoperative nausea and vomiting when other medicinal products are ineffective or not tolerated.

~~Psychomotor agitation encountered in different neuropsychotic affections. Prophylaxis and therapy of acute and chronic vomiting.~~

4.2 Posology and method of administration

~~There is considerable variation from patient to patient in the amount of medication required for treatment. As with all antipsychotic drugs, dosage should be individualized according to the needs and response of the individual patient. When initiating treatment, consideration should be given to the following factors: age of the patient, severity of the disease, history of response to other antipsychotic drugs, concomitant medication or disease state.~~
~~Haldol Injection is reserved for prompt control of the acutely agitated patient with moderately severe to very severe symptoms.~~
~~Haldol Injection is recommended for IM administration only.~~
~~Haldol Injection should be substituted by Haldol Tablets as soon as feasible.~~
~~The usual dosage is 2-5 mg (0.4-1 ml of a Haldol ampoule) administered intramuscularly.~~

J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

~~Depending on the response of the patient, subsequent doses may be given, administered as often as every hour, although 4- to 8-hour intervals may be satisfactory.~~
~~Acute and Chronic Vomiting:~~
~~5 mg administered IM.~~

Posology

Adults

A low initial dose is recommended, and this must be adjusted according to the patient's response in order to determine the minimal effective dose (see section 5.2).

The dose recommendations for HALDOL solution for injection are presented in Table 1.

Table 1: Haloperidol dose recommendations for adults aged 18 years and above

Rapid control of severe acute psychomotor agitation associated with psychotic disorder or manic episodes of bipolar I disorder when oral therapy is not appropriate • 5 mg intramuscularly. • May be repeated hourly until sufficient symptom control is achieved. • In the majority of patients, doses of up to 15 mg/day are sufficient. The maximum dose is 20 mg/day. • The continued use of HALDOL should be evaluated early in treatment (see section 4.4). Treatment with HALDOL solution for injection must be discontinued as soon as clinically indicated and, if further treatment is needed, oral haloperidol should be initiated at a 1:1 dose conversion rate followed by dose adjustment according to clinical response.
Acute treatment of delirium when non-pharmacological treatments have failed • 1 to 10 mg intramuscularly. • Treatment should be started at the lowest possible dose, and the dose should be adjusted in increments at 2- to 4-hour intervals if agitation continues, up to a maximum of 10 mg/day.
Treatment of mild to moderate chorea in Huntington's disease, when other medicinal products are ineffective or not tolerated, and oral therapy is not appropriate • 2 to 5 mg intramuscularly. • May be repeated hourly until sufficient symptom control is achieved or up to a maximum of 10 mg/day. There is no clinical experience with Haldol Ampoules for this indication.
Single or combination prophylaxis in patients at moderate to high risk of postoperative nausea and vomiting, when other medicinal products are ineffective or not tolerated • 1 to 2 mg intramuscularly, at induction or 30 minutes before the end of anaesthesia.

J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

Combination treatment of postoperative nausea and vomiting when other medicinal products are ineffective or not tolerated

- 1 to 2 mg intramuscularly.

Treatment withdrawal

Gradual withdrawal of haloperidol is advisable (see ~~Warnings and Precautions – Additional considerations~~ section 4.4)

Special populations

Elderly

The recommended initial haloperidol dose in elderly patients is half the lowest adult dose.

Further doses may be administered and adjusted according to the patient's response. Careful and gradual dose up-titration in elderly patients is recommended.

The maximum dose is 5 mg/day.

Doses above 5 mg/day should only be considered in patients who have tolerated higher doses and after reassessment of the patient's individual benefit-risk profile.

Renal impairment

The influence of renal impairment on the pharmacokinetics of haloperidol has not been evaluated. No dose adjustment is recommended, but caution is advised when treating patients with renal impairment.
However, patients with severe renal impairment may require a lower initial dose, with further doses administered and adjusted according to the patient's response (see section 5.2).

Hepatic impairment

The influence of hepatic impairment on the pharmacokinetics of haloperidol has not been evaluated. Since haloperidol is extensively metabolised in the liver, it is recommended to halve the initial dose. Further doses may be administered and adjusted according to the patient's response (see sections 4.4 and 5.2).

Paediatric population

The safety and efficacy of HALDOL solution for injection in children and adolescents below 18 years of age have not been established. No data are available.

J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

Method of administration

HALDOL solution for injection is recommended for intramuscular use only (see section 4.4). For instructions on handling HALDOL solution for injection, see section 6.6.

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Comatose state.
- Central Nervous system (CNS) depression.

……..