27 December 2020

HALDOL® 5mg/ml (HALOPERIDOL) solution for injection: Incorrect information on route of administration on outer carton

Dear Healthcare Professional,

Johnson & Johnson Middle East Branch would like to inform you of the following in agreement with the Saudi Drug and Food Authority:

Summary

This is to alert you that the outer carton of Haldol 5mg/ml solution for injection contains an incorrect route of administration:

- *Haldol 5mg/ml should only be injected intramuscular and not intravenously as is erroneously stated on the outer carton.*

There is also missing information in the package leaflet:

- *Information on the route of administration is missing.*
- *A warning is missing on the risk of ventricular arrhythmias associated with use of Haldol especially with high doses and with intravenous injections, see further information.*
- *The company is working to correct the carton error and the missing information in the package insert as soon as possible.*

Further information: -

Very rare reports of QTc interval prolongation and/or ventricular arrhythmias, in addition to rare reports of sudden death, have been reported with haloperidol. They may occur more frequently with high doses, in predisposed patients, or with a QTc interval that exceeds 500 ms. As QTc interval prolongation has been observed during HALDOL treatment, caution is advised in patients with QTc-prolonging conditions (long QT-syndrome, hypokalemia, hypomagnesemia, electrolyte imbalance, drugs known to prolong QTc, cardiovascular diseases, family history of QTc prolongation), especially if HALDOL is given parenterally. The risk of QTc prolongation and/or ventricular arrhythmias may be increased with higher doses or with parenteral use, particularly intravenous administration. Continuous ECG monitoring should be performed for QTc interval prolongation and for serious cardiac dysrhythmias if Haldol is administered intravenously. Haldol Injection is recommended for IM administration only.

The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Call for Reporting

Healthcare professional should report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system:

SFDA (National Pharmacovigilance Center)
Email: npc.drug@sfda.gov.sa
Telephone: 19999
Fax: +966 11 2057662
Online: http://ade.sfda.gov.sa

Company Contact Points:
If you have further question or require additional information, please contact our local safety department at:

Email: GCC-PV2@its.ini.com
Fax: +966 (11) 4339140

Yours faithfully,

Hesham Helwa

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Hesham Atef
Medical Affair Director- GCC Countries