hikma.

هاتف : ٨١٠٧٠٢٣ ١١ (٩٦٦+) / ٢١٤٢٤٧٢ ١١ (٩٦٦+)
فاكس : ٢٠٧٨١٧٠ ١١ ٩٦٦+
هاتف المبيعات : ٢٠٧٨١٧٢ / ٢٠٧٨١٧٣ ١١ ٩٦٦ +
فاكس الإدارة : ٢٠٧٨٠٩٧ ١١ ٩٦٦+

شركة الجزيرة للصناعات الدوائية
ص.ب ١٠٦٢٢٩ الرياض ١١٦٦٦
المملكة العربية السعودية

Date: 6 May 2019
Subject: Cyanocobalamin and the risk of medication error

Dear Healthcare Professional,
Please note that Hikma Pharmaceuticals marketing authorization holder (MAH) of Cyanocobalamin (Jectin-12®) in collaboration with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

Summary

- Anaphylactic shock and death have been reported after parenteral vitamin B12 administration.
- An intradermal test dose is recommended before Cyanocobalamin Injection. Moreover, use of this product intravenously will result in almost all of the vitamin being lost in the urine.
- The intravenous route should be avoided when treating patients with Cyanocobalamin (Jectin-12®).

Background on the safety concern
Jectin-12® is SFDA-approved for the treatment of clinically-chemically confirmed vitamin B12 deficiency.
Vitamin B12 deficiency may manifest itself as the following clinical pictures: -Hyperchromic macrocytic megaloblastic anaemia (pernicious anaemia, Biermer's anaemia, Addison's anaemia; all of these constitute maturation disorders of red blood cells), funicular spinal disease (damage to the spinal cord).

Summary of product characteristics (SPC) of the Cyanocobalamin (Jectin-12®) stated that "anaphylactic or anaphylactoid reactions have been noted in individual cases"

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance Center (NPC):

- SFDA call center: 19999
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: http://ade.sfda.gov.sa/
- Fax: +966-11-2057662

<u>Pharmacovigilance department:</u>

- Name of QPPV: Norah Al-Suwaidan
- Telephone: +966(11) 4173731 Ext: 1086
- Email: nalsuwaidan@hikma.com

Sincerely,
Norah Mohammed Al-Suwaidan

hikma. KSA
Jazeera Pharmaceutical Industries
شركة الجزيرة للصناعات الدوائية
س ت ١٠١٠١٢٤٣٧٣