Direct Healthcare Professional Communication Letter (DHPC)

1st February 2024

Infide Elixir ®(Dexamethasone 0.01% Elixir), potential risks associated with Ethanol as an excipient in Infide Elixir®

Dear Healthcare professional,

This letter is sent from Amman Pharmaceutical Industries, in agreement with Saudi Drug and Food Authority (SFDA), would like to raise awareness about the potential risks associated with Ethanol as an excipient.

Summary

- Infide Elixir® (Dexamethasone 0.01% Elixir) contains 242.5mg Ethanol 99% in each 5ml.
- Exposure to ethanol when used as an excipient in medicines may lead to impair cognitive and psychomotor functions. At high doses of Ethanol, it can cause stupor, coma, hypothermia, respiratory depression or failure and cardiovascular toxicities such as atrial tachycardia.
- In children, signs of ethanol intoxication are hypoglycemia, hypothermia, and coma.
- Other toxicities seen after acute toxic exposure include seizures, often due to hypoglycemia in children, hypotonia, hyporeflexia, gastritis, gastrointestinal bleeding, acute hepatitis, acute pancreatitis, rhabdomyolysis, hypokalemia, and lactic acidosis.
- Exposure to high levels of ethanol during pregnancy can result in foetal alcohol syndrome (FAS) or foetal alcohol spectrum disorder (FASD).
- The presence of ethanol excipients in Infide Elixir® medicine have central effects and may increase the risk of abuse in patients.
- Healthcare professionals need to be cautious and vigilante when prescribing Infide Elixir® to ensure the prevention of any potential risks associated with the misuse of Infide Elixir®.

Further information on the safety concern and the recommendations

- Below are the three levels of warning regarding the level of ethanol as follows.
  - ✓ Below 15 mg/kg/dose the patient should experience no noticeable effects.
  - ✓ In the middle range (15 mg to less than 75 mg/kg/dose) adults and adolescents should not experience any effect but effects on younger children are less certain.
  - ✓ At the third level (75 mg/kg/dose and above) warnings are given that task performance may be affected in all age groups. This level is based on when effects first became apparent in studies in adults performing complex tasks.

- To promote the safe and effective use of Infide Elixir®, its essential to adhere to proper prescribing and monitoring protocols. By exercising caution and monitoring patient's effects and behaviors, mitigation of the potential risks of abuse could be accomplished, ensuring the medication is used responsibly and with optimal results.

- ***Note:*** *Please refer to the summary of product characteristics (SPC) of Infide Elixir ® (Dexamethasone 0.01% Elixir) for more details.*

Call for reporting.

Please report any suspected adverse reactions associated with the use of Infide Elixir ® (Dexamethasone 0.01% Elixir) in accordance with the national requirements via the national spontaneous reporting system, to:

Amman Pharmaceutical Industries Patient Safety Department- Jordan
E: QPPV@ammanpharma.com
M: +962(79)668-4957

Saudi Food and Drug Authority National Pharmacovigilance Center
Unified Contact Center: 19999
Email: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

Company contacts point.

Should you need any further information, please do not hesitate to contact us:

Ghadah Rashed Alotaibi, responsible person for pharmacovigilance
Amman Pharmaceutical Industries
Riyadh, Saudi Arabia
Email: Ghadah.Alotaibi@ammanpharma.com
Mobile No: +966507917875

Sincerely,

Ghadah Alotaibi / Amman Pharmaceutical industries QPPV

Amman Pharmaceutical Industries
شركة عمان للصناعات الدوائية

Ghadah Alotaibi

شركة عمان للصناعات الدوائية
Amman Pharmaceutical Industries
Scientific Office
Kingdom of Saudi Arabia / Riyadh
T: +966 114646955 Ext: 202

References:

- **Information for the package leaflet regarding ethanol used as an excipient in medicinal products for human use (europa.eu)**
- **Questions and Answers on Ethanol in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00) (europa.eu)**