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This document is approved by Saudi Food and Drug Authority

Direct Healthcare Professional Communication (DHPC)

Almetra®(Pemetrexed)
500mg powder for concentrate for solution for infusion

Dear Healthcare provider,

MS Pharma Saudi in Agreement with the Saudi Food and Drug authority (SFDA) would like to inform you about the instructions for use, handling and disposal of Almetra®(Pemetrexed)

Summary

This communication is regarding a discrepancy identified in the reconstitution information on some of the product outer packs.

We are following up closely to minimize the risks, therefore,

1- Kindly consider the reconstitution information in this letter.

2- Kindly note that we have identified the locations of those packs, and a permanent adhesive sticker including the correct information will be added.

Further information on the safety concern and the recommendations

The following information is intended for medical or healthcare professionals only: Instructions for use, handling and disposal.

1. Use aseptic techniques during the reconstitution and further dilution of **Almetra®** for intravenous infusion administration.
2. Calculate the dose and the number of **Almetra®** for Injection vials needed. Each vial contains an excess of **Almetra®** to facilitate delivery of the label amount.

3. **Almetra®** for Injection 500 mg:

   Reconstitute each 500 mg vial with 20 ml of 9 mg/ml (0.9%) sodium chloride solution for injection, without preservative, resulting in a solution containing 25 mg/ml pemetrexed. Gently swirl each vial until the powder is completely dissolved. The resulting solution is clear and ranges in colour from colourless to yellow or green-yellow without adversely affecting product quality. The pH of the reconstituted solution is between 6.6 and 7.8. **Further dilution is required**.

4. The appropriate volume of reconstituted **Almetra®** solution must be further diluted to 100 ml with 9 mg/ml (0.9 %) sodium chloride solution for injection, without preservative, and administered as an intravenous infusion over 10 minutes.

5. **Almetra®** infusion solutions prepared as directed above are compatible with polyvinyl chloride and polyolefin lined administration sets and infusion bags. Pemetrexed is incompatible with diluents containing calcium, including lactated Ringer's Injection and Ringer's Injection.

6. Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration. If particulate matter is observed, do not administer.

7. **Almetra®** solutions are for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

Preparation and administration precautions: As with other potentially toxic anticancer agents, care should be exercised in the handling and preparation of Almetra® infusion solutions. The use of gloves is recommended. If a Almetra® solution contacts the skin, wash the skin immediately and thoroughly with soap and water. If pemetrexed solutions contact the mucous membranes, flush thoroughly with water. Pemetrexed is not a vesicant. There is not a specific antidote for extravasation of pemetrexed. There have been a few reported cases of pemetrexed extravasation, which were not assessed as serious by the investigator. Extravasation should be managed by local standard practice as with other non-vesicants.

Call For Reporting:

Report suspected adverse drug reactions associated with Pemetrexed by contacting:

- **Local representative at MS Pharma Saudi**
  Address: King Abdulaziz road - Alrabea District - Grand Center 1st floor
  Front of Kingdom Hospital
  P.O Box 54850 Riyadh, 11524 Saudi Arabia
  - Email: pharmacovigilance@mspharma.com
  - Mobile: +966548933555
  - Phone No: +966112790122 Ext. 6013
  - Website: www.mspharma.com
- **The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA):**
  - SFDA call center: 19999
  - Email: npc.drug@sfda.gov.sa
  - Website: http://ade.sfda.gov/