Healthcare Quality and Strategy Directorate
Pharmacy and Medicines Division

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The Scottish Government
Riaghaltas na h-Alba

LEGACY 2014
XX COMMONWEALTH GAMES
SCOTLAND

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

16 June 2016

Dear Healthcare Professional,

DRUG ALERT CLASS 4 no 9 2016 – Caution in Use

Please see the attached drug alert for onward transmission as below.
Could all Directors of Pharmacy please forward this alert to:-

- Hospital Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy and Medicines Division

D R U G A L E R T

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Hospital Pharmacy Level

Date: 16 June 2016 EL (16)A/09 Our Ref: MDR 81-05/16

Dear Healthcare Professional,

Caduceus Pharma Ltd.

Pemetrexed 25mg/ml Concentrate for solution for Infusion. 100mg in 4ml; 500mg in 20ml; 1000mg in 40ml

PL 24668/0187

Actavis UK Ltd on behalf of the Marketing Authorisation holder, Caduceus Pharma Ltd, has informed us that particulates have been identified in a small number of vials of Pemetrexed 100mg and 500mg vials following an investigation of some product complaints. The particulates have been identified as Cystine, the oxidation product of one of the excipients in the product, Cysteine. Further investigation of affected vials has shown that all other parameters of the Finished Product Specification, including assay, complied with the required specification.

In order to avoid shortages of the product, affected batches are not being recalled. Since the root cause has not as yet been identified, Actavis is advising that the following precautions should be taken when administering **any batch** and **any strength** of the product:

- The product should be inspected visually prior to use for particulates and discolouration. Any affected vials should be discarded. This reiterates the advice already given in the SPC.

- Diluted product should be administered via an in-line filter with a microporous membrane of ≤ 0.22 µm.

Further Information

For medical information enquiries, please contact Actavis Medical Information Department on 01271 385257

For information on product availability, please contact Actavis Customer Service Team on 0800 373573

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

Alison Bunce
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Medicines and Healthcare Products Regulatory Agency