13th May2026

Direct Healthcare Professional Communication
(DHPC)

Pemetrexed SUN 5 mg/ml, 6 mg/ml, 6.5 mg/ml, 7 mg/ml, 7.5 mg/ml, 8 mg/ml, 8.5 mg/m, 9 mg/ml, 10 mg/ml, and 11 mg/ml, solution for infusion

< pemetrexed disodium heptahydrate >

Recommendation to use an in-line filter when administering the product

Dear Healthcare Professional,

Sun Pharmaceutical Industries Europe, as Marketing authorisation holder of pemetrexed (procedure number NL/H/5223/001-010/DC), in agreement with the MHRA, would like to inform you of the following:

Summary

- Infusion bags of **Pemetrexed SUN 5 mg/ml, 6 mg/ml, 6.5 mg/ml, 7 mg/ml, 7.5 mg/ml, 8 mg/ml, 8.5 mg/m, 9 mg/ml, 10 mg/ml, and 11 mg/ml, solution for infusion** allow delivery of 100 ml of solution (equivalent to 500 mg/ 600 mg/ 650 mg/ 700 mg/ 750 mg/ 800 mg/ 850 mg/ 900 mg/ 1000 mg/ 1100 mg, respectively).

- **This product is a ready to use medication.** The Pemetrexed SUN infusion bags solution for infusion should not be confused with other pharmaceutical forms, like concentrate for solution for infusion.

- MAH has observed higher count of particulate matter by Laser Particle Counter (LPC) in recent batches of the drug product Pemetrexed SUN solution for infusion, 100 mL infusion bags. The particles, observed in the drug product, are of intrinsic in nature and comprise of Pemetrexed.

- Particulate matter in injections can be harmful when introduced into the bloodstream. The contamination of parenteral fluids and drugs by particulate matter has been recognized as a potential health hazard.

- In order to mitigate this risk, the use of an in-line filter is recommended. The PIL enclosed with the affected batches, includes the recommendation to **use an in-line filter** when administering the product as follows:

  Administer the solution using an in-line standard filter with a pore size between 0.2 and 1.5 microns, as these sizes are interchangeable."

- For affected batch numbers HAG2554A, HAG2372A and HAH0231A please visit the Sun Pharmaceutical Industries Europe website: United Kingdom - Educational Materials - Sun Pharmaceutical Industries Ltd.

Background

Pemetrexed SUN is indicated for:

Malignant pleural mesothelioma
Pemetrexed in combination with cisplatin is indicated for the treatment of chemotherapy naïve patients with unresectable malignant pleural mesothelioma.

Non-small cell lung cancer
Pemetrexed in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

Pemetrexed is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy

Pemetrexed is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

Considering the significant increase of particulate matter test result this out of specification (OOS) may have an important impact on patient safety.

As per particulate matter identification report, the particles, observed in the drug product, are of intrinsic in nature and comprise of Pemetrexed.

As a result, it is recommended to **use an in-line filter** when administering the affected batches as a temporary measure whilst the MAH undertakes investigations to resolve the issue.

In-line filters contain a membrane with pores of a specific size (e.g., 0.22 or 1.2 microns) that trap particles and microorganisms larger than the pore size. The filter should be placed in the IV line, close to the patient, to intercept potential contaminants before they enter the patient's bloodstream. Proper priming involves ensuring the filter is fully saturated with fluid and free of air bubbles before connecting to the patient**.**

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.
Please report:
all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals
- Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point

If you have any questions or require further information, please contact the Sunpharma Medical Information department at medinfoeurope@sunpharma.com or Medical Information Direct Line +44 (0) 208 848 5052.

Adverse events should also be reported to Sunpharma at drugsafetyeurope@sunpharma.com

Yours sincerely,

Dr Victoria Bodea, MD, Ph.D
Head Pharmacovigilance Europe
Sun Pharmaceutical Industries

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