28. January 2025

Direct Healthcare Professional Communication (DHPC)

Sodiofolin® (folinic acid) 50mg/ml solution for injection/infusion, strengths 100mg and 400mg, batches C240164A, C240218B and C240218C, PL 11587/0005 – requirement to use a PES or PVDF filter due to observation of particles and potential risk of thrombo-embolic event

Dear Healthcare Professional,

medac GmbH, in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA), would like to inform you of the following:

Summary:

- Visible particles were found in Sodiofolin® (folinic acid) 50 mg/ml solution for injection/infusion as part of the ongoing stability programme
- Until further notice, healthcare professionals are required to:
    - ensure that only **pump systems with particle filters made of PES (polyethersulfone) or PVDF (polyvinylidene fluoride)**, pore size **≤ 5 µm**, are used for **infusions**
    - use **syringe filters made of PES or PVDF** with a pore size **≤ 5 µm** for **bolus injections**
- The cause of the particles is still under investigation. The formation of the particles does not influence the concentration of the active ingredient, so no adjustment of the dosage is necessary.
    - However, as Sodiofolin is administered intravenously, the particles could lead to thrombo-embolic events.
    - Until further notice, this additional measure is being taken in the interest of patient safety solely due to a possible drug risk during intravenous administration. The risk of thrombo-embolic complications due to the observed particles can be mitigated by using a suitable particle filter.
- It is anticipated that product, without the risk of particle formation, will be available in 2025.

Background:

Sodiofolin® (folinic acid) 50 mg/ml solution for injection/infusion is used in combination with 5-fluorouracil as part of cytotoxic treatment and as an antidote to methotrexate to prevent side effects or in the event of an overdose. It can be administered intravenously either as an infusion or as a bolus injection.
SmPC Sodiofolin 50 mg/ml

As part of the ongoing stability programme, an out-of-specification result was found for visible particles in individual batches.

Call for the reporting of side effects:

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
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

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.

Please also report any adverse events by email to medac drug safety at drugsafety@medac.de.

Local contact point
medac Pharma, Scion House, Stirling University Innovation Park, Stirling, FK9 4NF
T: 01786 458086
email: info@medacpharma.co.uk

If you have any questions, please do not hesitate to contact us.

Yours faithfully

medac GmbH

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Dr. Michael Braun
Officer of the Graduated Plan