Better Health, Brighter Future

26th February 2020

MEPACT 4mg (mifamurtide): Potential for filter leakage or malfunction

Dear Healthcare Professional,

The Marketing Authorisation Holder, Takeda France SAS, in agreement with the European Medicines Agency and the Medicines and Healthcare products Agency (MHRA) would like to inform you of the following:

Summary:

- **Mepact is available as a vial containing a powder for reconstitution and one single-use filter.**
- **A small number of filter leakages or of malfunction during reconstitution of Mepact have been reported. They occur before Mepact is infused.**
- **To protect patients, if any leakage or malfunction of the filter are observed during reconstitution, do not administer Mepact and report the malfunction to Takeda.**
- **If case of leakage or malfunction, use a new filter and a new vial from a new pack of Mepact.**
- **Mepact must only be reconstituted using the filter provided in the package.**

Background on the safety concern:

Mepact is indicated in children, adolescents and young adults for treating high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection. It is used in combination with post-operative multi-agent chemotherapy.

Mepact is available as a vial containing a powder for reconstitution and one single-use filter. Mepact must only be reconstituted using the filter provided in the package; the vented spike filter ensures the uniformity of size of liposomes before infusion.

Healthcare professionals have reported a small number of instances of filter leakage or malfunction during reconstitution of Mepact. This occurs before Mepact is infused. Filters showed no visible defect prior to usage.

To safeguard patient safety and to ensure the correct concentration during reconstitution, if you observe any leakage or malfunction of the filter during reconstitution, do not administer Mepact and report the malfunction to Takeda on Tel: 03333 000181, Email: DSO-UK@takeda.com. A new Mepact package (vial and filter) must be used.

Takeda are currently working with the filter manufacturer on the investigation to help identify the

probable root cause for the complaints received specific to the Mepact Spike Filters. Appropriate corrective actions will be identified and implemented to mitigate against future issues with the Mepact Spike Filters. Target completion of the investigation is end of March 2020.

Call for reporting:

If you observe any leakage or malfunction of the filter during reconstitution, do not administer Mepact and report the malfunction to Takeda on Tel: 03333 000181, Email: DSO-UK@takeda.com.

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 hospitalization, and those that are considered medically significant for any other reason.

It is easiest and quickest to report ADRs online via the Yellow Card website: https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back for the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above).

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

For questions on the content of this communication please contact the Takeda Medical Information Department: Tel: 03333 000181, Email: DSO-UK@takeda.com.

Yours faithfully,

Dr Simon Meadowcroft
Medical Director
Takeda UK Ltd
Phone: +44(0)7766 526793
Email: simon.meadowcroft@takeda.com