

## Recommended Direct Healthcare Professional Communication

### Direct Healthcare Professional Communication on risk of dosing error with Pixuvri (pixantrone) 29 mg powder for concentrate for solution for infusion

This letter is to inform you that there is a risk of dosing error with Pixuvri (pixantrone) because the EU recommended dose is expressed differently to some trials and publications.

#### Summary

- Prescribers and pharmacists should ensure that they prescribe and dispense Pixuvri in accordance with the EU product information presented for the marketed product in the EU
- The recommended dose in the EU product information is 50mg/m<sup>2</sup> and refers to the base of the active substance (pixantrone).
- In some trials and publications, the dosing was based on the salt form (pixantrone dimaleate) which may lead to confusion at the time of prescription and dispensing.

#### Further information

Pixuvri (pixantrone) is indicated as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non Hodgkin B-cell Lymphomas (NHL).

Pixuvri is supplied in vials containing pixantrone dimaleate equivalent to 29mg of pixantrone.

The recommended dose of pixantrone is 50mg/ m<sup>2</sup> on days 1, 8, and 15 of each 28-day cycle for up to 6 cycles.

In the EU SmPC the dose of 50mg/ m<sup>2</sup> refers to pixantrone, the active part of the substance and not to pixantrone dimaleate which is the salt.

In some trials and publications the doses referred to are that of the pixantrone dimaleate salt.

Please see attached Summary of Product Characteristics (SmPC).

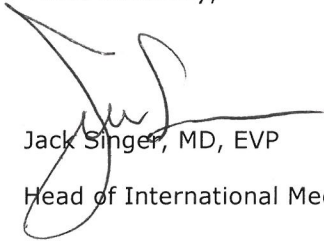
#### Call for reporting

Healthcare professionals should report any adverse reaction suspected to be associated with the use of Pixuvri to the IMB through the online reporting scheme at <http://www.imb.ie/> or by submitting a post-paid Report Card (Yellow Card).

#### Contact information

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Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Jack Singer', with a long horizontal flourish extending to the right.

Jack Singer, MD, EVP

Head of International Medical Affairs and Translational Medicine for CTI Life Sciences

Annex: Pixuvri Summary of Product Characteristics (SmPC)