



Greifswald, 2020-09-08

VISUDYNE® (verteporfin for injection)

Dear Healthcare Professional,

In order to mitigate a supply shortage of the medicinal product VISUDYNE® (manufactured by Alcami Carolinas Corporation for CHEPLAPHARM Arzneimittel GmbH), the European marketing authorisation holder, CHEPLAPHARM Arzneimittel GmbH, will provide VISUDYNE® licenced for the US market (also manufactured by Alcami Carolinas Corporation for Bausch Health US, LLC) to the customers in Ireland as an unlicensed product in agreement with the Health Products Regulatory Authority (HPRA).

VISUDYNE®, imported from the US, is labelled in accordance with the US license and therefore differs in the packaging from the EU product. For information about VISUDYNE®, please refer to the package leaflet in the national language approved by the European Medicines Agency instead of the package leaflet that is supplied with the US product.

The package leaflet and the summary of product characteristics are available in all European national languages on the EMA website: <https://www.ema.europa.eu/en/medicines/human/EPAR/visudyne>

It is at the discretion of healthcare professionals to prescribe VISUDYNE®, imported from the US, as an appropriate alternative for patients awaiting treatment.

In case of suspected adverse reactions please report via the national reporting system according to common practice:

HPRA Pharmacovigilance
Website: www.hpra.ie

Yours faithfully,

**CHEPLAPHARM
Arzneimittel GmbH**

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Raiffeisenbank Grävenwiesbach eG
IBAN: DE04 5006 9345 0000 0385 12 SWIFT-Code: GENODE51GWB
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