



TO WHOM IT MAY CONCERN

Greifswald, 2021-07-01

## Statement concerning the prolonged shortage of Visudyne®

We, CHEPLAPHARM Arzneimittel GmbH (Germany), as global product owner of Visudyne® 15 mg, verteporfin for injection (except for USA), and marketing authorization holder of the central registered product Visudyne® in the EU (EU/1/00/140/001), would like to inform about the **prolonged shortage** of Visudyne®.

As informed in our last statement, due to technical defects on the filling machine, the bulk manufacturer decided to transfer the production of Visudyne to a new line with equivalent machines, same technology and process in the same building. Validation activities and stability studies according to current international guidelines were initiated immediately.

Today, we regret to inform you, that validation processes are delayed due to unforeseeable technical malfunctions, which unfortunately requires new productions. For this reason, the previously communicated timelines can no longer be kept. At present, we assume that new goods will be available in January 2022.

Please be assured, that CHEPLAPHARM Arzneimittel GmbH is still working on this issue with highest priority.

Yours faithfully,  
**CHEPLAPHARM Arzneimittel GmbH**

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