

TO WHOM IT MAY CONCERN

Greifswald, 2022-04-08

Statement concerning the ongoing limited availability 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 centrally registered product Visudyne® in the EU (EU/1/00/140/001), would like to inform about the ongoing limited availability of Visudyne®.

In May 2020, the supply of Visudyne was interrupted due to a breakdown of the filling line that leads into a deinstallation of the line. Since then, CHEPLAPHARM has been engaging significant resources in resolving this interruption and has successfully amended the manufacturing process to restore supply. Newly manufactured Visudyne products are available since November 2021.

The restoring of the manufacturing process was accompanied by the use of alternative, equivalent equipment resulting in a reduced batch size and lower production yields.

Besides, the current market demand appears to be higher than in the past due to full market depletion during the six-month product shortage period in 2020, current market uncertainty triggered by missing safety stock and implemented rationing measures as well as the effect of resuming treatments which have been suspended or postponed during the Corona pandemic in 2020 until beginning 2022. CHEPLAPHARM therefore anticipates that, despite continuous deliveries, the upcoming productions will not cover the entire market demand in 2022 and 2023.

Therefore, CHEPLAPHARM would like to inform about the consistent deliveries, but limited availability for 2022 and 2023.

The limited availability continues to affect all countries where the product is marketed. Based on historic demands, CHEPLAPHARM will ensure the fair allocation of Visudyne to the markets to safeguard the treatment of urgent cases. For this purpose, the following measures were taken:

- Dispensing is only done through hospitals and specialized facilities and not through wholesalers.
- CHEPLAPHARM and its local distribution partners are in direct contact with ophthalmologists and hospital pharmacists in various EU member states to manage the supply most adequate.
- The delivery quantity per order is limited.

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ING Bank _ IBAN: DE73 5002 1000 0018 1127 06 _ SWIFT-Code: INGBDEFFXXX
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REGISTERING COURT

Stralsund _ HRB 5896

Further efforts are being made to support a stable supply capability:

- The bulk manufacturer has ordered a new filling line. This line will be delivered in the next month. After the installation, validation and registration of the new line, production with a higher capacity is expected to start at the end of 2023.
- Furthermore, to support the higher demand on the market, CHEPLAPHARM is evaluating a second Active Pharmaceutical Ingredient source.

Please be assured that CHEPLAPHARM Arzneimittel GmbH, especially with consideration of the fact of unique selling proposition of the product, prioritizes patient needs in all circumstances and is working on normalizing the product supply and product availability at the earliest.

Yours faithfully,

CHEPLAPHARM Arzneimittel GmbH