Medicine Shortage Communication (MSC)

19 September 2025

Visudyne (verteporfin, powder for solution for injection, 15 mg): Supply shortage to continue until the end of 2026

Dear Healthcare Professional,

CHEPLAPHARM Arzneimittel GmbH is providing healthcare professionals with an update on the shortage of Visudyne.

Overview of situation

- **There has been a shortage of Visudyne since May 2020 due to reduced manufacturing capabilities.**
- **Although Visudyne's supply capacity was partially restored in Q1/2022, it remains insufficient to fully meet demand. Consequently, the current approach of reduced and controlled deliveries will continue for the foreseeable future, resulting in continued shortages, until the end of 2026.**
- **A new supply chain is being established to ensure a more stable supply of Visudyne in EU/ EEA countries; however due to manufacturing delays this will not be established until July 2026.**
- **CHEPLAPHARM would like to emphasize that Visudyne is at present the sole medicinal product containing verteporfin in the EU/EEA.**
- **CHEPLAPHARM is committed to ensuring a fair and equitable allocation of Visudyne, based on historical demand, and will prioritise its supply to patients in Member States that are most affected by the shortage.**
- **The shortage is not due to any safety, efficacy or quality concerns with Visudyne.**

Mitigation measures

In order to manage the shortage, CHEPLAPHARM Arzneimittel GmbH is engaging with the European Medicines Agency and the [National Competent Authority] on mitigation measures, including careful allocation of stocks based on demand.

During the shortage, healthcare professionals should:

- ***Take the limited availability of Visudyne into account when planning, prioritising and prescribing treatments;***
- ***Coordinate with relevant health authorities and follow their guidance, where applicable, to ensure patients at greatest need receive therapy;***

- ***Consult EMA's shortage catalogue, your country's shortage register** (if available) **or your national competent authority for additional information.***

Background on the shortage

Visudyne is authorised for the treatment of adults with exudative ('wet') form of age-related macular degeneration (AMD) with predominantly classic subfoveal choroidal neovascularisation (CNV) or adults with subfoveal choroidal neovascularisation secondary to pathologic myopia.

Since May 2020, the supply of Visudyne has been interrupted due to an unexpected breakdown of the filling line. To restore supply, the manufacturing process has been transferred to an alternative existing production line in the same building, with equivalent machines and using the same technology and process. In Q1/2022 the production was restored, but with limited capacity unable to meet demand. As a result, deliveries will be consistent but quantities of Visudyne are expected to be limited, resulting in continued shortages until the end of 2026.

The limited availability continues to affect all EU/EEA countries where the product is marketed including Austria, Belgium, Cyprus, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Spain and Sweden. Based on historic demand, CHEPLAPHARM will ensure the fair and equitable allocation of Visudyne to all impacted markets in order to safeguard the treatment of urgent cases.

Two direct healthcare professional communications (DHPCs) have been disseminated over the past four years,find links below:.

- DHPC, published on EMA website on 05 November 2021:

  https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-visudyne-verteporfin-information-continuing-supply-restriction-until-end-q12022_en.pdf

- DHCP, published on EMA website on 12 August 2022:

  https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-visudyne-verteporfin-information-continuing-supply-limitation-until-end-2023_en.pdf

The present letter is to extend the duration of the shortage and inform the timeline for establishment of the new supply chain to ensure a stable supply of Visudyne to EU/ EEA countries in the future.

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