



5 November 2021
EMA/597325/2021 Rev. 1¹

Shortage of Visudyne (verteporfin) 15 mg powder for solution for infusion

Indication	Visudyne is used to treat adults with: <ul style="list-style-type: none">• the 'wet' form of age-related macular degeneration (AMD), a disease that affects the central part of the retina (called the macula) at the back of the eye;• choroidal neovascularisation caused by pathologic myopia.
Reason for shortage	Since May 2020, the supply of Visudyne has been interrupted due to a reduction in manufacturing capacity. The manufacturing process has been amended and production was restored in the first quarter of 2022, but with limited capacity. Quantities of Visudyne are therefore expected to be limited until the end of 2023.
Member States affected²	The shortage affects all Member States in which the product is marketed.
Information to healthcare professionals	<ul style="list-style-type: none">• There is a shortage of Visudyne due to a reduction in the company's manufacturing capacities.• The manufacturing process has been amended and production was restored in the first quarter of 2022, but with limited capacity. As a result, quantities of Visudyne are expected to be limited until the end of 2023.• For age-related macular degeneration and subfoveal choroidal neovascularisation, healthcare professionals should use alternative treatments where possible.• Visudyne is used off-label in a number of conditions. National competent authorities may

¹ This document was modified on 12 August 2022 to update information regarding supplies of Visudyne.

² This information may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.



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	<p>have set up programmes to make Visudyne available under controlled conditions for these patients.</p> <ul style="list-style-type: none">• A direct healthcare professional communication (DHPC) will be sent to healthcare professionals in affected member states. The DHPC is also available on the EMA website.• Additional advice may be available from the national competent authority.
Information to patients	<ul style="list-style-type: none">• There is a shortage of Visudyne due to a problem in manufacturing capacity. Although the manufacturing process has been amended and production was restored, capacity is limited and quantities of Visudyne are expected to be limited until the end of 2023.• If you are being treated for age-related macular degeneration or subfoveal choroidal neovascularisation, your doctor may prescribe another medicine.• If you are being treated with Visudyne for another condition, please check with your doctor regarding treatment options.• Additional advice may be available from the national competent authority.
Status	Ongoing