



5 November 2021
EMA/587325/2021

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. During the shortage situation the company has imported limited stocks from outside the EU and distributed these through a controlled distribution system. The manufacturing process has now been amended to restore supply. Supplies will resume in November 2021 with normal supplies expected by the end of the first quarter of 2022.
Member States affected¹	The shortage affects all Member States in which the product is marketed. The Member States affected may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.
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 now been amended to restore supply. The company plans to distribute newly manufactured Visudyne in the EU markets in November 2021 with normal supplies expected for the end of first quarter of 2022.For age-related macular degeneration and subfoveal choroidal neovascularisation, healthcare

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	<p>professionals should use alternative treatments where possible.</p> <ul style="list-style-type: none">• Visudyne is used off-label in a number of conditions. National competent authorities may have set up programs to make Visudyne available under controlled conditions for these patients.• 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.• If you are being treated for age-related macular degeneration or subfoveal choroidal neovascularisation your doctor may prescribe an alternative 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