



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/65461/2026
EMA/H/C/002450

Holoclar (ex vivo expanded autologous human corneal epithelial cells containing stem cells)

A plain-language overview of Holoclar and why it is authorized in the EU

What is Holoclar and what is it used for?

Holoclar is a stem-cell treatment used in the eye to replace damaged cells on the surface (epithelium) of the cornea, the transparent layer in front of the eye covering the iris (the coloured part).

It is used in adults with moderate to severe limbal stem-cell deficiency caused by burns, including chemical burns, to the eyes. Patients with this condition do not have enough limbal stem cells which normally act as a regeneration system, replenishing the outer corneal cells when they get damaged and when they age.

Holoclar is a type of advanced therapy medicine called a 'tissue engineered product'. It consists of cells taken from the patient's limbus (at the edge of the cornea) and then grown in a laboratory so that they can be used to repair the damaged corneal surface.

Limbal stem-cell deficiency due to burns to the eyes is rare, and Holoclar was designated an 'orphan medicine' (a medicine used in rare diseases) on 7 November 2008. Further information on the orphan designation can be found on the [EMA website](#).

How is Holoclar used?

Holoclar can only be obtained with a prescription. The medicine must only be given by an appropriately trained and qualified eye surgeon in a hospital, and to the patient whose limbal cells were used to manufacture the medicine.

In the first stage of treatment, a small part of healthy limbal tissue (1–2 mm² in size) is taken from the patient in hospital and sent to the manufacturer on the same day. Next, the cells in the tissue are grown in a laboratory and frozen until the date of surgery is confirmed. Thawed cells are used to make Holoclar by growing them on a membrane made of a protein called fibrin. Holoclar, comprising the cells and the membrane, is then sent back to the hospital, where it is immediately surgically implanted in the patient's eye.

Antibiotics to prevent eye infection should be given to patients after limbal tissue has been taken from them. Following the surgery, the patient should receive antibiotics and an appropriate anti-inflammatory medicine.

Holoclar is intended for a single treatment, although treatment can be repeated if the doctor considers it necessary.

For further information about using Holoclar, see the package leaflet or contact your doctor or pharmacist.

How does Holoclar work?

The active substance in Holoclar is the patient's own limbal cells, which include cells from the surface of the cornea and limbal stem cells grown in a laboratory. Before Holoclar is used, the damaged corneal surface tissue of the affected eye is removed. Once implanted in the eye, the corneal cells of Holoclar help to replace the corneal surface, while the limbal stem cells serve as a reservoir of new cells that continuously replenish the cornea.

What benefits of Holoclar have been shown in studies?

Holoclar was shown to be effective in restoring a stable corneal surface in patients with moderate or severe limbal stem-cell deficiency caused by burns in a study using patients' past medical records. One year after Holoclar implantation, 75 out of 104 patients studied (72%) were judged to have had successful implants based on the presence of stable corneal surface with no surface defects and little or no ingrown blood vessels (a common feature of limbal stem-cell deficiency). There were also reductions in patients' symptoms, such as pain and inflammation, and improvements in vision.

Studies carried out with Holoclar are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Holoclar?

For the full list of side effects and restrictions with Holoclar, see the package leaflet.

The most common side effects with Holoclar (which may occur in up to 1 in 10 people) include eye pain, defects in corneal epithelium, conjunctival haemorrhage (bleeding from the small blood vessels on the surface of the eye) and blepharitis (inflammation of the eye lid).

Why is Holoclar authorised in the EU?

Holoclar was shown to be effective in restoring healthy corneal surfaces in adults with moderate or severe limbal stem-cell deficiency caused by burns as well as in improving their symptoms and vision. Moderate to severe forms of limbal stem-cell deficiency are serious conditions which, if untreated, can lead to severe reduction or complete loss of vision. The side effects with Holoclar are generally manageable. The European Medicines Agency therefore decided that Holoclar's benefits are greater than its risks and it can be authorised for use in the EU.

Holoclar was originally given 'conditional authorisation'. The authorisation was then switched to standard authorisation as the company had provided additional data requested by the Agency.

What measures are being taken to ensure the safe and effective use of Holoclar?

The company that markets Holoclar will provide healthcare professionals with educational material on the safe use of this treatment, including on the selection and follow up of patients and on reporting side effects. Educational material will also be provided to patients undergoing treatment.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Holoclar have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Holoclar are continuously monitored. Suspected side effects reported with Holoclar are carefully evaluated and any necessary action taken to protect patients.

Other information about Holoclar

Holoclar received a conditional marketing authorisation valid throughout the EU on 17 February 2015. The conditional marketing authorisation was switched to a standard marketing authorisation on 22 February 2024.

Further information on Holoclar, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/holoclar.

This summary was last updated in 03-2026.