

Serum Eyedrops

Information for the Referring Ophthalmologist

Currently, Lifeblood manufactures and supplies Autologous Serum Eyedrops (AutoSEDs) for patients with various ocular conditions, as requested by their ophthalmologist.

Is your patient eligible for this treatment?

Your patient may be eligible if they have failed conventional therapies at maximum tolerated doses and have ongoing symptoms of moderate to severe dry eye based on a clinical assessment by an ophthalmologist.

Clinical indications for Severe Dry Eye Syndrome may include¹:

- Sjögren's Syndrome related dry eye,
- Ocular Mucous Membrane Pemphigoid,
- Stevens-Johnson-Syndrome/Toxic Epidermal Necrolysis
- Graft Versus Host Disease,
- Ulcerative keratitis,
- Neurotrophic cornea such as Diabetic cornea, Herpetic aetiology, other neuropathic disease including secondary to non-ocular, extra-ocular and neuro surgery.
- Acute management of corneal injury (mechanical, chemical, thermal, surgery)
- Supportive such as Ocular surface reconstruction, Corneal transplantation, Other supportive e.g. critical care unit/high dependency/burns unit
- Inherited Ocular Surface Disease
- Other indications on a case-by case basis

Your patient will also need to meet the Guidelines for the Selection of Blood Donors:

Some general points regarding eligibility are listed below. These are intended as a general guide and are not an exhaustive list:

- Must be able to safely tolerate venesection of up to 450mls of blood.
- Able to mobilise and transfer to donor couch independently
- Aged 16 years old or over and under the age of 81 (NB: In QLD and WA, parental consent will be required for patients under the age of 18 years)
- Generally well on the day of donation

¹ Adapted from Royal College of Ophthalmologists (UK) (2017). Clinical Guidelines: Serum eyedrops for the treatment of severe ocular surface disease'.

Patients with the following conditions will NOT be eligible for donation:

- Current symptomatic heart disease such as angina, myocardial ischemia and coronary artery disease
- Cardiac arrhythmias such as atrial fibrillation
- A history of transient ischaemic attack (TIA), stroke or peripheral vascular disease
- A history of significant lung disease with ongoing respiratory compromise
- Any condition increasing risk of bacterial contamination of the collection such as longstanding ulcers or pressure areas.
- Blood borne viral infection
- Anaemia (patients with chronic mild anaemia may be able to donate a smaller volume of blood)

These are some specific conditions that will render patients unsuitable to donate in which case the collection should be performed at a service other than Lifeblood. In some cases an impediment to donation may not become obvious until the full donor interview.

To find out more information regarding eligibility, contact Lifeblood on 1300 669 054 and ask to speak to a Medical Officer.

Completing a request form

The Autologous Serum Eyedrop Request Form can be downloaded from www.transfusion.com.au.

When completing the request form you will need to provide:

- Contact details (yours and the patients)
- Information about the patient's eye condition
- Any response to current AutoSED treatment
- General medical information about the patient
- Information about the treatment to your patient so they are aware of the process and the requirement to have sufficient freezer space for the Eyedrops once manufactured.

Once completed, you can fax or email the request form back to Lifeblood using the contact details on the form. The information provided will be assessed by a Lifeblood Medical Officer and if the patient is eligible one of our friendly staff will contact your patient to arrange a donation. If the patient is not eligible, we will inform both the patient and the ophthalmologist.

How are AutoSEDs manufactured

AutoSEDs are manufactured from a blood donation. After the blood is collected, it is allowed to clot and is then separated into its different components by centrifuging. Once the serum has been separated, it is diluted with 0.9% saline to 20%v/v. This diluted serum is then dispensed into vials, which are labelled, sealed and disconnected from one another. These are packaged into a carton, which is labelled with a unique batch number, and frozen.

Your patients' blood donation is tested for all the same things a routine donation is and at the end of the process a sample is screened for bacterial contamination.

Collecting & storing the Eyedrops

A Lifeblood staff member will contact your patient to arrange pick up of their Eyedrops from a nominated hospital once they are available. This can be several weeks after their donation. The Eyedrops will be provided to the patient in 2 large shippers that weigh approximately 7kg each and contain dry ice. This will keep them frozen for a maximum of 8 hours, however they should be transferred to a domestic freezer as soon as possible. All Eyedrops will be provided at one time so it's vital that the patient has organised sufficient freezer space as this could be up to 12 cartons depending on how much blood was donated.

Instructions for use

The instructions for use are printed on the outside of the carton and a set of animations are also available for you to go through with your patient using this QR code. Simply hover your phone's camera over the adjacent image.



A summary of the instructions for use is included below for your reference:

- Take vial out of freezer and thaw in a refrigerator (this will take about 30 minutes).
- Wash your hands.
- Once thawed, hold the neck and the lid of the container and twist to open.
- Tilt head back and gently squeeze the vial to dispense a droplet into the eye.
- Recap the vial and refrigerate for up to 24 hours. The same vial can be used, over and over throughout the day but at the end of the day you need to throw it out.
- **The dose will be as per your instructions – please ensure your patient knows how often & how many drops they should be using each day.**

What are the possible risks of this treatment?

There are some minor risks associated with the collection of blood. These include fainting, anaemia, nerve injury and bruising of the arm where the blood was taken. If Lifeblood staff assess your patient is at risk during the donation they will stop the collection immediately.

The Eyedrops, when made up, do not contain any preservatives and as such there is a small chance of bacterial contamination which may cause irritation, inflammation and rarely infection arising from the use of this product. For this reason, it is extremely important that your patient follows the instructions for use. Some of the main points for your patient to remember are:

- Always ensure that vials remain frozen until the day of use and are thawed in a refrigerator and, not at room temperature.
- Discard any expired or unused vials 24 hours after they are thawed.
- Always wash hands thoroughly before administering.
- Take care not to touch the eye or any other surface with the tip of the vial while administering Eyedrops.

The drops are tested for the presence of contaminating bacteria at the time of manufacture. If any bacterial growth is detected the drops will not be suitable for use. If a positive bacterial screening test result occurs after the issue of the drops Lifeblood will contact you immediately to assess and manage any risk to your patient. A negative result on this initial bacterial screening does not guarantee that the Eyedrops will remain bacteria free – correct storage and handling is still essential.

If at any stage your patient notices that the eye drops cause discomfort or irritation, they should stop using them immediately and contact you, their doctor as well as advising Lifeblood.

Please ensure you discuss these risks and how to use the eye drops with your patient.

Questions and feedback

If you have a question about the process or your patient's eligibility you can contact Lifeblood staff on 1300 669 054.