

## Allogeneic Serum Eyedrops (Vials)

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### Description

Eyedrop medication consisting of allogeneic serum. The serum may vary in colour and may be transparent or cloudy. The contents of each vial is approximately 3ml.

### Storage

To be stored frozen until required for use. Allow to thaw at room temperature. Once thawed keep in a refrigerator for one day only following which any remaining contents and vials must be discarded. Use the green cap opener to aid with opening and closing of the vial. Use a fresh vial each day.

### Dry Ice

The product is issued to you already frozen on dry ice. Dry ice is extremely cold and skin contact should be avoided. Once the product is unpacked the dry ice must be left to evaporate in a well ventilated area, and out of reach and sight of children.

### Indications for Use

For the treatment of severe dry eye conditions of any cause when prescribed by a GMC registered Clinician

### Dosage

Apply as advised by the eye clinic or your Consultant. Contact eye clinic or your Consultant if you have any queries.

### WARNINGS

THIS PRODUCT MUST ONLY BE USED BY THE PATIENT WHOSE NAME IS ON THE BOX.

If irritation or any other adverse affect occurs discontinue use and contact your eye clinic or Consultant.

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### **Serum Eyedrops: Patient Information for Patients Residing in England and Wales**

Some patients, for a variety of reasons, suffer from severe dryness of the eye that can lead to redness, itching and pain. Many can be helped by intensive treatment with artificial teardrops. However, some patients do not respond to this treatment, and may be prescribed serum eyedrops by their ophthalmologist. National Health Service Blood and Transplant (NHSBT) works with ophthalmologists to provide a serum eyedrops service. Your Consultant has referred you to receive serum eyedrops as they think that you may benefit from this type of treatment.

Please note this patient information leaflet does not replace the guidance provided by your treating clinician(s). Your clinician(s) should advise you of the options that exist for your treatment and advise of alternative treatment and associated risks. Your clinician should ensure that you are aware of the material risks of injury associated with this treatment. If you are unsure about any aspects of your treatment/care ask your clinician(s) to explain.

### **What are serum eyedrops?**

Serum Eyedrops are made from serum (the liquid part of blood), prepared from donated blood. There are two types of serum eyedrops. "Autologous serum eyedrops" are made from a patient's own blood. "Allogeneic serum eyedrops" are prepared from blood donated by volunteer blood donors. Your ophthalmologist will determine which type of serum eyedrop is most appropriate for your circumstances.

### **How are serum eyedrops made?**

Up to 420ml of blood is collected at a Blood Collection Centre. It is taken to a Blood Centre and processed to separate the liquid part of the blood (serum) from the clotted part of the blood (red blood cells). The serum is diluted with saline and dispensed into small vials.

### **What will happen if I am referred for autologous serum eyedrops?**

Before NHSBT can collect your blood, they must assess your general health to make sure that collecting your blood will not harm you. You will be contacted by a member of the Customer Care Team, who work for NHSBT. They will organise two appointments for you. The first will be a recorded telephone interview with one of our registered nurses, and the second will be an appointment to attend a Blood Donation Centre for the collection of your blood. The nurse at the Blood Donation Centre will review your medical history details and will be responsible for making the decision about your 'fitness to donate' when you arrive at the Blood Donation Centre.

If it is considered safe to proceed, up to 420ml of blood will be collected at the Blood Donor Centre. Your blood will be tested for hepatitis, HIV, syphilis and HTLV (Human T-cell lymphocytotropic virus - a virus that affects white cells) and you will be asked to consent to this testing when the blood is collected. This is routine for all blood donations. Following the collection of your blood, it may take NHSBT up to 4-6 weeks to test your blood and make your eyedrops. When your eyedrops are ready, NHSBT will contact you to

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arrange for them to be delivered to you directly and to arrange your next appointment. Your eyedrops will be supplied frozen, and you will be supplied with approximately 90 -120 vials; the precise quantity will depend on several factors, including how much blood NHSBT was able to collect from you.

### **What will happen if I cannot give my own blood?**

Many patients who require serum eyedrops, for a variety of reasons, for example their general health or age, are not healthy enough to donate their own blood. Some patients need treatment urgently and cannot wait for the time required to make autologous serum eyedrops, even if they are fit to give their own blood. Also, some patients may not be able to travel to a Blood Donation Centre to give their blood. These patients will receive allogeneic serum eyedrops, unless their ophthalmologist has instructed us not to do so.

### **What will happen if I am referred for allogeneic serum eyedrops?**

A member of the NHSBT Customer Care team will contact you by telephone to arrange delivery of a batch of eyedrops. You will be provided with a batch of allogeneic serum eyedrops, containing a minimum of 80 vials (the precise number varies from batch to batch).

### **What will happen when my eyedrops are delivered?**

A dedicated same day courier will deliver your eyedrops directly to you at your home. The eyedrops will be packaged in 'dry ice' to ensure they remain frozen in transit. **You must transfer the eyedrops to your home freezer as soon as you receive them.** The individual vials are packaged in small cardboard boxes, which are in turn packed into a larger cardboard box. The large cardboard box contains 9 smaller boxes. Some of these boxes are empty and are only included for space filling to reduce the risk of vials being damaged in transit. Empty boxes will be identifiable as such. The remaining boxes will each contain vials of serum eyedrops. We recommend that you keep the vials inside the boxes while in your freezer, as this will reduce the risk of them being damaged. The outer box is closed with a tamper evident seal, which you must remove to access the vials. If this is damaged when you receive the eyedrops, do not use any of the vials and please notify us **immediately**.

### **I used to receive my eyedrops in brown glass bottles; why are they now in plastic vials?**

We have recently changed our dispensing system. This has been driven by a large increase in clinical demand for the serum eyedrop service, and the new dispensing system allows us to make more batches in our current facility. It is also safer, as the design of the new dispensing system decreases the (already very small) risk that the eyedrops could be contaminated during the preparation process. We have extensively evaluated these plastic vials and found that the majority of patients prefer them to the glass bottles.

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### How should I use the eyedrops?

Each day you should remove one vial from the freezer and leave it to thaw at room temperature. Please do not immerse the vial in water, or run under a tap to speed up thawing, as this could result in the vial being contaminated. Please handle the vials with care when they are frozen, as the small sections of tubing attached to the end of the vial could snap if they are bent before they are thawed. In most cases, each vial contains 3ml of serum eyedrops, which is sufficient for one day's use for most people. Occasionally, serum eyedrops are dispensed in smaller, 1.5ml vials.

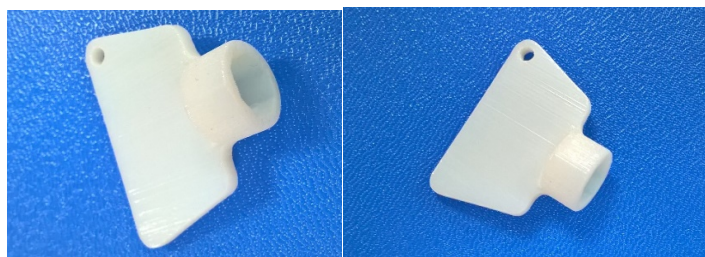
The vial is fitted with a white, hexagonal screw cap. These are tightly screwed in, to prevent them leaking, and you may find it difficult to undo the cap manually when the vial has thawed. If this is the case, a green cap opener is provided; this can be slotted onto the cap and used to unscrew it (see the photograph below). When you have opened the cap for the first time, you should be able to replace it securely by finger tightening it. However, you may find it more comfortable to use the cap opener to remove and re-apply the cap on each occasion.

### How to Apply the Cap Opener



When you receive your first batch of vials you will also receive one extra-large cap opener that can be used to aid opening if you find the green caps difficult to use. These extra-large cap openers have a small hole on the top right and can be fitted to a key ring. They can be used in the same way as described above for the green cap openers. You will only be supplied with one extra-large cap opener as most patients will not require this aid. However, if you lose or damage it, a replacement cap opener can be obtained by contacting our NHSBT Customer Services Team on 0300 0200 113.

### Extra-large Cap Opener



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You should apply the eyedrops as directed by your ophthalmologist. If you have previously received your eyedrops in the brown glass bottles with rubber droppers, you may find that eyedrops flow faster from the vials, and you will need to adjust to this change. After thawing, you should keep the eyedrops in a cool location (ideally a refrigerator), and at the end of the day discard the vial, even if there is some fluid remaining. It is important that you use a fresh vial each day, or there may be a risk of eye infection.

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### **What do the eyedrops look like?**

If you have previously received your eyedrops in brown glass bottles, this may be the first time you have clearly seen what colour they are. Serum eyedrops are naturally a pale yellow/brown colour. You may notice that the colour of different batches of eyedrops varies slightly. This is normal, and not a cause for concern. You may also notice small particles floating in the eyedrops; again, this is normal, and not a cause for concern.

### **What are the possible risks?**

#### **Autologous serum eyedrops**

For autologous serum eyedrops, there are some minor risks associated with collecting blood. These include fainting, anaemia and bruising or infection at the site where the blood was taken. NHSBT try to minimise these risks by assessing you before and during the collection of your blood. This includes checking your haemoglobin level to make sure that you are not becoming anaemic.

There is also a risk that we may not be able to return the eyedrops made from your serum.

The main reasons for this are:

- There was a problem with the manufacturing process e.g. the blood pack has become damaged during processing.
- If any of the blood screening tests are found to be positive.

The chances of this happening are approximately 1 in 100

If either of the above happens, you will be informed and offered allogeneic eyedrops unless your ophthalmologist has instructed us not to do so.

#### **Allogeneic serum eyedrops**

The likelihood of getting an infection transmitted from an Allogeneic Serum Eyedrops donor is very low. All blood donors are unpaid volunteers and are very carefully selected to be at low risk of infections. Furthermore, every donation is tested and those found positive will not be used for preparation of serum eyedrops. The tests that are used are very sensitive and the risk that hepatitis B, hepatitis C or HIV is not detected is less than one per million donations tested. The risk of getting variant Creutzfeld Jakob Disease (vCJD) is also probably very low. Each year approximately 2 million units of blood are transfused in the UK, and there have been just a handful of cases in the past 20 years where patients are known to have become infected with vCJD from a blood transfusion. To reduce the risk of disease transmission even further, each batch of allogeneic serum eyedrops is prepared from a single blood donation.

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### **Risks affecting both types of serum eyedrops**

Another possible risk is a bacterial or fungal infection caused by the eyedrops as they do not contain any preservative. To minimise the possibility of this occurring, NHSBT will test each batch of eyedrops for the presence of any infection before they issue the eyedrops to you. The risk of infection can also be minimised by only using one vial per day and discarding the vial and remaining contents at the end of each day as instructed.

If you experience persistent redness, itchiness or any other type of allergic reaction after applying the eyedrops, you should stop using the eyedrops and consult the doctor who prescribed them to you.

There is also a very small chance that a protein deposit could collect on the surface of the eye. This is very rare and can easily be resolved by stopping the treatment. If any adverse effects occur when using the eyedrops you should notify your Eye Clinic immediately and seek their advice.

### **After care**

The Eye Clinic will continue to monitor your progress while you are on this treatment and will decide whether the treatment should be continued.