

REQUEST FOR EXCEPTIONAL RELEASE OF NON-CONFORMING SERUM EYE DROPS

REASON FOR ISSUE: Add tick boxes for NZBS TMS / MO to confirm discussions with treating clinician in Section 2, change of document title, DCR26221 add tick box in Section 3 for completion of 150F089.

Autologous Serum Eye Drops ☐

Allogeneic Serum Eye Drops ☐

You have requested that the New Zealand Blood Service (NZBS) make non-conforming Serum Eye Drops (SEDs) available to your patient. Before this product can be supplied to your patient the NZBS requires you to read this form and to acknowledge full responsibility for the use and consequences of the use of this non-conforming product.

This batch of SEDs has not completed the required sterility testing and hence there is a small risk of ocular infection. Early release of the product is being made following advice given by you based on your clinical assessment of the patient. It is your responsibility to consider the risk and alternative treatments carefully when making this request.

Patient informed consent: You are responsible for explaining to your patient the risks associated with treatment you are considering, and the alternatives that are available. You are responsible for obtaining all necessary consents, and to comply in every respect with the Code of Health and Disability Services Consumer Rights 1996.

You may want to consult further with a NZBS Transfusion Medicine Specialist on the use of SEDs.

Terms and Conditions: This non-conforming product is given exceptional release in accordance with the NZBS Terms and Conditions Relating to the Exceptional Release of Nonconforming Blood Products. This document is available in the Clinical section of the NZBS web site, www.nzblood.co.nz. In requesting the supply of non-conforming SEDs you accept and become bound by these conditions.

INSTRUCTIONS FOR TREATING OPHTHALMOLOGIST

I have requested the exceptional release of non-conforming SEDs for this patient. I have read this document, and confirm that I have been advised and understand the risks associated with using non-conforming SEDs. I have considered the alternative treatment options that are available for my patient.

I have explained (or will explain) the risks and alternatives to my patient. I acknowledge that obtaining all necessary consents (and otherwise complying with the Code of Health and Disability Consumers' Rights) is my responsibility alone.

I am aware of the terms and conditions on which the non-conforming SEDs are supplied for use by NZBS, and agree to be bound by them.

I understand that non-conforming SEDs are supplied by the NZBS only where early use would be seen as beneficial to the patient, and confirm that to the best of my knowledge and belief such a situation exists for my patient.

Please complete Section One on the following page and fax to NZBS Auckland 09 523 5742

**REQUEST FOR EXCEPTIONAL RELEASE OF
NON-CONFORMING SERUM EYE DROPS****SECTION ONE: TO BE COMPLETED BY REQUESTING OPHTHALMOLOGIST**

Patient name: _____ NHI No: _____

Date required: _____

Reason for exceptional release of SEDs: _____

Ophthalmologist name: _____ NZMC Registration number: _____

Signature: _____ Date: _____

SECTION TWO: TO BE COMPLETED BY NZBS TRANSFUSION MEDICINE SPECIALIST☐ I have discussed the risks associated with the use of the non-conforming product with the treating ophthalmologist (where applicable).☐ I have discussed possible alternative treatments with the treating ophthalmologist (where applicable).

Non-conforming SEDs approved for release: YES / NO*

Name: _____

Signed: _____ Date: _____

*Reason exceptional release is not approved:

_____**SECTION THREE: TO BE COMPLETED BY NZBS BLOOD PROCESSING STAFF**

Batch number of SEDs: _____

Interim culture results negative: YES / NO* *If NO, contact the TMS for advice **without delay**

Date released: _____

Date sterility testing will be completed: _____

Final culture results negative: YES / NO**

If NO, contact TMS for advice **without delay, send bottles to LabPLUS for culture and attach a copy of results.

Completed by: _____

Signature: _____ Date: _____

☐ 150F089 entry complete