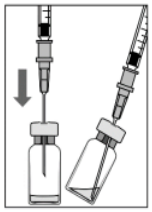
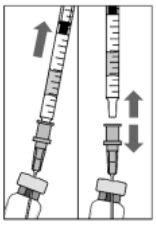
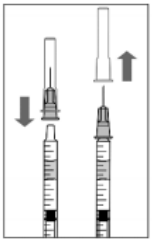
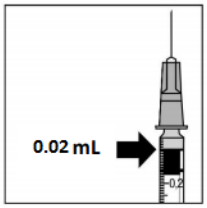
NEONATAL Medication Monograph

Ranibizumab

This document should be read in conjunction with this **DISCLAIMER**

Highly Restricted: Requires Neonatal or Paediatric Ophthalmologist approval before commencing. For the treatment of retinopathy of prematurity (ROP) where laser treatment is contraindicated, unable to be performed or has not been successful. For use by an ophthalmologist only

Presentation	Vial 2.3 mg/0.23 mL Contact Pharmacy for preparation
Description	Humanised Monoclonal Antibody Anti-Vascular Endothelial Growth Factor
Indications	Retinopathy of Prematurity (ROP) • When laser treatment has failed, contraindicated or unable to be performed
Medication Access	Ranibizumab is not readily available and must be ordered via the Compassionate Access Scheme through Novartis® This application is to be completed by the Ophthalmologist, which will allow the Pharmacy Department to procure stock. ReTCAM nursing staff are to notify the Pharmacy Department as soon as possible Delivery and process by company and Pharmacy
Precautions	The long term systemic safety of anti-VEGF medicines in neonates is unknown with further studies currently underway
Dosage	**To be administered by a qualified Ophthalmologist** **Intravitreal Injection:** 0.2mg per eye
Adverse Reactions	**Common:** Intraocular inflammation, eye pain, eye irritation **Serious:** Risk of arterial thromboembolic events
Preparation	**Use solution provided by CIVAS Pharmacy** **OR** **For 2.3mg vial:** 1. Before withdrawal, the outer part of the rubber stopper of the vial should be disinfected.

	2. Attach a 5 µm filter needle (18G) to a 1 mL syringe using an aseptic technique. Push the blunt filter needle into the centre of the vial stopper until the needle touches the bottom edge of the vial. 3. Withdraw all the liquid from the vial, keeping the vial in an upright position, slightly inclined to ease complete withdrawal. 4. Ensure that the plunger rod is drawn back sufficiently when emptying the vial in order to completely empty the filter needle. 5. Leave the blunt filter needle in the vial and disconnect the syringe from the blunt filter needle. The filter needle should be discarded after withdrawal of the vial contents and should not be used for the intravitreal injection. 6. Aseptically and firmly attach an injection needle (30G x ½ inch) onto the syringe. 7. Carefully remove the cap from the injection needle without disconnecting the injection needle from the syringe. Note: Grip at the yellow hub of the injection needle while removing the cap 8. Carefully expel the air from the syringe and adjust the dose to 0.02mL on the syringe. The syringe is ready for injection. Note: Do not wipe the injection needle. Do not pull back on the plunger.	A.  B.  C.  D. 
Administration	Must be administered by a qualified ophthalmologist experienced in intravitreal injections	
Monitoring	Patients should be reviewed for intraocular pressure rise pre-injection and 60 minutes post-injection	
Storage	Store at 2°C to 8°C (refrigerate- do not freeze). Protect from light	
Notes	The injection has a half-life of approximately 9 hours If the injection is prepared by CIVAS pharmacy: • Measure appropriate dose and ensure excess of at least 0.1mL. • Ensure an extra dose is supplied for Ophthalmologist- liaise with SCN pharmacist regarding number of doses to supply Lucentis pre-filled syringe intravitreal injection is available but not recommended as the barrel only marks the adult dose of 0.5 mg and any lesser dose cannot be identified.	

References	Stahl A, Krohne TU, Eter N, et al. Comparing Alternative Ranibizumab Dosages for Safety and Efficacy in Retinopathy of Prematurity: A Randomized Clinical Trial. *JAMA Pediatr.* 2018;172(3):278–286. doi:10.1001/jamapediatrics.2017.4838 Stahl A, Lepore D, Fielder A, et al. Ranibizumab versus laser therapy for the treatment of very low birthweight infants with retinopathy of prematurity (RAINBOW): an open-label randomised controlled trial. *Lancet*. 2019;394(10208):1551-1559. doi:10.1016/S0140-6736(19)31344-3 Wu, W., Shih, C., Lien, R., Wang, N., Chen, Y., Chao, A., Chen, K., Chen, T., Hwang, Y. and Lai, C., 2017. Serum vascular endothelial growth factor after Bevacizumab or Ranibizumab treatment for retinopathy of prematurity. Retina, [online] 37(4), pp.694-701.
Related clinical guidelines	Retinopathy of Prematurity (ROP) Screening, Treatment and Ophthalmology Consultations

Keywords:	ROP, Ranibizumab, Lucentis, Retinopathy of prematurity		
Publishing:	☒ Intranet ☒Internet		
Document owner:	Head of Department - Neonatology		
Author / Reviewer:	KEMH & PCH Pharmacy / Neonatology Directorate		
Date first issued:	January 2021	Version:	1.1
Last reviewed:	March 2021	Next review date:	January 2024
Endorsed by:	Neonatal Directorate Management Group	Date:	March 2021
Standards Applicable:	NSQHS Standards: 1 Governance, 3 Infection Control, 4 Medication Safety, 8 Acute Deterioration		