NHS
Kent and Medway
Cancer Collaborative

SOP for Reconstitution and Administration of Romiplostim

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1.0 INTRODUCTION

Romiplostim is a protein used to treat low platelet counts in patients with immune (idiopathic) thrombocytopenic purpura (called ITP). ITP is a disease in which the body's immune system destroys its own platelets. Platelets are cells in blood that form blood clots. Very low platelet counts can cause bruising and serious bleeding. Romiplostim is used to treat adult patients (aged 18 years and over) who may or may not have had their spleen removed for chronic ITP and who have been previously treated with corticosteroids or immunoglobulins, where these treatments don't work.

Romiplostim works by stimulating the bone marrow (part of the bone which makes blood cells) to produce more platelets. This should help to prevent bruising and bleeding associated with ITP.

Romiplostim 250 micrograms powder and solvent for solution for injection

Each vial contains 250 mcg of romiplostim. After reconstitution, a deliverable volume of 0.5 mL solution contains 250 mcg of romiplostim (500 mcg/mL). An additional overfill is included in each vial to ensure that 250 mcg of romiplostim can be delivered.

After reconstitution of the powder, the romiplostim solution for injection is administered subcutaneously. The injection volume may be very small. Caution should be used during preparation of romiplostim in calculating the dose and reconstitution with the correct volume of sterile water for injection. Special care should be taken to ensure that the appropriate volume of romiplostim is withdrawn from the vial for subcutaneous administration – a syringe with graduations of 0.01 mL should be used.

1.1 Storage

- Store in a refrigerator (2°C – 8°C).
- Do not freeze.
- Store in the original carton in order to protect from light.
- May be removed from the refrigerator for a period of 30 days at room temperature (up to 25°C) when stored in the original carton.

1.2 Contents

Powder:

5 mL single-dose vial (type 1 clear glass) with a stopper (chlorobutyl rubber), seal (aluminium) and a flip-off cap (polypropylene).

Solvent:

Romiplostim 250 micrograms powder and solvent for solution for injection: Pre-filled syringe (type 1 clear glass with bromobutyl rubber plunger) containing 0.72 mL of water for injections for reconstitution.

1.3 Pack Contents

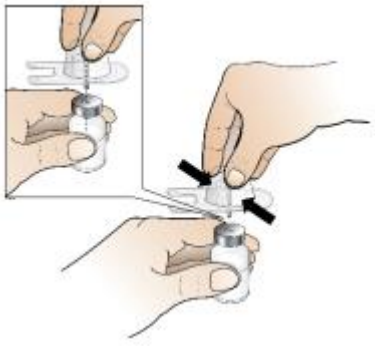
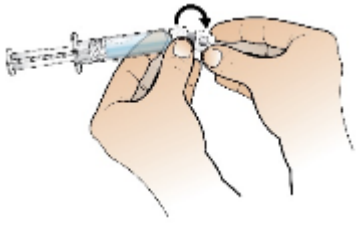
Romiplostim 250 micrograms powder and solvent for solution for injection:

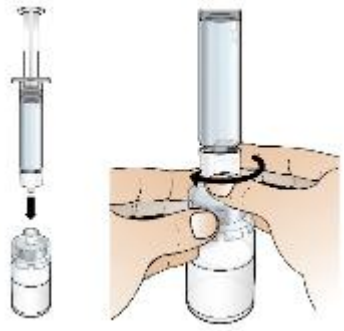
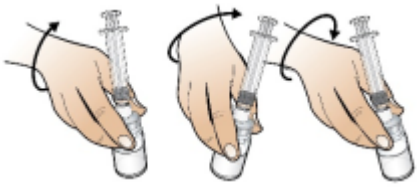
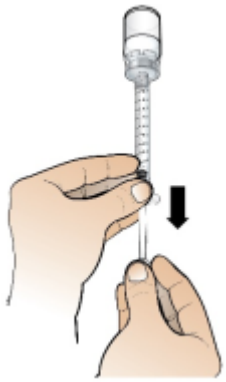
Romiplostim is supplied as a 1 pack or multipack comprising 4 packs.

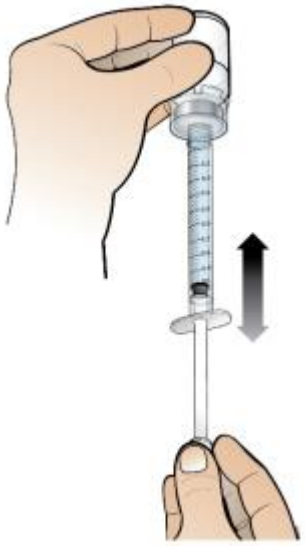
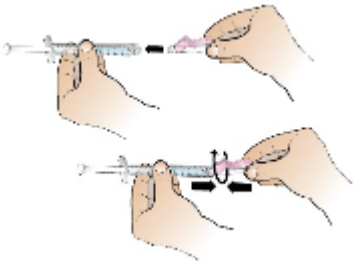
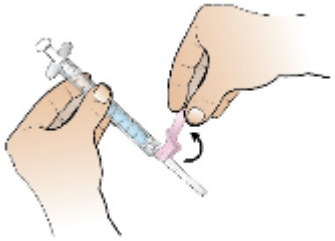
Each pack contains:
• 1 vial of 250 micrograms romiplostim.
• 1 pre-filled syringe containing 0.72 mL of water for injections for reconstitution.
• 1 plunger rod for the pre-filled syringe.
• 1 sterile vial adapter.
• 1 sterile 1 mL Luer lock syringe.
• 1 sterile safety needle.
• 4 alcohol swabs.

Romiplostim is a sterile but unpreserved medicinal product and is intended for single use only. Romiplostim should be reconstituted in accordance with good aseptic practice.

2.0 METHOD

1.	Remove the plastic cap from Romiplostim powder vial and clean rubber stopper using the provided alcohol swab.	
2.	Attach vial adapter to Romiplostim vial by peeling off **paper backing from vial adapter, keeping the vial adapter in its packaging.** Keeping the **vial on the bench,** push the vial adapter down onto the centre of the vial until it is firmly in place. **Note: To prevent contamination of the product, do not touch the vial adapter spike or Luer lock.**	
3.	**Remove and discard vial adapter packaging.**	
4.	**Attach plunger rod to the pre-filled syringe of water for injections** by twisting the plunger rod clockwise onto the syringe plunger, until you feel a slight resistance.	
5.	**Holding the pre-filled syringe of water for injections with one hand, bend the tip of the white plastic cover downward with your other hand. This will break the seal of the white plastic cover. Once the seal is broken, pull cover off to separate the grey rubber cap from the clear plastic tip on the syringe.**	

6.	**Keeping the vial on the bench, attach the pre-filled syringe of water for injections to vial adapter:** hold the outer edge of the vial adapter with one hand and twist the syringe tip clockwise onto the adapter with the other hand until you feel a slight resistance.	
7.	**Very slowly and gently expel all water** into powder vial. Water should flow slowly onto powder. GENTLY swirl the vial until all of the powder has dissolved and the liquid in the vial is clear and colourless. **Do not** shake the vial **Note: From a microbiological point of view, the product must be used immediately after reconstitution. If reconstituted product is not used immediately, the syringe should not be removed from the vial adapter to maintain microbiological integrity.**	 **Note:** This may take up to 2 minutes for the powder to completely dissolve.
Before continuing: **Do** visually inspect the reconstituted solution for particulate matter and/or discolouration. The reconstituted solution should be clear and colourless and should not be administered if particulate matter and/or discolouration are observed. **Do** make sure solution is fully dissolved before removing syringe.		
8.	Remove the empty pre-filled syringe from the vial adapter.	
9.	**Remove 1 mL administration syringe from package. Attach the 1 mL syringe to** vial adapter of reconstituted solution by twisting the syringe tip onto the vial adapter until you feel a slight resistance.	
10.	**Turn assembled syringe-vial unit upside down,** so the vial of reconstituted product is above the syringe. **Withdraw all** of the medicinal product solution into the administration syringe. **Do** ensure that the plunger remains in the syringe.	

11.	**Ensure the correct amount of solution** for the patient dose is in the administration syringe by injecting any excess solution back into the vial. **Note: Remove all air bubbles from syringe to ensure precise solution amount is in syringe.**	
12.	**Twist off administration syringe from vial adapter.** **Attach safety needle** to the filled administration syringe by twisting needle **clockwise** into syringe Luer lock tip.	
13.	Prepare injection site with a new alcohol swab. **Pull back on the pink safety cover** toward the syringe and away from the needle. **Remove clear needle shield from prepared needle** by holding syringe in one hand and carefully pulling shield straight off with the other hand.	
14.	**Administer subcutaneous injection** following local protocols and good aseptic technique.	
15.	**After injecting, activate the pink safety cover** by pushing the cover forward using the same hand until you hear and/or feel it click/lock.	
16.	**Immediately discard syringe and needle** into an approved Sharps Container.	

3.0 COMPETENCY STATEMENT

The registered Nurse demonstrates clinical knowledge and skill in Reconstitution and Administration of Romiplostim. Assessment in practice must be by a SACT Registered Nurse.

Performance Criteria	Summary of evidence demonstrating independence.	Date & assessors' signature
Demonstrates safe knowledge in Reconstitution and Administration of Romiplostim		
a) Awareness of pre-treatment blood results		
b) Preparation of equipment/trolley and aseptic field, with appropriate use of PPE		
c) Demonstrates knowledge and practice of safe reconstitution of Romiplostim		
d) Demonstrate safe knowledge and practice in the preparation required for administration of Romiplostim including;	☐ Assessment of patient ☐ Preparation of patient, ensuring patient comfort and safety	
e) Demonstrate correct use of aseptic technique during the procedure		
f) Demonstrate suitable sites for subcutaneous injection		
g) Demonstrate accurate administration		
h) Demonstrate correct disposal of waste and sharps.		
i) Demonstrate correct documentation following Administration.		

3.1 Competency Signatory Sheet

Reconstitution and administration of Romiplostim

Name:	
Job Title:	
Directorate:	
Ward/Site:	

This competency is intended solely for the use of Registered Nursing Staff. Reconstitution and administration of Romiplostim should take place under the guidance of a SACT competent, Registered Nurse.

This skill should be repeated under supervision a minimum of two times (or until the practitioner feels ready to demonstrate their practice to their supervisor

Date	Supervisor Signature	Practitioner Signature

I confirm that I have assessed the above-named Registered Nurse and that he/she has demonstrated an overall competence in the Reconstitution and administration of Romiplostim.

Signature of practitioner acting as supervisor	
Signature of Registered Nurse	
Date competency agreed	

Please photocopy this sheet once completed. One copy should go to your line manager for your personal file. Retain the other copy for your portfolio.

4.0 REFERENCES

- Nplate with Reconstitution Pack. January 2021. emc Summery of product. https://www.medicines.org.uk/emc/medicine/23117

5.0 DOCUMENT ADMINISTRATION

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