Remicade Infusion

PLEASE NOTE: DO NOT MIX MEDICATION UNTIL IV ACCESS IS ESTABLISHED

1-Wash Hands

2-Prepare a clean work area large enough for mixing medication.

3-Establish peripheral IV access utilizing a butterfly needle or IV catheters supplied. **(Please note an IV catheter will allow the patient more freedom to move around during the infusion)**

4-Once IV access is established you should begin the mixing process by removing 35ml from the 250ml saline bag utilizing the 60ml syringe and needle provided. Be certain to clean the injection port on the bag with an alcohol prep pad prior to inserting the needle. Discarded this syringe, needle, and saline into a sharps container.

5-Prepare for mixing by gathering the following supplies: 20 alcohol preps,4 -10ml empty sterile syringes, 4-needles, 4 vials of Remicade, and 4 vials of sterile water.

6-Attatch a needle to a new sterile 10ml syringe and draw up 10ml of air.

7-Now, remove the cap from a vial of sterile water and swab the top with an alcohol prep pad.

8-Next insert the needle into the vial of sterile water and push the air into vial and remove all 10ml of sterile water.

9-Next remove the cap from a vial of Remicade and swab the top with an alcohol prep pad. Then insert the needle from the syringe filled with 10ml of sterile water into the Remicade vial at an angle and slowly allow the saline to instill into the Remicade vial. **(Please note reconstitution of Remicade should be done slowly with care taken note to force the the sterile water directly onto the freeze dried drug. The proteins in Remicade are very fragile and the saline should trickle down the side of the vial and not directly onto the freeze dried drug to prevent damaging the proteins.)**

10-Remove the needle and syringe and discard in the sharps container then **gently swirl** the vial to allow the medication to mix.

11-Set the mixed vial aside and repeat this process for all 4 vials of Remicade. Allow approximately 5 minutes for reconstitution. The fluid should be clear but please note that there may be some particles left on the bottom of the vial that may not completely dissolve and may remain in the bottle even after the medication is drawn up. The main concern is that the fluid is clear not cloudy or discolored.

12-Clean the tops of all 4 Remicade vials with an alcohol prep pads.

13-Attatch a needle to the other 60ml Luer lock syringe supplied and draws up 35ml of air.

14-Withdraw 10ml of the Reconstituted Remicade from 3 of the vials and 5ml from the last vial for a total of 35ml/350mgs of Remicade. The 5ml of Remicade remaining in the last vial should be discarded as it cannot be used due to its short shelf life.

15-Cleanse the injection port on the 250ml bag of NS with alcohol prep. Insert the needle of the 60ml Syringe with the 35ml of Remicade and **gently and slowly** instill the entire drug into the bag. Remove the syringe and needle and discard in a sharps container.

16-**Gently** invert the bag a few times to allow the medication to mix with the saline.

17-Insert and prime the filtered tubing provided.

18-Flush the patients PIV with 3ml of 0.9%NS from the prefilled syringes provided.

19-Connect the end of the IV tubing and begin the infusion at the rates listed below.

20-When the infusion is completed flush the PIV with 3 ml of 0.9%NS with a new prefilled syringe.

21-Remove PIV apply pressure to site for approximately 3 minutes to prevent a hematoma. Then cover with a 2x2 gauze pad and secure with tape included in the IV start kits.

Preparation and administration

Preparation and administration instructions. Use Aseptic Technique.
REMICADE® vials do not contain antibacterial preservatives. Therefore, the vials after reconstitution should be used immediately, not re-entered or stored. The diluent to be used for reconstitution is 10 mL of Sterile Water for Injection, USP. The total dose of the reconstituted product must be further diluted to 250 mL with 0.9% Sodium Chloride Injection, USP. The infusion concentration should range between 0.4 mg/mL and 4 mg/mL.

The REMICADE® infusion should begin within 3 hours of preparation.

1.

Calculate the dose and the number of REMICADE® vials needed. Each REMICADE® vial contains 100 mg of infliximab. Calculate the total volume of reconstituted REMICADE® solution required.

2.

Reconstitute each REMICADE® vial with 10 mL of Sterile Water for Injection, USP, using a syringe equipped with a 21-gauge or smaller needle. Remove the flip-top from the vial and wipe the top with an alcohol swab. Insert the syringe needle into the vial through the center of the rubber stopper, and direct the stream of Sterile Water for Injection, USP, to the glass wall of the vial. Gently swirl the solution by rotating the vial to dissolve the lyophilized powder. Avoid prolonged or vigorous agitation. DO NOT SHAKE. Foaming of the solution on reconstitution is not unusual. Allow the reconstituted solution to stand for 5 minutes. The solution should be colorless to light yellow and opalescent; the solution may develop a few translucent particles, as infliximab is a protein. Do not use if opaque particles, discoloration, or other foreign particles are present.

3.

Dilute the total volume of the reconstituted REMICADE® solution dose to 250 mL with 0.9% Sodium Chloride Injection, USP, by withdrawing a volume of 0.9% Sodium Chloride Injection, USP, equal to the volume of reconstituted REMICADE® from the 0.9% Sodium Chloride Injection, USP, 250-mL bottle or bag. Slowly add the total volume of reconstituted REMICADE® solution to the 250-mL infusion bottle or bag. Gently mix.

4.

The infusion solution must be administered over a period of not less than 2 hours and must use an infusion set with an in-line, sterile, non-pyrogenic, low-protein-binding filter (pore size of 1.2 µm or less). Any unused portion of the infusion solution should not be stored for reuse.

5.

No physical biochemical compatibility studies have been conducted to evaluate the coadministration of REMICADE® with other agents. REMICADE® should not be infused concomitantly in the same intravenous line with other agents.

6.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If visibly opaque particles, discoloration, or other foreign particulates are observed, the solution should not be used.

Administration instructions regarding infusion reactions

Adverse effects during administration of REMICADE® have included flu-like symptoms, headache, dyspnea, hypotension, transient fever, chills, gastrointestinal symptoms, and skin rashes. Anaphylaxis might occur at any time during REMICADE® infusion. Approximately 20% of patients treated with REMICADE® in all clinical trials experienced an infusion reaction compared with 10% of patients treated with placebo (see ADVERSE REACTIONS, Infusion-Related Reactions). Prior to infusion with REMICADE®, premedication may be administered at the physician's discretion. Premedication could include antihistamines (anti-H1 +/- anti-H2), acetaminophen, and/or corticosteroids. During infusion, mild to moderate infusion reactions may improve following slowing or suspension of the infusion and, upon resolution of the reaction, reinitiation at a lower infusion rate and/or therapeutic administration of antihistamines, acetaminophen, and/or corticosteroids. For patients who do not tolerate the infusion following these interventions, REMICADE® should be discontinued. During or following infusion, patients who have severe infusion-related hypersensitivity reactions should be discontinued from further REMICADE® treatment. The management of severe infusion reactions should be dictated by the signs and symptoms of the reaction. Appropriate personnel and medication should be available to treat anaphylaxis if it occurs.

Storage

Store the lyophilized product under refrigeration at 2°C to 8°C (36°F to 46°F). Do not use beyond the expiration date. This product contains no preservatives.