Rituximab and Hyaluronidase Human Injection (Rituxan Hycela™)

Pronounced: ri-TUX-i-mab hahy-uh-look-i-deys

Classification: Monoclonal Antibody

About Rituximab and Hyaluronidase Human Injection (Rituxan Hycela™)

Rituximab and hyaluronidase human injection is a synthetic (man made) antibody directed against a protein called CD20, found on the surface of normal and cancerous B-cells, which are part of the immune system. Once the medication attaches itself to the B cells expressing CD20, it causes these cells to die. This process kills cancer cells, but can also kill functioning B cells, temporarily affecting the ability of the immune system to fight infections. Hyaluronidase is an enzyme that is used in this medication to increase the absorption of rituximab when it is given subcutaneously (into the skin).

How to Take Rituximab and Hyaluronidase Human Injection

Rituximab and hyaluronidase human injection is given by subcutaneous injection (a needle inserted under the skin in the stomach (abdomen) area). Do not inject into areas where the skin is red, bruised, tender or hard, or where there are moles or scars. The injection may be given over several minutes. The dosage and schedule is determined by the type of cancer and treatment regimen.

Prior to each dose, you will be given acetaminophen, diphenhydramine, and possibly a corticosteroid, to help prevent any reactions. This form of rituximab is only used after having received at least one dose by intravenous (IV) infusion, without any reactions.

Possible Side Effects of Rituximab and Hyaluronidase Human Injection

There are a number of things you can do to manage the side effects of rituximab and hyaluronidase human injection. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Skin & Mouth Reactions**
Severe skin and mouth reactions can occur on this medication. Notify your healthcare provider right away if you develop any rash, peeling skin, or painful sores or blisters on your skin, lips, inside of your mouth or genitals.

**Hepatitis B Reactivation**
This medication can cause Hepatitis B reactivation in patients who have previously had hepatitis. This can occur up to 24 months after receiving this medication. Be sure your healthcare provider is aware of any previous Hepatitis B diagnosis and treatment. You will also be tested for the Hepatitis B virus prior to beginning treatment with this medication. Notify your healthcare provider if you develop yellowing of your skin or the whites of your eyes.

**Progressive Multifocal Leukoencephalopathy (PML)**
PML is a rare but very serious brain infection that has been reported with this medication. The signs of PML may develop over several weeks or months. They may include changes in mood or usual behavior, confusion, thinking problems, loss of memory, changes in vision, speech, or walking, and decreased strength or weakness on one side of the body. If you develop any of these signs, notify your healthcare provider immediately.
Infection and Low White Blood Cell Count (Neutropenia)

This medication can increase your risk of developing an infection and lower the ability of your immune system to fight infections, with or without a decrease in white blood cell counts. This risk can last for up to a year after stopping this medication.

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent **mouth care**.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your doctor or nurse before scheduling dental appointments or procedures.
- Ask your doctor or nurse before you, or someone you live with has any vaccinations.

Infusion and Allergic Reactions

Allergic or infusion reactions may occur during the treatment or up to 24 hours after the dose. This is less common after the first treatment. You will be given an antihistamine, such as diphenhydramine, acetaminophen (Tylenol®), and possibly a corticosteroid, before your treatment to reduce the chances of having a reaction.

Notify your healthcare provider or get medical help right away if you experience any of the following during or after an injection of this medication: difficulty breathing or swallowing, chest pain, feel like your heart is racing, sudden cough or wheezing, swelling of lips, tongue, throat or face, develop itching, rash or hives, lightheadedness, fever, chills, or shakes. Additional medications may be given to alleviate your discomfort. You may experience pain, swelling, hardness, redness, bleeding, itching, or rash at the injection site.

Nausea and/or Vomiting

Talk to your doctor or nurse so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try antacids, (e.g. milk of magnesia, calcium tablets such as Tums), saltines, or ginger ale to lessen symptoms.

Call your doctor or nurse if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Immune Suppression

This medication affects how well your immune system works and makes it harder for your body to fight infections. You should not receive rituximab and hyaluronidase human injection if you have an active infection. You, or anyone you live with, should avoid having live or live-attenuated vaccines while receiving this medication. These include oral polio, measles, nasal flu vaccine (FluMist®), rotavirus and yellow fever vaccines.

If you have chronic lymphocytic leukemia (CLL), you will also receive medications to prevent certain infections during treatment, and for up to 12 months after treatment is finished.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your doctor or nurse know if you experience any shortness of breath, difficulty breathing, or
pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Low Platelet Count (Thrombocytopenia)**

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your doctor or nurse know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

- Do not use a razor (an electric razor is fine).
- Avoid contact sports and activities that can result in injury or bleeding.
- Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin®, Aleve®, Advil®, etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
- Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Constipation**

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Loss or Thinning of Scalp and Body Hair (Alopecia)**

Your hair may become thin, brittle, or may fall out. This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats, and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

**Less common, but important side effects can include:**

- **GI Obstruction or Tear:** This medication can cause a bowel obstruction (blockage) or a tear in the intestinal wall, also called a gastrointestinal perforation. Signs of this can include: severe constipation, new or worsening pain in the abdomen, new abdominal swelling, chills, fever, constipation, nausea or vomiting. If you experience any of these, contact your healthcare provider immediately or go to the emergency room.

- **Tumor Lysis Syndrome:** If there are a large amount of tumor cells in your body prior to treatment, you are at risk for tumor lysis syndrome. This happens when the tumor cells die too quickly and their waste overwhelms the body. You may be given a medication (allopurinol) and IV fluids to help prevent this. If you experience nausea, vomiting, diarrhea or become lethargic (drowsy, sluggish), notify your oncology team right away. TLS can affect your kidney function. Your provider will monitor your kidney function with blood work. Notify your provider if you have little or no urine output.

- **Heart Problems:** This medication can cause chest pain, irregular heartbeats, and heart attack. Let your provider know if you have any history of heart problems. Notify your healthcare provider right away if you develop irregular heartbeats or call 911 if you experience chest pain.

- **Kidney Problems:** This medication can cause kidney problems, including an increased creatinine level, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 12 months after treatment. Even if
your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while receiving this medication, or for 6 months after your last dose.

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