

WinRho[®] SDF

INFORMATION FOR PATIENTS BEING TREATED FOR ITP

You should read this leaflet carefully each time before you are scheduled to receive a treatment for your Immune Thrombocytopenic Purpura (ITP) with WinRho[®] SDF. This leaflet is a summary of the important information you need to know about your medicine, and does not take the place of talking with your doctor and does not contain all of the information available about WinRho[®] SDF. If you have any questions after reading this leaflet, make sure you ask your doctor or nurse.

1. WHAT IS WinRho[®] SDF? Pronounced, “Win Row S D F”

WinRho[®] SDF is a medicine that belongs to the group of medicines called immune therapy and is used to treat people with the bleeding disorder called ITP. ITP is a bleeding disorder caused by an abnormally low number of platelets. Platelets are found in the bloodstream and are needed for your blood to clot properly. When blood does not clot properly, there is a tendency to bruise and bleed easily.

WinRho[®] SDF is also used as a form of protection against the development of antibodies in a person with Rh-negative blood who is given Rh-positive blood, and in pregnancy to prevent an Rh-negative mother’s immune system from destroying an Rh-positive baby’s red blood cells.

2. HOW DOES WinRho[®] SDF WORK?

WinRho[®] SDF is a medicine that contains antibodies. Antibodies are made by your body’s immune system and help your body fight infections caused by bacteria and viruses and defend your body against other foreign substances. When your immune system is working properly, the antibodies made by your body coat the bacteria, viruses or foreign substances, which are then removed by an organ in your abdomen called the spleen. But, sometimes, these antibodies can also attack the healthy cells in your body, which is what happens when you have ITP. In ITP, the body mistakenly produces antibodies against its own platelets. These antibodies coat your platelets, and the spleen removes them so the number of platelets in your blood stream decreases.

WinRho[®] SDF is thought to protect the platelets of Rh-positive people by coating their red blood cells, causing the red blood cells to be removed by the spleen instead of the platelets. As a result, there is an increased number of platelets in your blood and fewer symptoms of ITP. But, because your red blood cells are being removed, you could become severely anemic (See WHAT IS THE MOST IMPORTANT INFORMATION I NEED TO KNOW ABOUT TREATMENT WITH WinRho[®] SDF for ITP?)

3. WHAT IS THE MOST IMPORTANT INFORMATION I NEED TO KNOW ABOUT TREATMENT WITH WinRho® SDF for ITP?

A small decrease in the amount of red blood cells is expected after treatment with WinRho® SDF. However, a small number of patients have experienced a potentially life threatening reaction in which a large number of red blood cells are destroyed while in the blood stream. In the patients that experienced this reaction, most had symptoms within 4 hours of receiving WinRho® SDF.

If you experience any of the following symptoms after receiving WinRho® SDF, you should **seek medical attention immediately**:

- shaking chills, fever or back pain,
- discolored or darkened urine,
- decreased urine production,
- swelling,
- shortness of breath.

If you have a condition that causes on-going red blood cell destruction (hemolytic anemia) you should not use WinRho® SDF to treat your ITP.

If you have been told that you have an IgA deficiency, you have a greater risk of having an allergic reaction to WinRho® SDF. While there is only a rare chance that you may experience a sudden, severe allergic reaction after receiving WinRho® SDF, you should be aware of the early symptoms of an allergic reaction. These are:

- hives,
- rash,
- chest tightness,
- wheezing,
- shortness of breath,
- feeling light-headed or dizzy when you stand (this could mean a drop in blood pressure).

If you experience any of these symptoms, **seek medical attention immediately**.

WinRho® SDF is prepared from donated human plasma. When products of this type are administered, the possibility of passing on infection from the donors can not be totally ruled out. This also applies to viruses or infections that are not yet known. A number of measures are taken to reduce the risk of passing on infection/viruses by WinRho® SDF including careful selection of blood and plasma donors to make sure those at risk of carrying infections/viruses can not donate, and the testing of each donation and the pools of plasma for signs of viruses such as AIDS virus HIV, hepatitis B virus and hepatitis C virus. The manufacturing process for WinRho® SDF also includes a number of steps that remove or inactivate viruses such as a solvent/detergent step and a special filter for removing viruses.

4. WHAT ARE THE MOST COMMON SIDE EFFECTS OF WinRho[®] SDF?

Like all medicines, WinRho[®] SDF can have side effects.

The most common side effects of WinRho[®] SDF are muscle pain or tenderness at the injection site, chills, skin reactions (rash and itching), fever and headache.

5. WHO SHOULD NOT USE WinRho[®] SDF

If you have had a severe allergic reaction such as swelling of the airway, difficulty breathing, or feeling light-headed or dizzy when you stand (drop in blood pressure), after receiving WinRho[®] SDF or other human immune globulins, or have been told you have an IgA deficiency, you should tell your doctor before you are given WinRho[®] SDF. Your doctor may choose another treatment for you.

If you know your blood type and you are Rh-negative, or if you are Rh-positive and have had your spleen surgically removed, you should not be given WinRho[®] SDF.

6. CAN I GET WinRho[®] SDF IF I AM TAKING OTHER MEDICINES?

Tell your doctor or healthcare provider that will be giving you the injection of WinRho[®] SDF if you are taking or have recently taken other prescription or over the counter medicines, and any supplements.

You should tell your doctor if you have recently been vaccinated or are planning to be vaccinated. WinRho[®] SDF may interfere with the response to certain vaccines (e.g. measles, rubella, mumps, and chicken pox) and it may be necessary to delay vaccination.

WinRho[®] SDF can interfere with certain blood tests. If you have a blood test after your WinRho[®] SDF injection, tell the person taking your blood or your doctor that you have received WinRho[®] SDF.

7. HOW CAN I ACCESS BAXTER'S PATIENT RESOURCES?

You can contact Baxter to receive more product information.

Product information Hotline: 1-800-4WINRHO (1-800-494-6746)

Product Website: www.winrho.com

You can call Baxter at 1-800-423-2090 to receive more information on patient assistance programs available to you.