What Should You Know About RESTOLAR?

Important Safety Information

RESTOLAR can cause serious side effects that can lead to death, including **infusion reactions, tumor lysis syndrome (TLS; kidney failure due to fast breakdown of cancer cells), severe skin and mouth reactions, and progressive multifocal leukoencephalopathy (PML; a rare, serious brain infection).**

Infusion Reactions

Serious infusion reactions can happen during your infusion or within 24 hours of receiving RESTOLAR. Your doctor should give you medicines before your infusion of RESTOLAR to decrease your chance of having a severe infusion reaction. If a serious reaction occurs, the infusion may be stopped and you should receive medical care. Tell your doctor or get medical help right away if you get any of these symptoms:

* Hives or rash
* Itching
* Swelling of your lips, tongue, throat, or face
* Sudden cough, shortness of breath
* Difficulty breathing or wheezing
* Weakness
* Dizziness or feel faint
* Palpitations
* Chest pain

Tumor Lysis Syndrome (TLS)

TLS is caused by the fast breakdown of cancer cells and can occur after treatment with RESTOLAR. TLS can cause you to have kidney failure and the need for dialysis treatment. TLS may also cause abnormal heart rhythm. Your doctor may give you medicines to help prevent TLS and do blood tests to check you for TLS.

Severe Skin and Mouth Reactions

Severe skin and mouth reactions can occur in patients who receive RESTOLAR. Tell your doctor or get medical help right away if you get any of these symptoms at anytime during your treatment with RESTOLAR:

* Painful sores or ulcers on your skin, lips or in your mouth
* Blisters
* Peeling skin
* Rash
* Pustules

Progressive Multifocal Leukoencephalopathy (PML)

PML is a rare, serious brain infection caused by a virus. People with a weakened immune system can get PML. Tell your doctor right away if you have any of the following symptoms:

* Confusion or problems thinking
* Loss of balance
* Change in the way you walk or talk
* Decreased strength or weakness on one side of your body
* Blurred vision or loss of vision

RESTOLAR has also been associated with serious and life-threatening side effects, including:

* The return of active hepatitis B virus infection with sudden and serious liver problems including liver failure, and death
* Other serious infections that can lead to death
* Heart problems
* Kidney problems
* Stomach and serious bowel problems including blockage and tears in the bowel that can sometimes lead to death

The most common side effects of RESTOLAR in patients with non-Hodgkin's lymphoma (NHL) include:

* Infusion reactions
* Fever
* Chills
* Low white blood cells
* Infections
* Body aches
* Tiredness

The most common serious side effect in NHL patients was low white blood cells.

Tell your doctor about any side effect that bothers you or that does not go away. These are not all of the possible side effects with RESTOLAR. Fore more information, ask your doctor.

*Please see full* *Prescribing Information, including Medication Guide.*

This information does not take the place of talking with your doctor. Discuss with your doctor any questions you have about your medical condition or your treatment.