

MEDICATION GUIDE
NULOJIX® (noo-LOJ-jiks)
(belatacept)
For Injection, For Intravenous Use

Read this Medication Guide before you start receiving NULOJIX and before each treatment. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about NULOJIX?

NULOJIX increases your risk of serious side effects, including:

- **Post-transplant lymphoproliferative disorder (PTLD).** PTLD is a condition that can happen if certain white blood cells grow out of control after an organ transplant because your immune system is weak. PTLD can get worse and become a type of cancer. PTLD can lead to death.

People treated with NULOJIX have a higher risk of getting PTLD. If you get PTLD with NULOJIX you are at especially high risk of getting it in your brain. Your risk for PTLD is also higher if you:

- have never been exposed to the Epstein-Barr virus (EBV). Your doctor should test you for EBV. Do not receive NULOJIX unless you are EBV positive (you have been exposed to EBV).
- get an infection with a virus called cytomegalovirus (CMV).
- receive treatment for transplant rejection that lowers certain white blood cells called T lymphocytes.
- **Increased risk of getting cancers other than PTLD.** People who take medicines that weaken the immune system, including NULOJIX, have a higher risk of getting other cancers, including skin cancer. Talk to your doctor about your risk for cancer. See "**What should I avoid while receiving NULOJIX?**"
- **Progressive multifocal leukoencephalopathy (PML).** PML is a rare, serious brain infection caused by JC virus. People with weakened immune systems are at risk for getting PML. PML can result in death or severe disability. There is no known prevention, treatment, or cure for PML.
- **Increased risk of getting other serious infections, including tuberculosis (TB) and other infections caused by bacteria, viruses, or fungi.** These serious infections may lead to death. Also, a virus called BK virus can affect how your kidney works and cause your transplanted kidney to fail.

Tell your doctor right away if you get any of the following symptoms during treatment with NULOJIX:

- change in mood or your usual behavior
- confusion or problems thinking or with memory
- change in the way you walk or talk
- decreased strength or weakness on one side of your body
- change in vision
- fever, night sweats, or tiredness that does not go away
- weight loss
- swollen glands
- flu, cold symptoms, or cough
- stomach-area pain
- vomiting or diarrhea
- tenderness over your transplanted kidney
- change in the amount of urine that you make, blood in your urine, pain or burning on urination
- a new skin lesion or bump, or change in size or color of a mole

See "**What are the possible side effects of NULOJIX?**" for more information about side effects.

Liver transplant patients should not receive NULOJIX because of an increased risk of losing the transplanted liver (graft loss) and death. Talk to your doctor if you would like more information about this risk.

What is NULOJIX?

NULOJIX is a prescription medicine used in adults to prevent transplant rejection in people who have received a kidney transplant. Transplant rejection happens when the body's immune system senses that the new transplanted kidney is different or foreign, and attacks it. NULOJIX is used with corticosteroids and certain other medicines to help prevent rejection of your new kidney.

It is not known if NULOJIX is safe and effective in children under 18 years of age.

NULOJIX is only used in people who have been exposed to the EBV virus.

It is not known if NULOJIX is safe and effective in people who receive an organ transplant other than a kidney transplant.

Who should not receive NULOJIX?

Do not receive treatment with NULOJIX if you are EBV negative. Your doctor will do a test to see if you were exposed to EBV in the past.

What should I tell my doctor before receiving NULOJIX?

Before receiving NULOJIX, tell your doctor if you:

- plan to receive any vaccines. Talk to your doctor about which vaccines are safe for you to receive during your treatment with NULOJIX. See "**What should I avoid while receiving NULOJIX?**"
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if NULOJIX will harm your unborn baby. If you become pregnant while taking NULOJIX:
 - **Tell your doctor right away.** You and your doctor should decide if you will keep receiving NULOJIX while you are pregnant.
 - Talk with your doctor about enrolling in the National Transplant Pregnancy Registry (NTPR). This Registry collects information about pregnancies in women who have received NULOJIX or if their partner has received NULOJIX, and had a transplant. You can also enroll by calling 1-877-955-6877.
- are breast-feeding or plan to breast-feed. It is not known if NULOJIX passes into your breast milk. You and your doctor should decide if you will receive NULOJIX or breast-feed. You should not do both.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine. Do not take any new medicine without talking with your transplant doctor first.

How will I receive NULOJIX?

- To help prevent rejection of your new kidney, you will receive NULOJIX regularly as prescribed by your doctor. It is important for you to keep all your appointments for NULOJIX treatment and follow up.
- You will receive NULOJIX as an intravenous (IV) infusion in your arm. Each IV infusion takes about 30 minutes.

- During treatment with NULOJIX, your doctor will test your blood and urine to check how your kidney is working.
- Take all the medicines prescribed by your doctor to prevent infection or transplant rejection. Take them exactly as your doctor tells you. Talk to your doctor or pharmacist if you have any questions about how to take your medicines.

What should I avoid while receiving NULOJIX?

- Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. People who take medicines that weaken the immune system, including NULOJIX, have a higher risk of getting cancer, including skin cancer. Wear protective clothing and use sunscreen with a high protection factor (SPF) when you have to be in the sun.
- **Avoid receiving live vaccines during treatment with NULOJIX.** Talk to your doctor to find out which vaccines are safe for you during this time. Some vaccines may not work as well while you are receiving NULOJIX. See **"What should I tell my doctor before receiving NULOJIX?"**

What are the possible side effects of NULOJIX?

NULOJIX increases your risk of serious side effects that can cause death. See **"What is the most important information I should know about NULOJIX?"**

Common side effects of NULOJIX include:

- low red blood count (anemia)
- diarrhea
- kidney or bladder infection
- swollen legs, feet, or ankles
- constipation
- high blood pressure
- fever
- new kidney not working well
- cough
- nausea or vomiting
- headache
- low potassium or high potassium in your blood
- low white blood cell count

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to BMS at 1-800-321-1335.

General information about NULOJIX

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about NULOJIX. If you would like more information about NULOJIX, talk with your doctor. You can ask your pharmacist or doctor for information about NULOJIX that is written for healthcare professionals.

For more information, go to www.NULOJIX.com or call 1-800-321-1335.

What are the ingredients in NULOJIX?

Active ingredient: belatacept

Inactive ingredients: monobasic sodium phosphate, sodium chloride, and sucrose

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Bristol-Myers Squibb Company
Princeton, New Jersey 08543

1274492

Iss June 2011