

For the Patient: LYNIV

Other Names: Treatment of Relapsed or Refractory Hodgkin Lymphoma Using Nivolumab

LY = LYphoma NIV = NIVolumab

ABOUT THIS MEDICATION

What is this drug used for?

 Nivolumab (nye vol' ue mab) is a drug that is used to treat a type of lymphoma called Hodgkin lymphoma.

How does this drug work?

 Nivolumab is a type of protein designed to target and interfere with the growth of cancer cells in your body.

INTENDED BENEFITS

This treatment is being given to slow down the growth of cancer cells in your body. This treatment can help with controlling some of the symptoms the cancer may be causing and may delay or prevent new symptoms from starting.

TREATMENT SUMMARY

How is this drug given?

 Nivolumab is given as an infusion (injection) into a vein. The infusion will last about 30 minutes. You will have an infusion every 2 weeks. This 2 weeks period is called a cycle.

What will happen when I get this drug?

- A blood test is done before starting each treatment cycle. You will see your oncologist at least every 2 weeks, before treatments.
- The dose of your treatment may be changed based on your blood test results and/or other side effects.

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OTHER INSTRUCTIONS

• It is very important to report side effects immediately to your doctor. Do not manage side effects at home without speaking with your doctor. Be aware that symptoms may be delayed and can develop months after your last dose.

What other drugs or foods can interact with nivolumab?

- Other drugs may interact with nivolumab. Check with your doctor or pharmacist before you start or stop taking any other drugs including all prescription and nonprescription medicines, steroids or other medicines that lower your immune response, vitamins, and herbal supplements.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of nivolumab.

Other important things to know:

- Before you are given nivolumab, talk to your doctor or pharmacist if you:
 - have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn's disease, lupus, rheumatoid arthritis or sarcoidosis.
 - take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone.
 - o had an organ transplant, such as a kidney transplant.
 - o have any other medical conditions.
- Nivolumab may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while being treated with nivolumab and for at least 5 months after the last dose. Tell your doctor right away if you or your partner becomes pregnant. Do not breast feed during treatment.
- Nivolumab may pass into your breast milk. Do not breastfeed during treatment
- Tell doctors or dentists that you are being treated with nivolumab before you receive any treatment from them.

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SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Nivolumab may cause serious immune reactions against your own body (autoimmune) affecting many parts.

Are there any risks?

Unexpected and unlikely side effects can occur with any drug treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the drug in your treatment plan.

What is the most important information I should know about SERIOUS SIDE EFFECTS?

- Nivolumab can cause serious side effects in many parts of your body. These side effects are most likely to begin during treatment; however, side effects can show up months after your last treatment with nivolumab.
- **Tell** your doctor as soon as possible if you have any of serious side effects listed in the table below or your symptoms get worse.
- **Do not try to treat or diagnose symptoms yourself**. Getting medical treatment right away may keep the problem from becoming more serious.

The following side effects were most frequently reported:

Very common (more than 1 in 10 people)

- diarrhea
- itching, rash
- joint pain
- feeling tired
- feeling less hungry
- cough

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SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the intestines (colitis)	Common
Symptoms may include:	
 diarrhea (loose stools) or more bowel movements than usual. Do not treat the diarrhea 	(less than 1 in 10 but
yourself.	more than 1 in 100)
 blood or mucus in stools or dark, tarry, sticky stools 	
severe stomach pain (abdominal pain) or tenderness	
Inflammation of the thyroid gland (hyperthyroidism, hypothyroidism)	Common
Symptoms may include:	
rapid heart beat	(less than 1 in 10 but
weight loss or gain	more than 1 in 100)
increased sweating	
hair loss	
feeling cold	
constipation or diarrhea	
your voice gets deeper	
muscle aches	
changes in sleep patterns	
Inflammation of the pituitary gland (hypophysitis, hypopituitarism, including secondary	Common
adrenal insufficiency)	
Symptoms may include:	(less than 1 in 10 but
weight loss	more than 1 in 100)
increased sweating, hot flashes	
hair loss (includes facial and pubic)	
feeling cold	
headaches that will not go away or unusual headache	
decreased sex drive	
vision problems	
excessive thirst and urination	

SERIOUS SIDE EFFECTS	How common is it?
Inflammation of the lungs (pneumonitis)	Common
Symptoms may include:	
shortness of breath	(less than 1 in 10 but
chest pain	more than 1 in 100)
• coughing	
Problems with muscles	Common
Symptoms may include:	
back pain	(less than 1 in 10 but
• spasms	more than 1 in 100)
• weakness	
muscle pain	
Skin problems	Common
Symptoms may include:	
• rash	(less than 1 in 10 but
dry skin	more than 1 in 100)
Problems in other organs (nervous system, eyes)	Common
Symptoms may include:	
tingling, numbness, lack of energy	(less than 1 in 10 but
changes in eyesight	more than 1 in 100)
• dizziness	
Inflammation of the liver (hepatitis)	Uncommon
Symptoms may include:	
nausea or vomiting	(less than 1 in 100 but
loss of appetite	more than 1 in 1000)
pain on the right side of your stomach	
 yellowing of your skin or the whites of your eyes 	
dark urine	
bleeding or bruise more easily than normal	
Inflammation of the kidneys (nephritis)	Uncommon
Symptoms may include:	
changes in the amount or colour of your urine	(less than 1 in 100 but
	more than 1 in 1000)

SERIOUS SIDE EFFECTS	How common is it?
Problems in the pancreas	Rare
Symptoms may include:	
abdominal pain	(less than 1 in 1000
nausea and vomiting	but more than 1 in
	10000)
Blood sugar problems (type 1 diabetes mellitus)	Rare
Symptoms may include:	
hunger or thirst	(less than 1 in 1000
a need to urinate more often	but more than 1 in
weight loss	10000)
Infusion reactions	Rare
Symptoms may include:	
shortness of breath	(less than 1 in 1000
itching or rash	but more than 1 in
dizziness	10000)
fever	
wheezing	
flushing	
feeling like passing out	

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Pain or tenderness may occur where the needle was placed.	Very rare	Apply cool compresses or soak in cool water for 15-20 minutes several times a day.
Nausea and vomiting may occur after your treatment. Most people have little or no nausea.	Common	 You may be given a prescription for antinausea drug(s) to take before your treatment and/or at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. Drink plenty of fluids. Eat and drink often in small amounts. Try the ideas in Food Choices to Help Control Nausea.* If nausea and vomiting is persistent and you have other symptoms of hepatitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Fever may sometimes occur.	Common	 Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day. If you have other symptoms of colitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Constipation may sometimes occur.	Common	 Exercise if you can. Drink plenty of fluids. Try ideas in Suggestions for Dealing with Constipation.* If you have other symptoms of colitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Headache may sometimes occur.	Common	 Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day. If headache is persistent and you have other symptoms of inflammation of glands or Inflammation of the nerves, tell your doctor as soon as possible. (see the table above for serious side effects.)

OTHER SIDE EFFECTS	How common is it?	MANAGEMENT
Loss of appetite and weight loss sometimes occur.	Very common	 Try the ideas in Food Ideas to Help with Decreased Appetite. If loss of appetite is persistent and you have other symptoms of hepatitis, tell your doctor as soon as possible. (see the table above for serious side effects.)
Tiredness and lack of energy may sometimes occur.	Very common	 Do not drive a car or operate machinery if you are feeling tired. Try the ideas in Fatigue/Tiredness – Patient Handout.* If tiredness is persistent and you have other symptoms of hepatitis or inflammation of glands, tell your doctor as soon as possible. (see the table above for serious side effects.)
Hair loss is rare with nivolumab.	Rare	If hair loss is a problem, refer to For the Patient: Hair Loss Due to Chemotherapy.*

^{*}Please ask your oncologist or pharmacist for a copy.

If you experience symptoms or changes in your body that have not been described above but worry you, or in any symptoms are severe, contact:
at telephone number: