



What to expect when starting Niktimvo

INDICATIONS AND USAGE

Niktimvo™ (axatilimab-csfr) is a prescription medicine used to treat adults and children who weigh at least 88.2 pounds (40 kg) with chronic graft-versus-host disease (cGVHD) after receiving at least 2 prior treatments (systemic therapy) and they did not work.

It is not known if Niktimvo is safe and effective in adults and children weighing less than 88.2 pounds (40 kg).

Please see the [Important Safety Information](#) on pages 10 and 11 and the [Full Prescribing Information](#), which include a more complete discussion of the risks associated with Niktimvo.

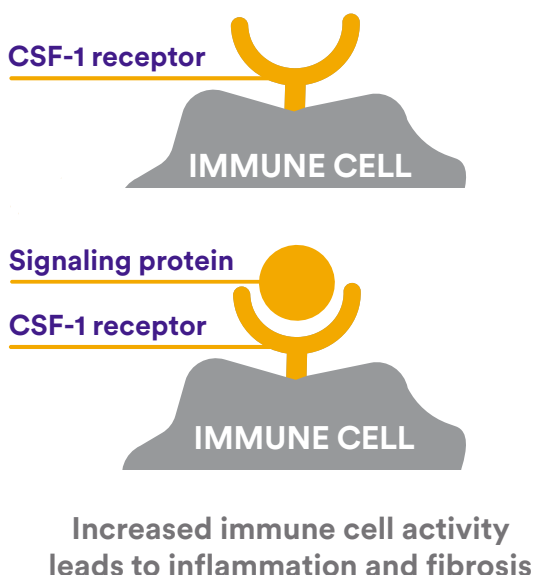
What makes Niktimvo™ (axatilimab-csfr) different?

Niktimvo is the **FIRST AND ONLY** treatment to block the CSF-1 receptor in chronic graft-versus-host disease (GVHD)

Other treatments you may have tried target different immune cells, such as T cells and/or B cells.

Why does the CSF-1 receptor matter?

The CSF-1 receptor is located on the surface of certain immune cells. When a signaling protein binds to the CSF-1 receptor, it sends signals that increase the activity of immune cells, leading to inflammation and fibrosis—two key contributors to chronic GVHD symptoms.



Inflammation: Part of the body's immune response to fight off infection or heal damaged tissue. Chronic inflammation is an abnormal immune response that can damage cells and organs over time.

Fibrosis: The growth of scar tissue in the body.

CSF-1=colony stimulating factor-1.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of Niktimvo?

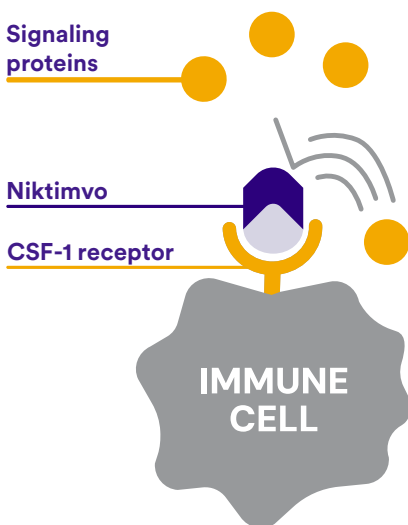
Niktimvo may cause serious side effects, including:

Infusion-related reactions. Infusion-related reactions are common with Niktimvo and can be serious. Your healthcare provider will monitor you for infusion-related reactions during your treatment. If you have a reaction, your healthcare provider may temporarily or completely stop your treatment with Niktimvo.

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Niktimvo™ (axatilimab-csfr) works differently to treat chronic GVHD

Niktimvo blocks the CSF-1 receptor to help reduce inflammation and fibrosis in chronic GVHD



Niktimvo blocks signaling proteins, potentially addressing both inflammation and fibrosis

IMPORTANT SAFETY INFORMATION (continued)

Niktimvo may cause serious side effects, including (continued):

Tell your healthcare provider right away if you have fever, chills, rash, flushing, shortness of breath, trouble breathing, nausea, vomiting, or symptoms of high blood pressure such as chest pain, headaches, or blurred vision during an infusion of Niktimvo.

The most common side effects of Niktimvo include:

- infections
- increased blood level of liver enzymes
- decreased blood level of phosphate
- low red blood cell count (anemia)
- muscle, bone, or joint pain
- increased blood level of pancreatic enzymes
- low energy
- increased blood level of calcium
- increased blood level of a muscle enzyme
- increased blood level of a bone enzyme

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In a study, Niktimvo™ (axatilimab-csfr) delivered fast and lasting responses

Niktimvo was studied in 79 people who had received a stem cell transplant, received at least 2 prior treatments for chronic GVHD, and weighed at least 88.2 pounds (40 kg).

People in the study were given Niktimvo 0.3 mg/kg every 2 weeks. The main goal of the study was to see how many people saw a response to treatment through 24 weeks.

Most people achieved a response with Niktimvo



75% of people (59 out of 79) experienced a response

In the study, a response to treatment with Niktimvo was defined as:

- A resolution of all signs and symptoms of chronic GVHD (complete response), or
- Improvement in at least one affected area without worsening signs or symptoms in other areas (partial response)



Some people saw a **fast response**

Of the people who responded to treatment, half saw their first response in **6 weeks or less**.

Time to first response ranged from **4 weeks to 22 weeks**.



Niktimvo provided **lasting responses**

More than half (60%) of the people who showed a response to Niktimvo continued to respond for **at least 1 year**.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of Niktimvo include (continued):

- nausea
- headache
- diarrhea
- cough
- fever
- shortness of breath

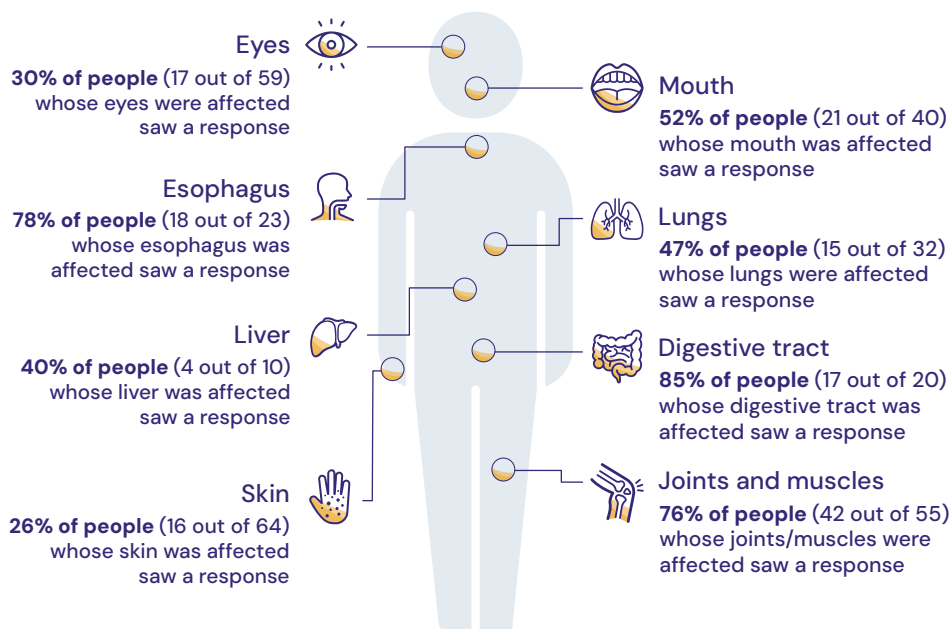
These are not all the possible side effects of Niktimvo. Call your doctor for medical advice about side effects.

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50 mg/mL for injection, for intravenous use

In the study, people achieved responses in multiple affected organs

A complete or partial response in each organ was evaluated by recording changes in chronic GVHD severity from the beginning of the study to the end.



Niktimvo™ (axatilimab-csfr) offered symptom improvement

44 out of 79 people who received Niktimvo (56%) reported improvement in the specific chronic GVHD symptoms assessed in the study.

Symptom improvement was defined as a reduction in chronic GVHD symptoms compared to the start of the study.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving Niktimvo, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems.
- are pregnant or plan to become pregnant. Niktimvo may harm your unborn baby.

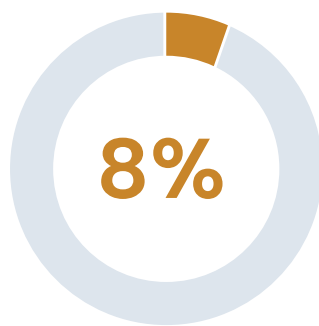
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Some people stopped taking or reduced their dose of Niktimvo™ (axatilimab-csfr) because of side effects



10% of people

stopped taking
Niktimvo because
of side effects



8% of people

reduced their dose
of Niktimvo because
of side effects

44% of people had their dose of Niktimvo temporarily stopped because of side effects.

It's important to keep an eye out for any possible side effects while taking Niktimvo and report them to your doctor right away.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving Niktimvo, tell your healthcare provider about all of your medical conditions, including if you (continued):

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with Niktimvo.
- You should use an effective method of birth control during your treatment and for 30 days after your last dose of Niktimvo. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with Niktimvo.

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Receiving treatment with Niktimvo™ (axatilimab-csfr)



How will I receive Niktimvo?

- Niktimvo is given to you as an intravenous (IV) infusion at your doctor's office or infusion center
- Infusion-related reactions may occur. Before you receive each Niktimvo infusion, your doctor may give you medications like diphenhydramine (ie, Benadryl) or acetaminophen (ie, Tylenol) to help prevent infusion-related reactions



How long does each infusion last?

Each IV infusion of Niktimvo lasts about 30 minutes.



How often will I need to receive Niktimvo?

- Niktimvo is given once every 2 weeks to start
- Your doctor will decide how many treatments you will need
- Your doctor will do blood tests to check you for side effects



What is my starting dose of Niktimvo?

Your starting dose is based on your weight.

IMPORTANT SAFETY INFORMATION (continued)

Before receiving Niktimvo, tell your healthcare provider about all of your medical conditions, including if you (continued):

- are breastfeeding or plan to breastfeed. It is not known if Niktimvo passes into your breast milk. Do not breastfeed during treatment and for 30 days after your last dose of Niktimvo.

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Questions to ask your doctor

It's important to talk with your doctor and ask any questions you may have about chronic GVHD and your treatment with Niktimvo™ (axatilimab-csfr).

Before your next appointment, take a moment to think about anything you would like to discuss with your doctor and write down any questions or concerns.

The following questions may help get you started

How should I prepare for my Niktimvo infusions?



What kind of lab work will I need? How often?

Will I need additional monitoring after my 30-minute infusion? If so, for how long?

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Questions to ask your doctor (continued)

What’s the best way to track my progress?

What side effects should I watch out for and how soon should I contact you about them?

Additional notes

Please see the [Important Safety Information](#) on pages 10 and 11 and the [Full Prescribing Information](#), which include a more complete discussion of the risks associated with Niktimvo.



IMPORTANT SAFETY INFORMATION

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IMPORTANT SAFETY INFORMATION

(continued)

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- are pregnant or plan to become pregnant. Niktimvo may harm your unborn baby.

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- are breastfeeding or plan to breastfeed. It is not known if Niktimvo passes into your breast milk. Do not breastfeed during treatment and for 30 days after your last dose of Niktimvo.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call **1-800-FDA-1088**.

You may also report side effects to Incyte Medical Information at 1-855-463-3463.



Meaningful relief from chronic GVHD is possible

Niktimvo takes a different approach to stay one step ahead of chronic GVHD

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.



IncyteCARES for Niktimvo can help with access and support for your treatment.

Visit
IncyteCARES.com

Or call **1-855-452-5234**
Monday through Friday,
8 AM – 8 PM ET



Scan the code below to learn more



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