PATIENT INFORMATION
NIKTIMVO™ (nik tim voe)
(axatilimab-csfr)
injection, for intravenous use

What is NIKTIMVO?

NIKTIMVO 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 you have received 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).

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.
  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.
- 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.

How will I receive NIKTIMVO?

- Your healthcare provider will give you NIKTIMVO through an intravenous (IV) infusion over 30 minutes.
- NIKTIMVO is given every 2 weeks.
- Your healthcare provider will decide how many treatments you will need.
- Before you receive each NIKTIMVO infusion, your healthcare provider may give you medicines called diphenhydramine and acetaminophen to help prevent infusion-related reactions.
- Your healthcare provider will do blood tests to check you for side effects.

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. Tell your healthcare provider right away if you get 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
- 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. You may report side effects to FDA at 1-800-FDA-1088.

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

General information about the safe and effective use of NIKTIMVO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your healthcare provider for information about NIKTIMVO that is written for health professionals.

What are the ingredients in NIKTIMVO?

Active ingredient: axatilimab-csfr

Inactive ingredients: citric acid monohydrate, glycine, polysorbate 80, sodium citrate, sucrose, and Water for Injection.

Manufactured by: Incyte Corporation, Wilmington, DE 19803
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For more information, call 1-855-463-3463 or go to www.incyte.com/patents.

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