PATIENT & CAREGIVER EDUCATION

What To Expect During Your Child’s Naxitamab (Danyelza®) Treatment

This information explains what to expect during your child’s naxitamab (nak-SIH-tuh-mab) treatment. It explains what to do and expect before, during, and after their treatment appointments.

Naxitamab used to be called humanized 3F8 or Hu3F8.

What is naxitamab?

Naxitamab is a cancer medicine used to treat high-risk neuroblastoma. It’s a type of medicine called a monoclonal antibody.

- An **antibody** is a protein your immune system makes. Antibodies help your body fight off disease and kill harmful cells. Each antibody recognizes and binds to a specific type of antigen.
- An **antigen** is a small marker on a cell or virus’s surface. There are many different types of antigens.
- A **monoclonal antibody** is an antibody made in a lab. It’s designed to find and bind to a certain antigen.

Neuroblastoma cells have the antigen GD2. Naxitamab works by attaching to the GD2 antigen on neuroblastoma cells, helping the immune system recognize and destroy them.

Most people get granulocyte-macrophage colony-stimulating factor (GM-CSF) along with naxitamab.

What is GM-CSF?

GM-CSF is a medicine that helps your child's body make more white blood cells. Having more white blood cells helps the naxitamab work better to kill the neuroblastoma cells.

Your child will get the GM-CSF medicine sargramostim (Leukine®) before every naxitamab treatment. They'll get the Leukine as an injection (shot) into the fatty part of their leg or arm. They may get the injection in clinic, or you can give it to them at home.

What to do before your child's naxitamab treatment appointments

Follow the instructions in *How To Give Your Child a Sargramostim (Leukine®) Injection* (www.mskcc.org/pe/leukine) if you're giving your child their Leukine injection at home.

What to expect during your child’s treatment appointments

Your child’s treatment appointments will be in MSK’s Pediatric Ambulatory Care Center (PACC). Each appointment will have 4 general parts:

1. **Initial assessment.** We will check your child’s vital signs. We’ll also do blood tests to make sure it’s safe for your child to get treatment. The initial assessment takes about 30 to 45 minutes. How long it takes to get the blood test results can vary.
2. **Medicines before treatment (pre-meds).** Your child will get medicines to help get their body ready for treatment. Getting pre-meds takes about 2 hours.
3. **Naxitamab infusion.** Your child will get the naxitamab infusion. An infusion is when a medicine is put into their bloodstream slowly over time. The naxitamab infusion takes about 1 hour.
4. **Monitoring after treatment.** We will monitor (watch) your child after their naxitamab infusion and manage any side effects from treatment. This takes 1 hour or longer. We will monitor your child longer if we give them certain medicines or if they have certain side effects.

Your child’s appointment will take most of the day. Please get there on time. We may need to reschedule your child’s treatment if you are late.

We only let 2 family members be at the bedside during treatment appointments. This is so we have enough space to safely care for your child.

Initial assessment

Your treatment nurse will measure your child’s vital signs (temperature, heart rate, blood pressure, and breathing rate), height, and weight. They will access your child’s central line to take a blood sample. Your child’s central line may be an implanted port (also called a Mediport or Broviac™) or a peripherally inserted central catheter (PICC).

A nurse practitioner (NP) will come to see your child and check their overall health. They will review the blood test results and check that it’s safe to move forward with the treatment.

Pre-meds

Pre-meds help get your child’s body ready for the naxitamab infusion. They also help lessen side effects. They’re an important part of the treatment. These are the normal pre-meds you can expect:

- **Sargramostim (Leukine).** If you did not give your child a

Leukine injection at home, we will give it in clinic. We will give the Leukine injection at least 1 hour before the naxitamab treatment.

- **Intravenous (IV) fluids.** Your child will get a steady flow of IV fluids through their central line throughout their treatment or as needed. This is to make sure they're well-hydrated. Being well-hydrated helps keep their blood pressure steady and lessens side effects.
- **Fluid bolus.** This is an extra dose of IV fluids.
- **Famotidine (Pepcid®).** This can help control allergic reactions and general stomach issues. For example, it helps control problems such as nausea (feeling like you're going to throw up) or vomiting (throwing up). It's given through your child's central line.
- **Loratidine (Claritin®) or cetirizine (Zyrtec®).** This helps control potential allergic reactions. It's a liquid or pill your child swallows.
- **Hydroxyzine (Vistaril®).** This helps control potential allergic reactions. It's given either through your child's central line or as a liquid or pill they swallow.
- **Acetaminophen (Tylenol®).** This lowers fevers and lessens pain. It's given through your child's central line.
- **Ondansetron (Zofran®).** This helps prevent nausea and vomiting. It's given through your child's central line.

- **Oxycodone.** This helps control pain during the infusion. It's a liquid or pill your child swallows.
- **Methylprednisolone (Solu-Medrol®).** This lowers the risk of an allergic reaction. It's given on the first day of treatment and then as needed for future treatments. It's given through your child's central line.

Naxitamab infusion

We will put electronic sensors on your child to track their vital signs throughout their treatment. This is called continuous monitoring. Your child will have:

- Cardiac leads (stickers attached to wires) on their chest to measure their heart rhythm.
- A pulse oximetry sticker on their finger or toe to measure their oxygen levels.
- A blood pressure cuff on their arm or calf to measure their blood pressure.

A treatment nurse will stay with your child for the whole treatment. They will check your child's vital signs every 10 minutes, or more often if needed. They will carefully watch your child so they can help manage side effects and adjust the treatment as needed.

Rules during your child’s naxitamab infusion

To keep your child safe, you and your child must follow these rules:

- **Your child must stay in bed during the naxitamab infusion.** The treatment may make them feel faint, so they’re safer lying in bed.
- **Your child must keep the monitoring equipment on until they’re discharged from the hospital.** It’s important that we can track their vital signs.
- **Do not touch the monitoring equipment.** Please also help your child avoid touching any of the monitors or pumps. They need to stay connected to your child.
- **A parent or guardian must be with the child during their whole infusion.** We may need your permission to give certain types of care to your child.

It’s also best if your child stays awake during their naxitamab infusion. This is so we can check in with them about how they’re feeling. We will work together with you to keep them awake during their infusion.

Side effects during naxitamab infusion

Your child may have a range of side effects during their naxitamab infusion. We will closely watch your child and manage their side effects to keep them safe and as comfortable as possible. Your treatment nurse may need to pause the naxitamab infusion to manage your child's side effects safely.

These are the most common side effects and how they're managed.

- **Hypotension (low blood pressure).** If your child's blood pressure drops, we may give them a fluid bolus to raise it. In some cases, we may pause their infusion to let their blood pressure go back to normal. We'll restart the infusion once it's normal.
- **Hypertension (high blood pressure).** If your child's blood pressure gets high, we may pause their infusion to let their blood pressure go back to normal. We'll restart the infusion once it's normal.
- **Allergic reactions.** These often show up as a skin reaction, such as a rash, hives, itching, or swelling. If these reactions are mild (not strong), we will closely watch your child. We will give your child more medicine to manage the reactions if they get worse.
- **Pain.** Pain can happen anywhere in your child's body. We will first try to manage the pain without using medicine, such as with hot or cold packs. We can also manage the pain in other ways, such as with massage or distraction. If the pain does not go away, we will give your child pain

medicine. Your nurse will talk with you about pain medicines we may use.

- **Trouble breathing.** If this happens, your child may tell us it's hard to breathe or show signs of feeling anxious. We may give your child a medicine they breathe in through a face mask if they're having trouble breathing. This is called a nebulized (NEH-byoo-lyzed) medicine. It will help open their airways and ease their breathing.

We are ready and able to manage any side effects your child has. We will adjust their treatment plan as needed so they're safe and as comfortable as possible throughout their infusion.

We may give your child an epinephrine (EpiPen®) injection if their symptoms are severe (very bad) at any point. It will control their allergic reaction symptoms. If we give your child an EpiPen injection, they will need to stay in the PACC so we can watch them. They will need to stay for at least 4 hours.

We may call the Rapid Response Team (RRT) if your child has a strong allergic reaction or bad side effects. The RRT is a team of healthcare providers with special emergency training. They will help manage the emergency and care for your child. When the RRT arrives, it can be scary. It will be a team of people you most likely have not met before. The team will be 3 or more healthcare providers. They will be there to help and keep your child safe.

Monitoring after treatment

We'll keep checking your child's vital signs and watch for delayed side effects after they finish the naxitamab infusion. Some reactions to naxitamab or the pre-medications can show up after the infusion ends. Monitoring your child after treatment lets us make sure they're stable and comfortable before they go home.

If your child's blood pressure gets high after their infusion, we may give them medicine to help it go back to normal. If their blood pressure does not go back to normal, we may admit them into the hospital so we can monitor them. Your care team will tell you what to expect if this happens.

We may give your child more medicine to help manage lingering effects from the naxitamab or pre-meds. For example, we may give them:

- **Hydroxyzine (Vistaril).** This helps lessen any leftover allergic reactions or skin irritation your child might get after the infusion. It helps with symptoms like itching, hives, or rashes that can happen as the medicines work through your child's body.
- **Acetaminophen (Tylenol).** This extra dose helps manage

any pain or fever that could happen in the hours following treatment. Each dose of acetaminophen must be given 4 hours apart.

Your child will stay in the PACC until their vital signs are normal and their treatment side effects are well-managed. After that, an advance practice provider will clear you to go home.

Your treatment nurse will give you a paper with instructions for giving your child medicines at home.

What to expect after your child's treatment appointments

If your child feels well enough, it's safe for them to do all their usual activities after and between their treatments.

Common side effects at home

- **Pain:** This is the most common side effect of naxitamab. It's usually strongest during the naxitamab infusion, but your child may also have pain once they're home. Everyone feels a different amount of pain. We will give you instructions for giving your child acetaminophen (Tylenol), oxycodone, or both to help manage their pain.
- **Allergic reactions:** Your child may have an allergic reaction, such as an itchy rash, redness, or swelling. These reactions can happen at any time between

naxitamab treatments. We will prescribe an allergy medicine for your child to take at home, such as hydroxyzine (Vistaril) or diphenhydramine (Benadryl). Make sure you have the medicine with you before you leave the hospital.

  - Changes in your child’s breathing or shortness of breath (trouble breathing) can be a sign of an allergic reaction. Call 911 and seek emergency care if you have any concerns about your child’s breathing.

- **Fever:** Your child may have a fever after their treatment. The fever may be related to their treatment or a sign of infection. Make sure you have a thermometer at home. Call your child’s healthcare provider for instructions if your child has:
  - A fever of 100.4 to 100.9 °F (38 to 38.2 °C) that lasts for longer than 1 hour.
  - A fever of 101°F (38.3 °C) or higher.

- **Trouble going to the bathroom:** Your child may be constipated (have trouble pooping) or have trouble urinating (peeing). This is a common side effect of many pain medicines. We may prescribe medicine for this, if needed.

- **Nausea and vomiting:** Your child may have some nausea and vomiting. We will prescribe medicine for this if needed.

What happens after each naxitamab treatment cycle

Blood pressure check

Naxitamab infusions can cause high blood pressure. We will work closely with you to manage your child’s blood pressure so it’s safe for them to get treatment.

Your child must have their blood pressure checked 72 hours (3 days) after the last naxitamab infusion of each treatment cycle.

After their first treatment cycle, your child must come to the PACC so we can check their blood pressure. They will also have a follow-up visit with a Neuroblastoma team healthcare provider.

For later treatment cycles, you can check your child’s blood pressure at home. Measure their blood pressure 72 hours (3 days) after their last naxitamab infusion of the cycle. Send your child’s care team a message in MSK MyChart or call them to tell them the blood pressure.

How to get a blood pressure cuff for home

The Band of Parents charity (www.bandofparents.org) can give you a blood pressure cuff to use. Talk with your child’s care team for instructions for how to get one. You can also buy a blood pressure cuff online or at some pharmacies.

If you get a home blood pressure cuff, bring it into the PACC during treatment cycle 2. Your treatment nurse will set it up for you.

About posterior reversible encephalopathy syndrome (PRES)

PRES is a set of symptoms caused by liquid and swelling in your child’s brain. It’s a rare but serious problem. Symptoms of PRES include:

- Very high blood pressure
- Headache
- Vision problems
- Seizures
- Changes in mood, behavior, or alertness

Call your child’s care team right away if your child has any of these symptoms. We will need to closely monitor your child at the hospital if there is a concern for PRES.

When to call your child’s care team

Call 911 and seek emergency care if:

- Your child has shortness of breath.
- Your child has trouble breathing.
- You have any concerns about your child's breathing.

Call your child's care team if:

- Your child's lips, tongue, or throat are swelling.
- Your child has a fever of 100.4 to 100.9 °F (38 to 38.2 °C) for longer than 1 hour.
- Your child has a fever of 101°F (38.3°C) or higher.
- Your child has pale skin, sweating, or chills. These can be signs of an infection.
- Your child has not urinated (peed) in _____ hours.
- Your child has not had a bowel movement (pooped) in _____ days.
- Your child has pain that does not get better or gets worse after taking their medicine.
- Your child has nausea or vomiting that will not stop.
- Your child vomits every time they drink.
- Your child has a sudden headache that will not go away.
- Your child's vision changes.
- Your child has a seizure.
- You see changes in your child's mood, behavior, or

alertness.

- Your child has a cough that will not stop.
- The area where your child's central line enters their body is red, swollen, or tender.

Contact information

Contact a member of your care team directly if you have questions. You can reach them Monday through Friday from 8 a.m. to 6 p.m. After 6 p.m., during the weekend, and on holidays, call 212-639-2000 and ask for the pediatric fellow.

If you have a question that does not need an answer right away, you can send a message to your care team though MSK MyChart. MSK MyChart is MSK's patient portal.

About MSK's Pediatric Urgent Care Center (UCC)

Depending on your child's symptoms, their care team may tell you to bring them to MSK's Pediatric UCC.

The Pediatric UCC is on the 9th floor of Memorial Hospital (MSK's main hospital). The closest entrance is at 1275 York Avenue (at E. 68 Street). This entrance is always open. Once you're in the hospital, take the M elevators to the 9th floor and check in at the desk.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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Memorial Sloan Kettering
Cancer Center