

Giving NULIBRY[®] (fosdenopterin) to a Child With MoCD Type A

- How do I get NULIBRY for injection?
- How is NULIBRY stored?
- Important information you need to know
- How is NULIBRY prepared?
- How is NULIBRY administered?
- Additional tips related to NULIBRY

See how to inject NULIBRY
Watch the dosing demonstration video now
at nulibry.com/prepare-store-give-nulibry



Scan
here.

This guide is meant to familiarize you with the use of NULIBRY. Refer back to it often.

Always talk to your child's Healthcare Professional or care team if you have questions, or refer to the **Instructions for Use** that is provided with each shipment of NULIBRY. This guide should not replace any advice or information you receive from a licensed Healthcare Professional or the approved product insert.

If you have any questions, please contact us at **1-888-251-2800** or visit NULIBRY.com/sentynlcares. We will provide updates to this guide as new information becomes available; it is important to check NULIBRY.com regularly for updates.

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

INDICATION

NULIBRY is indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Potential for Photosensitivity

NULIBRY can make the patient oversensitive to sunlight. NULIBRY-treated patients or their caregivers are advised to avoid or minimize patient exposure to sunlight and artificial UV light and adopt precautionary measures when exposed to the sun, including wearing protective clothing and sunglasses, and use broad-spectrum sunscreen with high SPF in patients 6 months of age and older. If photosensitivity occurs, caregivers/patients are advised to seek medical attention immediately and consider a dermatological evaluation.

SIDE EFFECTS

The most common side effects in NULIBRY-treated patients were infusion catheter-related complications, pyrexia (fever), viral infection, pneumonia, otitis media (ear infection), vomiting, cough/sneezing, viral upper respiratory infection (common cold/flu-like infection), gastroenteritis (stomach flu-like symptoms), diarrhea, and bacteremia (bacteria in the blood). Side effects for rcPMP-treated patients were similar to the NULIBRY-treated patients.

PATIENT COUNSELING INFORMATION

Please read the FDA-approved NULIBRY Prescribing Information and Instructions for Use and follow the instructions on how to prepare and administer NULIBRY.

NULIBRY has a potential for photosensitivity; see Warnings and Precautions. Seek medical attention immediately if the patient develops a rash or if they notice symptoms of photosensitivity reactions (redness, burning sensation of the skin, blisters).

**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](tel:1-800-FDA-1088).**

TO LEARN MORE ABOUT NULIBRY, VISIT NULIBRY.COM

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

How do I get NULIBRY[®] (fosdenopterin)?

NULIBRY will be delivered to your home by a specialty pharmacy.

Each NULIBRY delivery comes with¹:

- A quantity of NULIBRY vials based on your child's Healthcare Professional's prescription. NULIBRY comes in a clear glass vial containing 9.5 mg of fosdenopterin
- The full Prescribing Information and the Instructions for Use for NULIBRY
- A treatment log to keep track of your child's treatments that you will bring with you to each appointment with their Healthcare Professional

How is NULIBRY for injection stored?

Frozen vials:

- Store NULIBRY in a medical-grade freezer between -13°F to 14°F (-25°C to -10°C)
- Keep each NULIBRY vial in the original carton to protect from light until you are ready to use it

Vials of NULIBRY after mixing:

- Store vials of NULIBRY that have been mixed at room temperature 59°F to 77°F (15°C to 25°C) or refrigerated 36°F to 46°F (2°C to 8°C) for up to 4 hours, including infusion time

Vials of NULIBRY are for 1 time use only. Throw the vial away after use, even if there is medicine left in the vial. **Do not** save for later use.

If your freezer is not working or supplies are missing, call Sentynl Cares | NULIBRY at **1-888-251-2800**, Monday-Friday, 8 AM-8 PM ET immediately. You can also call your home care provider about getting supplies. You may also call after 8 PM ET if it is an **Urgent Matter** and someone will assist you with any questions you may have.

Call Sentynl Cares | NULIBRY at [1-888-251-2800](tel:1-888-251-2800),
Monday-Friday, 8 AM-8 PM ET for any questions regarding your deliveries.

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

Important information you need to know

What is the right dose for my child?¹

- Your child's dose of NULIBRY is based on their weight. Your child's Healthcare Professional will prescribe the amount of NULIBRY needed for each dose for your child
- The amount of NULIBRY needed for each dose and the number of vials needed to prepare each dose may change at each visit with your child's Healthcare Professional
- The dose will be measured as the amount (volume) of solution needed in milliliters (mL)

What should I do if my child misses a dose?

If your child misses a dose of NULIBRY, give the dose as soon as possible. Give the next scheduled dose at least 6 hours after finishing the infusion of the missed dose.

See the Additional Tips section "How should I throw away (dispose of) used needles and syringes?" to learn more.

How do I keep track of my child's treatments/infusions?

Keep a treatment log and write down:

- The number of vials needed to prepare each dose
- The date of each infusion
- The lot number from each NULIBRY vial used
- The total amount (volume) of NULIBRY that was infused
- The start time of infusion and the time that the infusion was finished

Be sure to keep this information up-to-date when the dose changes. Bring your child's treatment log sheets to each follow-up appointment with your child's Healthcare Professional. Treatment log sheets will be included with each NULIBRY shipment.

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

How is NULIBRY for injection prepared?

Step 1: Gather supplies

- Use a clean, flat work surface
- Remove from the freezer the NULIBRY vials needed to prepare your child’s prescribed dose. You may need more than 1 vial to prepare the total amount needed for 1 dose. Allow the NULIBRY vials to reach room temperature. This can be done by rolling each vial gently between your hands for 3 to 5 minutes as shown, or by allowing the vials to sit at room temperature for about 30 minutes
- Gather supplies needed to prepare and administer an injection of NULIBRY (Figure A):
 - 1 vial of Sterile Water for Injection for each vial of NULIBRY needed for 1 dose
 - Check the expiration date on the vial. **Do not** use the vial if the expiration date has passed
 - **Do not** use the vial if the flip-off seal on the vial is broken or missing
 - 1 sterile 5 mL syringe for each vial of NULIBRY needed for 1 dose to mix (dissolve) NULIBRY with Sterile Water for Injection
 - 1 sterile syringe large enough to hold the total amount of NULIBRY needed for one dose. Your child’s Healthcare Professional should tell you what size and type of syringe to use
 - sterile needles (18-gauge recommended)
 - alcohol wipes
 - 1 sharps disposal container for throwing away used needles and syringes. **See the Additional Tips section “How should I throw away (dispose of) used needles and syringes?” to learn more**
 - gloves, if your child’s Healthcare Professional instructs you to wear gloves when preparing and giving NULIBRY
 - 1 intravenous administration set with non-DEHP tubing and a 0.2 micron filter
 - 1 infusion pump used to give the NULIBRY injection as directed by your child’s Healthcare Professional
 - other materials, if recommended by your child's Healthcare Professional to properly care for your child’s intravenous access line or port before and after giving a dose of NULIBRY

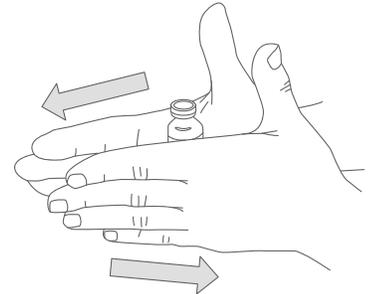


Figure A



Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

Step 2: Wash your hands

- Wash your hands well with soap and water. Use a clean towel to dry your hands or allow them to air dry
- If you have been told to wear gloves to prepare and give the infusion, put them on now

Step 3: Prepare the vials

- Remove the flip-off cap from each vial of Sterile Water for Injection needed to prepare 1 dose (Figure B)
- Clean the rubber stopper of each vial with an alcohol wipe and allow to air dry. **Do not** blow on the stopper to dry it faster (Figure C)

Note: If you touch the vial stopper, you will need to clean it again with an alcohol wipe

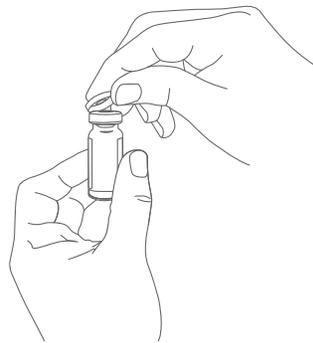


Figure B



Figure C

Step 4: Prepare the syringe used for drawing up Sterile Water for Injection

- Open the wrapper that contains 1 needle. **Do not** remove the needle cover yet (Figure D)
- Open the wrapper that contains a 5 mL syringe. Attach the needle to syringe tip with a screw action in the direction of the arrow as shown (Figure E). Your needle and syringe may look different than shown

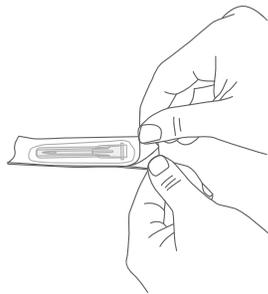


Figure D

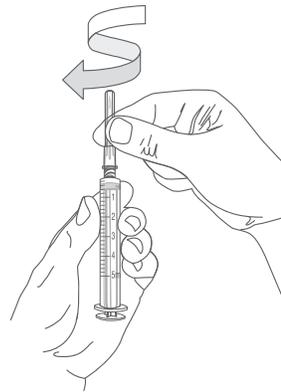


Figure E

Step 5: Fill syringe with Sterile Water for Injection

- Remove the needle cover by pulling the cover straight off. **Do not** touch the needle or let the needle touch any surface (Figure F)
- Hold the syringe with one hand. Use your other hand to pull back the plunger of the syringe until the top of the plunger reaches the 5 mL line on the syringe (Figure G)
- Hold the vial of Sterile Water for Injection firmly on your work surface and insert the needle into the center of the vial stopper (Figure H)

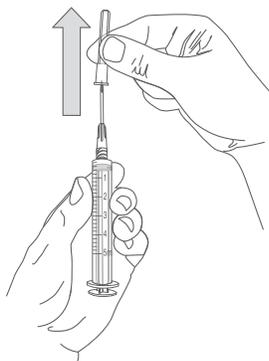


Figure F

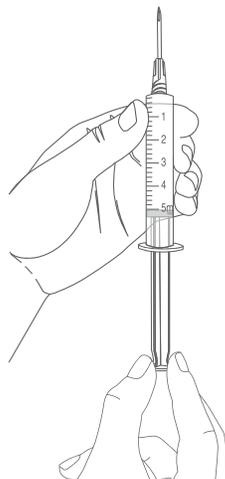


Figure G

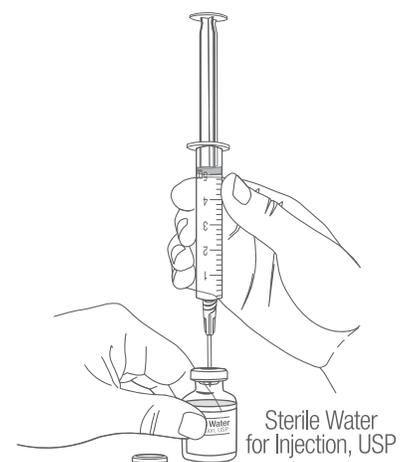


Figure H

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

Step 5: Fill syringe with Sterile Water for Injection (continued)

- Slowly turn the vial upside down. Check that the tip of the needle is not in the solution. Then, push up on the plunger to push all of the air from the syringe into the vial (Figure I)
- Next, move the needle so that the tip is in the solution. Slowly pull down on the plunger of the syringe to fill the syringe with 5 mL of Sterile Water for Injection (Figure J)

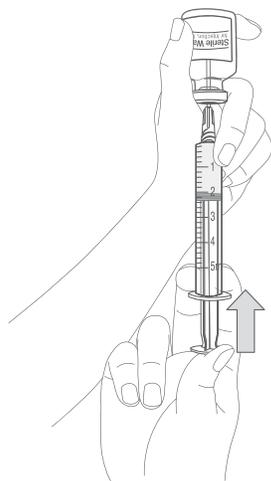


Figure I

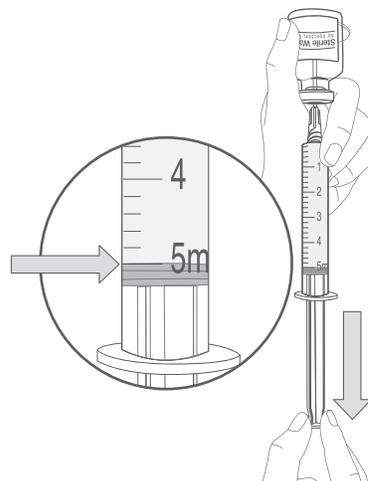


Figure J

- Tap the syringe with your fingers until any air bubbles rise to the top of the syringe then gently push up on the plunger to push the air out of the syringe (Figures K and L)
- After removing the air bubbles, check the syringe to be sure that 5 mL of solution is in the syringe before removing the needle from the vial (Figure M)

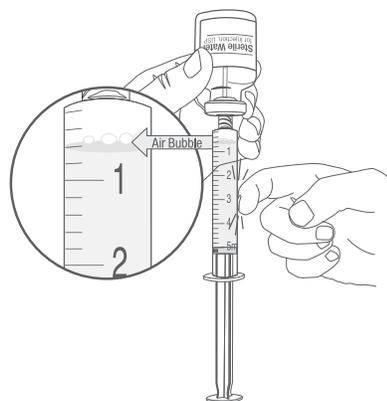


Figure K

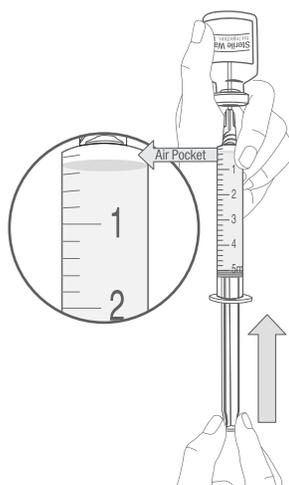


Figure L

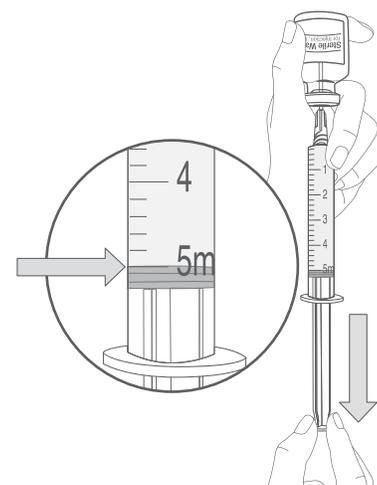


Figure M

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

Step 6: Mix (dissolve) NULIBRY for injection

- Remove the flip-off cap from the vial of NULIBRY
- Wipe the rubber stopper on the vial of NULIBRY with a new alcohol wipe
- Hold the NULIBRY vial firmly on your work surface. Take the syringe with the Sterile Water for Injection and slowly insert the needle into the center of the vial stopper (Figure N)

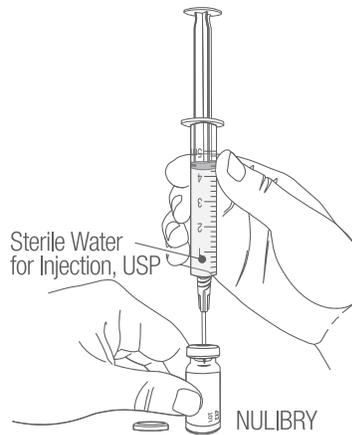


Figure N

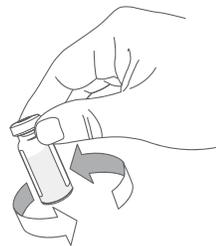


Figure O

- Slowly push down on the plunger all the way to push the Sterile Water for Injection into the vial. Then carefully remove the needle from the vial. Throw away (dispose of) the used needle and syringe in your sharps disposal container right away. **Do not** try to recap the needle. **See the Additional Tips section “How should I throw away (dispose of) used needles and syringes?” to learn more**
- Gently swirl the vial continuously until the powder or cake is completely dissolved. **Do not** shake the vial (Figure O)

Repeat steps 4 through 6 if more than 1 vial of NULIBRY is needed to prepare your child’s prescribed NULIBRY dose. Use a new 5 mL syringe and new needle for each vial of NULIBRY.

Note: When mixed, the NULIBRY solution should be clear, and colorless to pale yellow.

- **Do not** use the solution if it is discolored or cloudy, or if there are any particles in it. If the solution is discolored or cloudy or if there are particles in it, tell your pharmacist and ask for a replacement vial
- **Do not** throw the vial away because the pharmacist may ask that you return it

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

Step 7: Prepare a syringe with the prescribed dose of NULIBRY for injection

If you stored the mixed NULIBRY solution in the refrigerator, remove the vials of mixed NULIBRY solution from the refrigerator and allow them to reach room temperature. This can be done by rolling each vial gently between your hands for 3 to 5 minutes as shown, or by allowing the vials to sit at room temperature for about 30 minutes (Figure P).

- Open the wrapper that contains a new sterile needle. **Do not** remove the needle cover yet
- Open the wrapper that contains a sterile disposable syringe that is large enough to hold the total volume of NULIBRY needed for one dose. Attach the needle to the syringe tip with a screw action. **Do not** remove the needle cover yet
- Wipe the vial stopper of each mixed NULIBRY vial with a new alcohol wipe
- Remove the needle cover by pulling the cover straight off. **Do not** touch the needle or let the needle touch any surface
- Hold the syringe with one hand. Insert the needle into the center of the NULIBRY vial stopper and slowly turn the vial upside down (Figure Q)

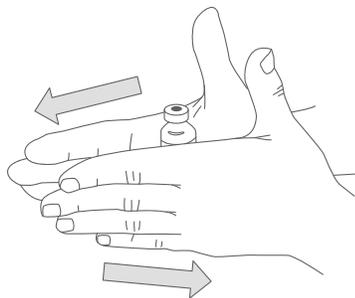


Figure P

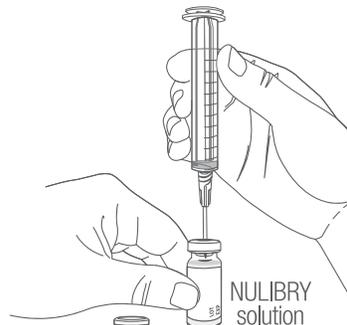


Figure Q



Figure R

- Next, move the needle so that the tip is in the NULIBRY solution. Slowly pull back on the syringe plunger to fill the syringe with the amount of NULIBRY solution in mL for your child's prescribed dose
- Remove any air bubbles from the syringe. Tap on the syringe barrel so that any bubbles rise to the top of the vial. Push up on the plunger to push any air bubbles back into the vial (Figure R). Check to make sure that the correct amount of NULIBRY solution has been drawn into the syringe. If needed, pull down slightly on the plunger until the prescribed amount of NULIBRY solution is in the syringe

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Step 7: Prepare a syringe with the prescribed dose of NULIBRY for injection (continued)

Follow the steps below if more than 1 vial of NULIBRY is needed to make up the total amount of solution needed for 1 daily dose.

- Remove the needle and syringe from the first vial of NULIBRY. Hold the syringe with one hand. Insert the needle into the center of the next NULIBRY vial stopper and slowly turn the vial upside down (Figure S)

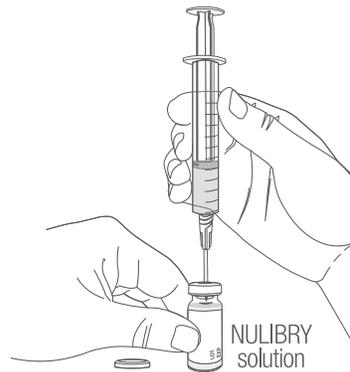


Figure S

- Next, move the needle so that the tip is in the NULIBRY solution. Slowly pull back on the syringe plunger to fill the syringe with the amount of NULIBRY solution in mL for your child's prescribed dose
- Remove any air bubbles from the syringe. Tap on the syringe barrel so that any bubbles rise to the top of the vial. Push up on the plunger to push any air bubbles back into the vial. Then check to be sure that the prescribed amount of NULIBRY solution has been drawn into the syringe. If needed, pull down slightly on the plunger until the total prescribed amount of NULIBRY solution is in the syringe (Figure T)

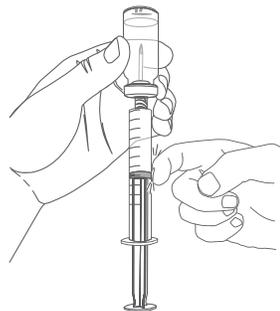


Figure T

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

Step 7: Prepare a syringe with the prescribed dose of NULIBRY for injection (continued)

- Repeat this step if additional vials of NULIBRY are needed to make up your child's dose
- When the needle is removed from the last vial of NULIBRY, all of the mixed dose of NULIBRY is in 1 syringe
- Replace the needle cover before removing the needle from the syringe by placing the cover on a flat surface and sliding the needle into the cover as shown. With one hand, hold the syringe and use the needle to "scoop up" the cover. Once the cover is on the needle, use the other hand to secure the cover on the needle hub (Figures U, V, and W)
- Remove the covered needle from the syringe tip with a screw action in the direction of the arrow as shown (Figure X)
- **Do not** touch the tip of the syringe after removing the needle

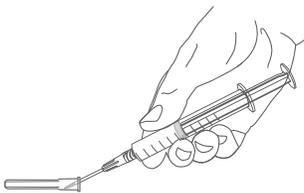


Figure U

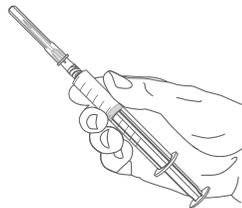


Figure V

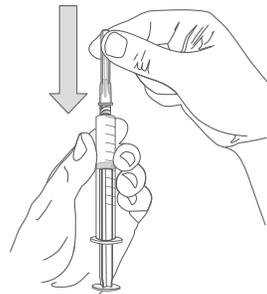


Figure W

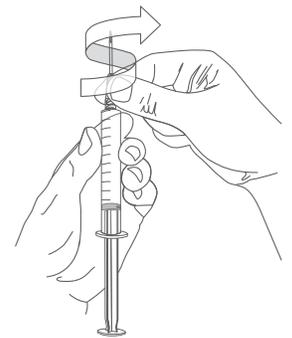


Figure X

- Throw away (dispose of) the needle in the sharps disposal container right away (Figure Y). See the **Additional Tips** section "How should I throw away (dispose of) used needles and syringes?" to learn more
- Throw away the used NULIBRY vial(s) after use, even if there is medicine left in the vial
- The dose of NULIBRY is now ready to be given to your child



Figure Y

Please see additional Important Safety Information in this brochure and full Prescribing Information including Instructions for Use at <https://bit.ly/3tOMDHI>.

How is NULIBRY for injection administered?

Step 8: Giving a dose of NULIBRY

- NULIBRY is given into your child's vein (intravenously) through a special access catheter or port placed by your child's Healthcare Professional
- When NULIBRY is given through an infusion pump, infuse NULIBRY at a rate of 1.5 mL per minute
- If the amount (volume) in mL for your child's prescribed dose of NULIBRY is less than 2 mL, your child's Healthcare Professional may tell you to give NULIBRY by a slow intravenous push using a syringe. Follow your child's Healthcare Professional's instructions for how to give your child's dose of NULIBRY by slow intravenous push
- Follow your child's Healthcare Professional's instructions for proper care of your child's intravenous access catheter or port before and after giving a dose of NULIBRY

Step 9: Record the infusion

After giving each dose of NULIBRY, record information about the dose in the treatment log sheet. See the "Important Information You Need to Know" section of this guide to learn more.

Additional tips related to NULIBRY

How often is NULIBRY administered?

NULIBRY should be administered daily, following the instructions from your child's Healthcare Professional.

Who can I call if I have questions about NULIBRY?

Call Sentynl Cares | NULIBRY at **1-888-251-2800**, Monday-Friday, 8 AM-8 PM ET. You may also call after 8 PM ET if it is an **Urgent Matter** and someone will assist you with any questions you may have.

How should I throw away (dispose of) used needles and syringes?

Put your used needles and syringes in an FDA-cleared sharps disposal container right away after use.

- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container
- **Keep the sharps disposal container out of the reach of children**



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What should I avoid during treatment with NULIBRY for injection?

NULIBRY may cause skin reactions.

- Limit or avoid your child's exposure or time in sunlight and artificial ultraviolet (UV) light, such as UVA or UVB phototherapy
- To help protect against sun exposure, your child should wear clothing, a hat, and sunglasses. If your child is 6 months of age or older, apply a broad spectrum sunscreen with high sun protection factor

In case of emergency, call 911 immediately. Get medical help right away if your child develops a rash, or if you notice symptoms of a skin reaction, including: skin redness, blisters, or if your child feels like their skin is burning.

**Report side effects to the FDA at [1-800-FDA-1088](tel:1-800-FDA-1088)
or www.fda.gov/medwatch.**

For any concern about side effects, call your child's Healthcare Professional right away. You are encouraged to report negative side effects of prescription drugs to the FDA by calling 1-800-FDA-1088 or visiting www.fda.gov/medwatch. You may also call **1-888-507-5206**.

INDICATION

NULIBRY is indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Potential for Photosensitivity

NULIBRY can make the patient oversensitive to sunlight. NULIBRY-treated patients or their caregivers are advised to avoid or minimize patient exposure to sunlight and artificial UV light and adopt precautionary measures when exposed to the sun, including wearing protective clothing and sunglasses, and use broad-spectrum sunscreen with high SPF in patients 6 months of age and older. If photosensitivity occurs, caregivers/patients are advised to seek medical attention immediately and consider a dermatological evaluation.

SIDE EFFECTS

The most common side effects in NULIBRY-treated patients were infusion catheter-related complications, pyrexia (fever), viral infection, pneumonia, otitis media (ear infection), vomiting, cough/sneezing, viral upper respiratory infection (common cold/flu-like infection), gastroenteritis (stomach flu-like symptoms), diarrhea, and bacteremia (bacteria in the blood). Side effects for rcPMP-treated patients were similar to the NULIBRY-treated patients.

PATIENT COUNSELING INFORMATION

Please read the FDA-approved NULIBRY Prescribing Information and Instructions for Use and follow the instructions on how to prepare and administer NULIBRY.

NULIBRY has a potential for photosensitivity; see Warnings and Precautions. Seek medical attention immediately if the patient develops a rash or if they notice symptoms of photosensitivity reactions (redness, burning sensation of the skin, blisters).

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](tel:1-800-FDA-1088).

TO LEARN MORE ABOUT NULIBRY, VISIT NULIBRY.COM

Reference: 1. NULIBRY [prescribing information]. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4f67cc4e-84ed-4f4e-a5d9-6ffb84eddd>.

NULIBRY.com

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