



My Treatment Journal

What is GOMEKLI?

GOMEKLI (mirdametinib) is a prescription medicine used to treat adults and children 2 years of age and older with neurofibromatosis type 1 (NF1) who have plexiform neurofibromas (PN) that cause symptoms and cannot be completely removed by surgery.

It is not known if GOMEKLI is safe and effective in children under 2 years of age.

Important Safety Information

Before taking GOMEKLI tell your healthcare provider about all of your medical conditions, including if you:

- Have eye problems
- Have heart problems
- Are pregnant or plan to become pregnant. GOMEKLI can harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if GOMEKLI passes into your breastmilk.

Please see Important Safety Information at the end of this journal, and [click here](#) for full Prescribing Information, including Patient Information and Instructions for Use.

Get Going with GOMEKLI!

Starting GOMEKLI is an important step in your journey. Keeping track of how you feel during treatment is also important. That's where this journal can help.

This journal is your place to take notes on how you're feeling. That way you'll have notes to share with your care team on your next visit.

Your feelings and experiences are important to share! Try not to downplay anything that's happening with your body when you talk to your care team. Being open and honest will allow them to give you the best support they can.

This journal belongs to: _____

I started taking GOMEKLI on: _____

Starting dose: _____ capsules dispersible tablets



My Care Team

Use this grid to record information about the healthcare providers you see to manage your condition so everything is in one convenient place. There is also space to keep track of your appointments.

Name	Why I see them	Address	Phone

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My Appointments

Appointment date:	
Who I saw:	Why I saw them:
Notes:	

Appointment date:	
Who I saw:	Why I saw them:
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How to Use Your Treatment Journal

On the next pages you'll see grids to fill in with notes about how you're feeling during a GOMEKLI treatment cycle. Use a separate grid for each cycle to keep your notes organized. You can share these forms with your care team at your next visit.

As a reminder:

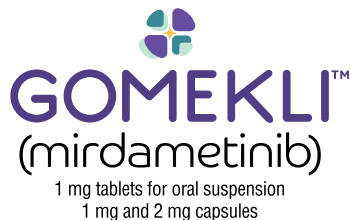
- Each GOMEKLI dosing cycle is 28 days (4 weeks)
- You take GOMEKLI twice a day for 21 days (3 weeks)
- This is followed by 7 days (1 week) without treatment

You should write down any changes in your plexiform neurofibromas or any side effects you feel.

Important Safety Information

The most common side effects associated with GOMEKLI treatment for both adults and children were diarrhea, nausea, muscle, joint, and bone pain, and vomiting. Some adults also experienced tiredness. Some children also experienced stomach (abdominal) pain, headache, and skin redness, swelling, or pain around the fingernails or toenails.

These are not all of the possible side effects of GOMEKLI. Call your doctor for medical advice about side effects. You may also report side effects to the FDA at 1-800-FDA-1088.



Here is an example of how to fill out this form:

Treatment cycle # 2	
<ul style="list-style-type: none">• Fill in the start and end dates for each week• Describe any side effects or changes in your body• Keep track of how you feel, good or bad	
Week 1: From: APRIL 6 To: APRIL 12	STARTED GOMEKLI FOR THE FIRST TIME.
Week 2: From: APRIL 13 To: APRIL 19	DIDN'T NOTICE ANYTHING NEW THIS WEEK.
Week 3: From: APRIL 20 To: APRIL 26	
Week 4: treatment break From: APRIL 27 To: MAY 3	IT'S NICE TO NOT TAKE PILLS EVERY DAY. WILL START AGAIN NEXT WEEK.

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Treatment cycle #	
Week 1: From: To:	
Week 2: From: To:	
Week 3: From: To:	
Week 4: treatment break From: To:	

Additional notes: _____

Questions to ask my care team: _____

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Additional notes: _____

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Indication and Important Safety Information

What is GOMEKLI?

GOMEKLI (mirdametinib) is a prescription medicine used to treat adults and children 2 years of age and older with neurofibromatosis type 1 (NF1) who have plexiform neurofibromas (PN) that cause symptoms and cannot be completely removed by surgery.

It is not known if GOMEKLI is safe and effective in children under 2 years of age.

Important Safety Information

Before taking GOMEKLI, tell your healthcare provider about all of your medical conditions, including if you:

- Have eye problems
- Have heart problems
- Are pregnant or plan to become pregnant. GOMEKLI can harm your unborn baby

Females who are able to become pregnant:

- Your healthcare provider should check to see if you are pregnant before you begin treatment with GOMEKLI.
- Use effective birth control (contraception) during treatment with GOMEKLI and for 6 weeks after your last dose.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with GOMEKLI.

Males with female partners who are able to become pregnant:

- Use effective birth control (contraception) during treatment with GOMEKLI and for 3 months after your last dose.
- Tell your healthcare provider right away if your female partner becomes pregnant or thinks she may be pregnant during treatment with GOMEKLI.
- Are breastfeeding or plan to breastfeed. It is not known if GOMEKLI passes into your breastmilk.
 - Do not breastfeed during treatment with GOMEKLI and for 1 week after your last dose.
 - Talk to your healthcare provider about the best way to feed your baby during this time.

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

How should I take GOMEKLI?

- Take GOMEKLI exactly as your healthcare provider tells you to take it. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with GOMEKLI if you develop certain side effects.
- Take GOMEKLI twice a day, about 12 hours apart, for 21 days, followed by 7 days off treatment, to complete a 28-day treatment cycle. Your healthcare provider will decide how many treatment cycles are right for you.
- Take GOMEKLI with or without food.
- GOMEKLI comes in two different dosage forms, GOMEKLI capsules and GOMEKLI tablets for oral suspension. Your healthcare provider will decide the dosage form and dose of GOMEKLI that is right for you.
- **If you take GOMEKLI capsules:** Swallow each capsule whole with drinking water. If more than 1 capsule is required, swallow 1 capsule at a time. Do not open, break or chew the capsules.
- **If you take GOMEKLI tablets for oral suspension, either:**
 - Swallow each tablet for oral suspension whole with drinking water. If more than 1 tablet is required, swallow 1 tablet at a time.
 - OR**
 - Disperse the tablets for oral suspension in drinking water to make a liquid (suspension) before you take or give GOMEKLI. See the “Instructions for Use” that come with your medicine for instructions on how to prepare and take GOMEKLI tablets for oral suspension.
- If you miss a dose of GOMEKLI, skip the missed dose and take your next dose at your regularly scheduled time.
- If you vomit at any time after taking GOMEKLI, do not take an additional dose. Take your next dose at your regularly scheduled time.

Important Safety Information (cont'd)

What are the possible side effects of GOMEKLI?

GOMEKLI may cause serious side effects, including:

- **Eye problems.** GOMEKLI may cause eye problems that can lead to blindness. Your healthcare provider will check your vision before and during treatment with GOMEKLI. Tell your healthcare provider right away if you get any of the following signs or symptoms of eye problems:
 - Blurred vision
 - Loss of vision
 - Other changes to your vision
- **Heart problems.** GOMEKLI may lower the amount of blood pumped by your heart, which is common in children during treatment with GOMEKLI and can also be severe. Your healthcare provider will do tests before you start GOMEKLI treatment, every 3 months during your first year of treatment, and then as needed to make sure your heart is working properly. Tell your healthcare provider right away if you get any of the following signs or symptoms of heart problems:
 - Coughing or wheezing
 - Shortness of breath
 - Swelling of your ankles and feet
 - Tiredness
 - Increased heart rate
- **Skin problems.** Skin rashes are common with GOMEKLI in both adults and children and can also be severe. GOMEKLI can also cause hair loss (alopecia). Tell your healthcare provider if you develop any of the following signs or symptoms of skin problems:
 - Flat skin rash
 - Raised bumps on the skin
 - Skin bumps that look like acne
 - Skin redness
 - Itchy rash
 - Peeling skin

The most common side effects of GOMEKLI in adults include:

- Diarrhea
- Nausea
- Muscle, joint, and bone pain
- Vomiting
- Tiredness

The most common severe abnormal blood tests in adults include an increased enzyme called creatine phosphokinase (CPK).

The most common side effects of GOMEKLI in children include:

- Diarrhea
- Muscle, joint, and bone pain
- Stomach (abdominal) pain
- Vomiting
- Headache
- Skin redness, swelling, or pain around the fingernails or toenails
- Nausea

The most common severe abnormal blood tests in children include decreased white blood cell (neutrophil) counts and increased CPK. GOMEKLI may cause fertility problems in females, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of GOMEKLI. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

