

# Getting started with GOMEKLI

A guide on what to expect

## 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 on pages 14–15, and [click here](#) for full Prescribing Information, including Patient Information and Instructions for Use.**

## What you'll find inside

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Everyone has a different experience with NF1-PN—even when it comes to what they call plexiform neurofibromas. In this guide, you'll see them referred to as plexiforms.

NF1-PN=neurofibromatosis type 1 with plexiform neurofibromas.

Please see Important Safety Information on pages 14-15, and [click here](#) for full Prescribing Information, including Patient Information and Instructions for Use.

## Tests you may need as you get going on GOMEKLI

Your healthcare provider may order some tests before and during your treatment, including:



**Echocardiogram** to look at your heart



**Blood tests**



**Eye exam** to check your vision and the health of your eyes



**Pregnancy test**, if appropriate




These tests help your care team understand if GOMEKLI is right for you.

### Important Safety Information (cont'd)

#### What are the possible side effects of GOMEKLI?

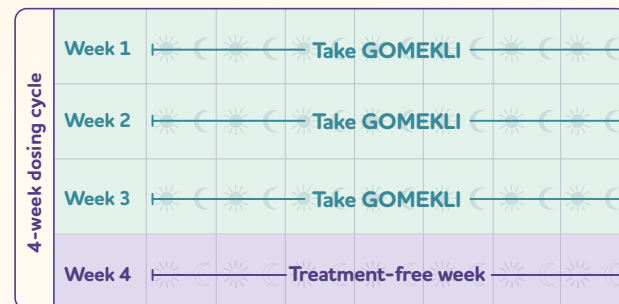
#### GOMEKLI may cause serious side effects, including:

- **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

  
**GOMEKLI™**  
(mirdametinib)  
1 mg tablets for oral suspension  
1 mg and 2 mg capsules

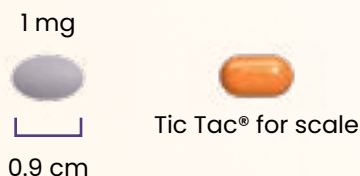
## How to take GOMEKLI

- Each GOMEKLI dosing cycle is 28 days (4 weeks)
  - GOMEKLI is taken by mouth twice a day (about 12 hours apart) for the first 21 days (3 weeks)
  - For the next 7 days, GOMEKLI is **not** taken
- The next cycle then begins with 21 days of treatment

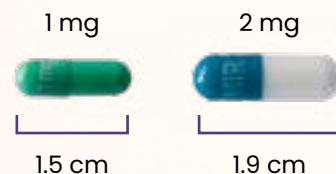


## GOMEKLI comes in 2 forms to fit your needs

### Grape-flavored tablets for oral suspension



### Capsules that come in 2 sizes



Oral suspension means the tablets mix or disperse into water, so the medicine can be taken as a liquid. This may make taking GOMEKLI easier for people who have difficulty swallowing. Tablets can also be swallowed whole.

[Click here to see how to take GOMEKLI.](#)

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## How to stay on track with GOMEKLI

You may take GOMEKLI for a while. The GOMEKLI clinical trial was about 2 years long. After that, >80% of eligible adults and children chose to keep taking GOMEKLI in an optional long-term follow-up phase of the study.


It's important to take GOMEKLI as directed by your care team. You can use tools from the starter kit, like the pillbox and dry-erase calendar, to help stay on track.

### Tips to help you stay on schedule:

1. Set alarms on your cellphone or other device to remind you when it's time to take your pills
2. Pair your GOMEKLI doses with other activities you do every morning and night (like brushing your teeth)
3. Keep your pillbox in an easy-to-remember place

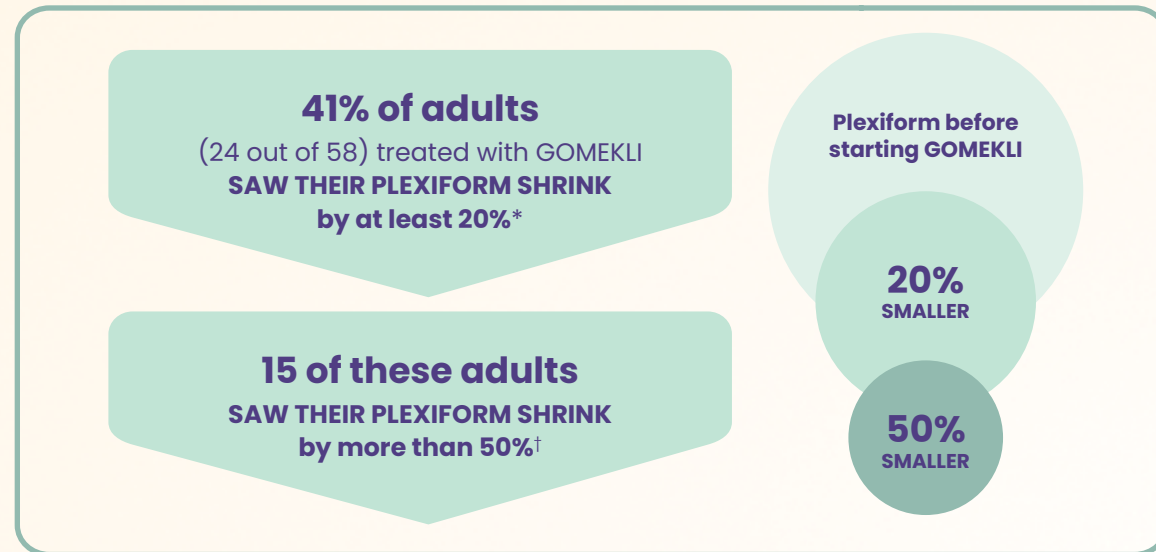
### Important Safety Information (cont'd)

- **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

  
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## How GOMEKLI can help adults (age 18+)

GOMEKLI is proven to shrink plexiforms in adults and children/adolescents with NF1-PN



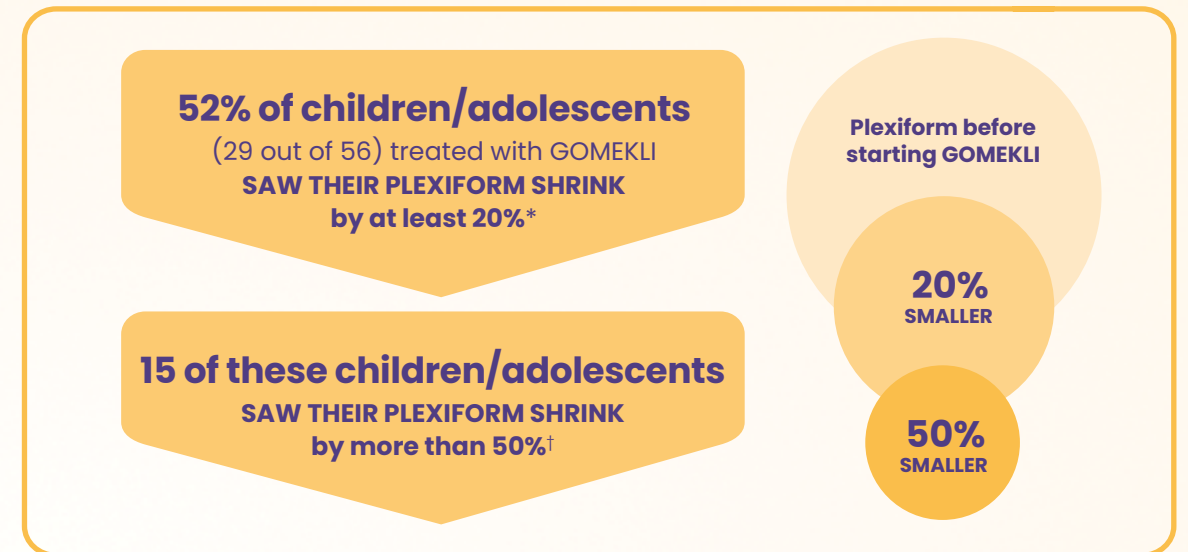
†The 50% reduction in plexiform size was an exploratory analysis, meaning it was not specifically defined in advance of the trial.

### It takes time for plexiforms to shrink

In the clinical trial, about 45% of people who benefited from treatment started seeing results after 4 months. For others, it took a bit longer. The median (middle) amount of time it took for plexiforms to begin shrinking was 7.8 months for adults and 7.9 months for children. In both cases, the plexiforms got smaller, which was the treatment goal for GOMEKLI.

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## How GOMEKLI can help children and adolescents (age 2–17)



\*Reduction in plexiform size had to be confirmed on a later magnetic resonance imaging (MRI) scan.


†The 50% reduction in plexiform size was an exploratory analysis, meaning it was not specifically defined in advance of the trial.



**Don't get discouraged if you don't see results right away. Staying on treatment is the best way to let GOMEKLI help.**

### Important Safety Information (cont'd)

- **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

  
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# Possible side effects with GOMEKLI

Most side effects were mild to moderate in the clinical trial

## In adults, the most common side effects were:

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

## In children and adolescents, the most common side effects were:

- 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 test result in adults and children/adolescents** involved an increased enzyme called creatine phosphokinase (CPK). Some children also experienced decreased white blood cell (neutrophil) counts.

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.

Please see Important Safety Information on pages 14–15, and [click here](#) for full Prescribing Information, including Patient Information and Instructions for Use.

GOMEKLI may also cause serious side effects, including:



**Eye problems.** 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.** 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.** 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

**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 the FDA at 1-800-FDA-1088.**

Most people taking GOMEKLI did not have to stop treatment due to a side effect

Among adults

**22%**  
(13/58)

had to stop treatment due to a side effect

Among children/adolescents

**9%**  
(5/56)

had to stop treatment due to a side effect

Your healthcare provider may interrupt, reduce, or permanently stop GOMEKLI treatment if you experience certain side effects.

  
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## Tips that may help with common side effects

### If you have skin-related side effects:

- Use gentle skin care practices including daily baths and the use of mild cleansers
- Limit soap use to only the face, underarms, groin, and between the toes
- Moisturize with hypoallergenic creams and ointments (anything in a tub-like container) to keep skin from drying out

### If you have stomach-related side effects:

- Avoid eating greasy foods
- Consider following the BRAT diet (bananas, rice, applesauce, toast, plain pasta)



Your care team will know how to treat these side effects. Keep notes on how you're feeling in the GOMEKLI treatment journal to discuss with your healthcare provider.

Please see Important Safety Information on pages 14-15, and [click here](#) for full Prescribing Information, including Patient Information and Instructions for Use.

## Supporting your journey with GOMEKLI

### Get support and resources through SpringWorks CareConnections™

A free, personalized patient support program to help you or your loved one navigate insurance coverage, answer questions about treatment, and help you stay on track with GOMEKLI.

### Insurance navigation and financial help




- If you or your loved one has commercial health insurance, you may pay as little as a \$0 copay per 21-day supply of GOMEKLI with the **Commercial Copay Program\***
- SpringWorks CareConnections may also help with certain eligible out-of-pocket costs for certain treatment-related tests, examinations, and/or specialty visits during treatment with GOMEKLI\*
- If you or the person you care for is uninsured, lack coverage for GOMEKLI, or are experiencing financial hardship, the **Patient Assistance Program†** may help you obtain GOMEKLI at no cost



\*Terms and conditions apply. Copay program for GOMEKLI and reimbursement for eligible treatment-related costs are subject to annual benefit maximums. To receive the reimbursement of eligible treatment-related expenses, an Explanation of Benefits (EOB) form must be submitted, along with copies of receipts for any payments made. Full terms and conditions are provided during the enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

†Terms and conditions apply. PAP eligibility criteria and annual household income limits apply. Full terms and conditions are provided during the enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

  
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# Nurse Advocates are here to help

## Personalized educational and emotional support



Our team of Nurse Advocates is your dedicated single point of contact at SpringWorks CareConnections™.\*

- Our team of Nurse Advocates are available to:
  - Help you or your loved one stay on track and take the medication as prescribed
  - Answer questions to help you manage treatment for you or your loved one throughout the treatment journey
  - Help plan conversations with your care team
  - Work with the doctor’s office and pharmacy so that you receive GOMEKLI as prescribed, including prescription refill reminders



[Click here](#) to see all the ways SpringWorks CareConnections can support your journey with GOMEKLI.

\*The SpringWorks CareConnections Patient Support Program is not intended to take the place of your healthcare provider, and our team of Nurse Advocates cannot provide medical or clinical advice.

Please see Important Safety Information on pages 14–15, and [click here](#) for full Prescribing Information, including Patient Information and Instructions for Use.

# Enrolling in SpringWorks CareConnections™

## Getting started is simple

To start receiving personalized support from SpringWorks CareConnections for you or your loved one, first complete and submit an enrollment form, including the patient authorizations.

## Steps to enroll online



- Visit [www.springworkstxcares.com/gomekli](http://www.springworkstxcares.com/gomekli) and click “Enroll”
- Complete the online form, read and agree to the authorizations and certifications, sign, and click “submit”
- Once you are enrolled, expect a welcome call from one of our Nurse Advocates

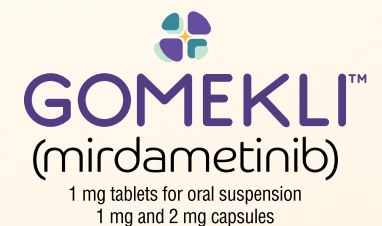
## Steps to enroll via email or fax



- Download and complete the patient section of the form, read the patient authorizations and certifications, and sign the form where noted
- Send the completed form via email to [info@springworkstxcares.com](mailto:info@springworkstxcares.com) or fax it to 844-227-3747
- Once you are enrolled, expect a welcome call from one of our Nurse Advocates



For help enrolling in SpringWorks CareConnections, call today at 844-CARES-55 (844-227-3755).





## 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.

#### **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.

Please [click here](#) for full Prescribing Information, including Patient Information and Instructions for Use.



# Starting GOMEKLI is an important step in your NF1-PN journey

**GOMEKLI is an FDA-approved treatment proven to shrink plexiforms in both adults and children (age 2+) with NF1-PN\***

- You may need to have some tests done before and during GOMEKLI treatment

## **Most side effects were mild to moderate**

- The most common side effects with GOMEKLI were diarrhea, muscle, joint, and bone pain, stomach (abdominal) pain, vomiting, headache, skin redness, swelling, or pain around the fingernails or toenails, tiredness, and nausea

## **Twice-daily oral dosing**

- Use the pillbox and dry-erase calendar to stay on track with treatment

**SpringWorks CareConnections provides personalized support to help you on your journey with GOMEKLI.**

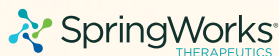
\*In adults and children 2 years and up with plexiforms that cause symptoms and cannot be completely removed by surgery.

## **Important Safety Information (cont'd)**


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.

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