

NOW APPROVED


GOMEKLI[™]
(mirdametinib)

1 mg tablets for oral suspension
1 mg and 2 mg capsules

**SEE BEYOND THE
LIMITS OF NF1-PN**

GO. BE.

Actor portrayal.

Where you want to go. Who you want to be.

**NEW GOMEKLI is here for adults
and children living with NF1-PN**

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.

Living with NF1-PN

The reality of life with neurofibromatosis type 1 with plexiform neurofibromas (NF1-PN)

The most common symptoms of NF1-PN include



- Plexiform neurofibromas, which can be called PNs or plexiforms, are tumors that form in some people living with NF1
- Because plexiforms can press up against internal organs or grow into surrounding tissues, people with NF1-PN may also experience problems with their hearing, vision, or breathing
- In some cases, it is possible for plexiforms to become cancerous

NF1-PN is not curable, but it can be manageable

- Surgery may be an option in some cases, but even when it is possible, up to 85% of plexiforms cannot be completely removed by surgery
- Nearly 1 in 4 plexiforms regrow after surgery*
- There are other factors to consider with surgery, including recovery time

*In a study of medical records of 52 children and adults with NF1 who had surgery to remove plexiforms.

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

What is GOMEKLI?

GOMEKLI is the first and only FDA-approved medicine proven to shrink plexiforms in both adults and children with NF1-PN



GOMEKLI is a MEK inhibitor, which is targeted therapy—not traditional chemotherapy

It works by helping to block certain signals in the body that cause plexiforms to grow.

GOMEKLI was studied in one of the largest (N=114) NF1-PN clinical trials

- A broad range of both adults and children/adolescents was included in the trial
 - 58 adults (age 18+) and 56 children/adolescents (age 2 to 17) were enrolled
- At the start of the trial, pain and changes in appearance were the most common PN-related symptoms reported by adults and children
- Before enrolling in the trial, 69% of adults and 36% of children/adolescents had tried surgery to remove or shrink their plexiforms

Important Safety Information (cont'd)

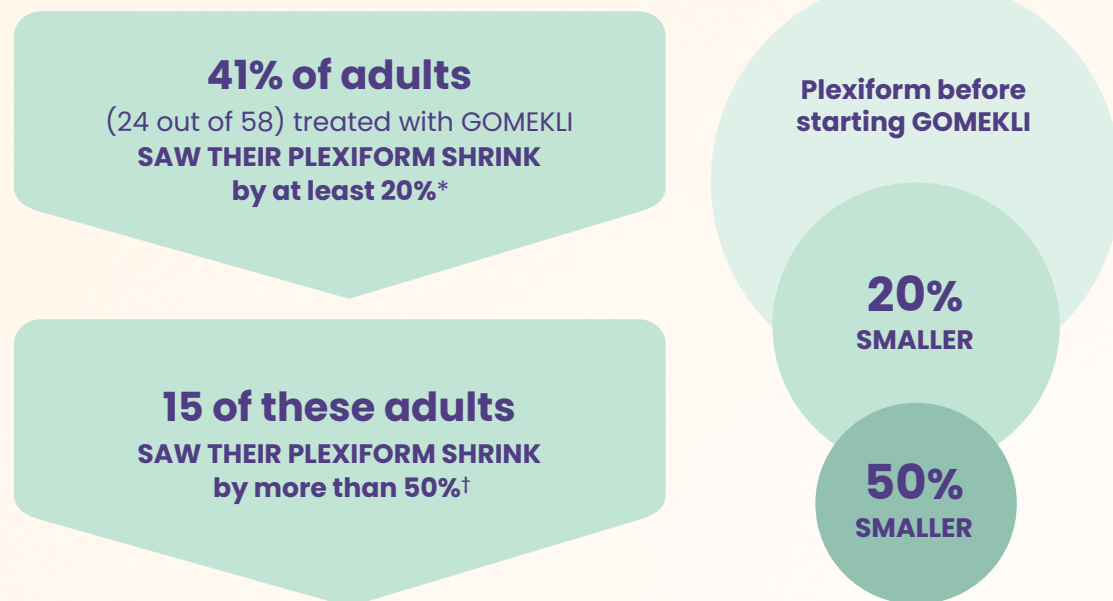
What are the possible side effects of GOMEKLI?

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 is the first and only treatment proven to shrink plexiforms in adults (age 18+)

Results for adults with NF1-PN

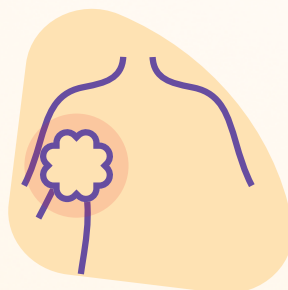


*Reduction in plexiform size had to be confirmed on a later magnetic resonance imaging (MRI) scan.

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

Why 20%?

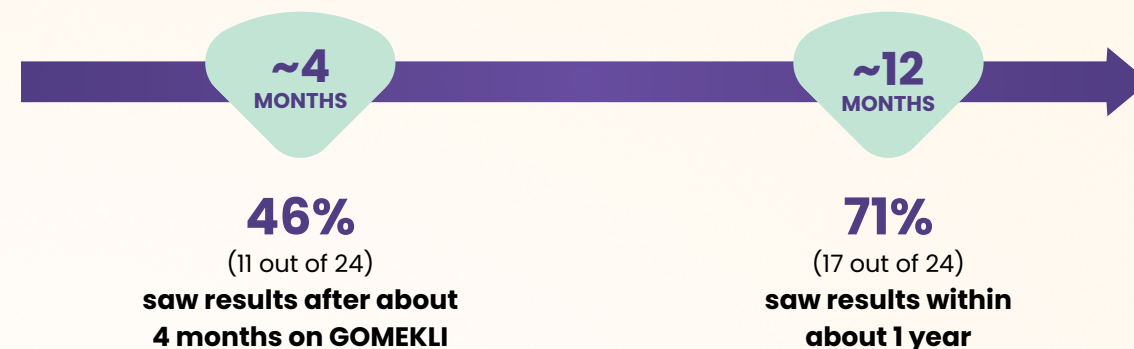
The 20% change in plexiform volume is the standard benchmark used in NF1-PN trials.



✦ **Until GOMEKLI, there were no FDA-approved medicines for adults living with NF1-PN.**

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

In adults who benefited from treatment, plexiforms started to shrink within months of taking GOMEKLI



In adults who benefited from treatment, plexiforms began to shrink by at least 20% between 4 and 19 months of starting GOMEKLI. The median (middle) amount of time it took for plexiforms to begin shrinking was 7.8 months.



The GOMEKLI clinical trial was about 2 years long. After that, **84% of adults** chose to keep taking GOMEKLI in an optional long-term follow-up phase of the study.

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

GOMEKLI is proven to shrink plexiforms in children and adolescents (age 2–17)

Results for children/adolescents with NF1-PN

52% of children/adolescents

(29 out of 56) treated with GOMEKLI
**SAW THEIR PLEXIFORM SHRINK
by at least 20%***

**15 of these children/
adolescents**

**SAW THEIR PLEXIFORM SHRINK
by more than 50%†**

Plexiform before
starting GOMEKLI

**20%
SMALLER**

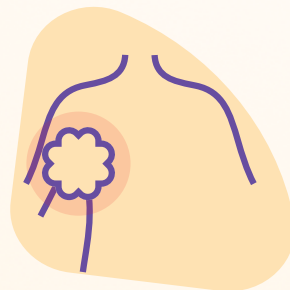
**50%
SMALLER**

*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.

Why 20%?

The 20% change in plexiform volume is the standard benchmark used in NF1-PN trials.



In children/adolescents who benefited from treatment, plexiforms started to shrink within months of taking GOMEKLI



In children/adolescents who benefited from treatment, plexiforms began to shrink by at least 20% between 4 and 19 months of starting GOMEKLI. The median (middle) amount of time it took for plexiforms to begin shrinking was 7.9 months.



The GOMEKLI clinical trial was about 2 years long. After that, **85% of children/adolescents** chose to keep taking GOMEKLI in an optional long-term follow-up phase of the study.

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)

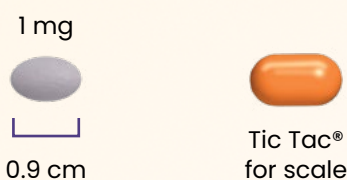
had to stop treatment due to a side effect

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

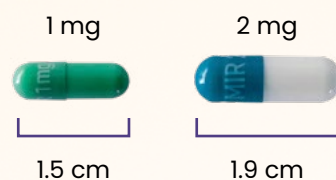
Twice-daily oral dosing designed with patients in mind

GOMEKLI comes in 2 forms to fit your needs

Grape-flavored tablets for oral suspension



Capsules that come in two sizes



- GOMEKLI is taken by mouth twice a day (about 12 hours apart)
- GOMEKLI can be taken with or without food
- Your healthcare provider will decide the right dose of GOMEKLI based on weight and height (body surface area)



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 pills or tablets. Tablets can also be swallowed whole.

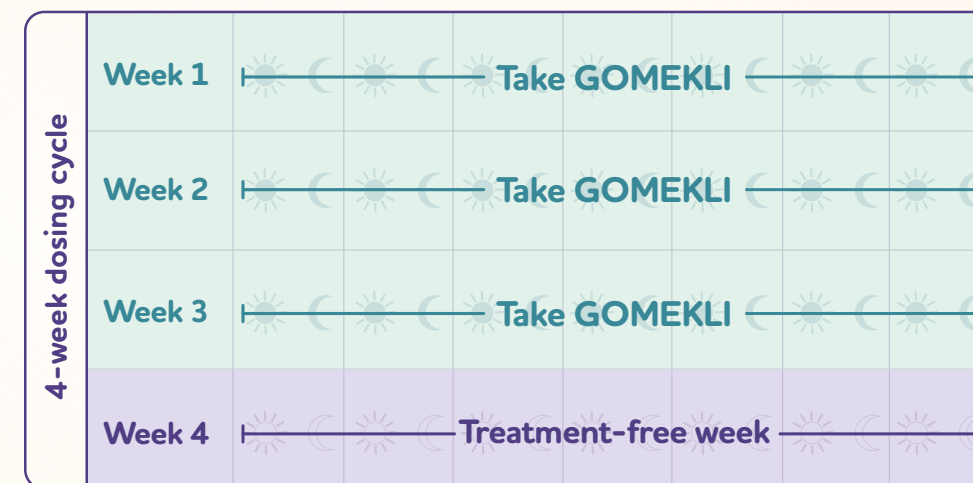
Tic Tac® and its three-dimensional design are registered trademarks of Ferrero S.A.

It's important to take GOMEKLI as directed by your healthcare provider.

With GOMEKLI, there's a built-in treatment break

- Each GOMEKLI dosing cycle is 28 days (4 weeks)
 - GOMEKLI is taken twice a day 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 Dosing Schedule



For 1 week each month, you don't have to worry about taking or giving treatment.

Supporting your journey with GOMEKLI

Nurse Advocates are here to help



SpringWorks CareConnections™ offers support and resources for people taking GOMEKLI

A free, personalized patient support program to help you or your loved one navigate insurance coverage, answer questions about treatment, and help you start and 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 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, lacks coverage for GOMEKLI, or is 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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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 the team of Nurse Advocates cannot provide medical or clinical advice.

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.

Actor portrayal.



Get going with GOMEKLI



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

- GOMEKLI shrank plexiforms by at least 20% in **41% of adults** and **52% of children/adolescents**[†]



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

- GOMEKLI is available in capsules or as tablets that mix in water so the medicine can be swallowed as a liquid



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

Go to [GOMEKLI.com](https://www.gomekli.com) to learn more.

*Those with plexiforms that cause symptoms and cannot be completely removed by surgery.

[†]Confirmed on a later magnetic resonance imaging (MRI) scan.

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.

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1 mg and 2 mg capsules