

TAFINLAR + MEKINIST is for children aged 1 year and older who have *BRAF* V600E+ low-grade glioma (LGG)

TRANSFORM WHAT'S POSSIBLE WITH TAFINLAR + MEKINIST

A Caregiver's Guide to Treatment for Pediatric
BRAF V600E+ LGG



Not an actual patient.

APPROVED USE

TAFINLAR and MEKINIST are prescription medicines that can be used in combination to treat a type of brain tumor called glioma in children 1 year of age and older

- that is low-grade glioma (LGG), **and**
- that have a certain type of abnormal "*BRAF*" gene, **and**
- who require a medicine by mouth or injection (systemic therapy)

TAFINLAR, in combination with MEKINIST, is not for use in treating people with wild-type *BRAF* solid tumors.

Your health care provider will perform a test to make sure that TAFINLAR and MEKINIST in combination is right for you.

It is not known if TAFINLAR, in combination with MEKINIST, is safe and effective in children younger than 1 years of age. It is not known if TAFINLAR used alone is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TAFINLAR in combination with MEKINIST? TAFINLAR and MEKINIST may cause serious side effects, including:

Risk of new skin cancers. TAFINLAR, when used in combination with MEKINIST, may cause a type of skin cancer called cutaneous squamous cell carcinoma, keratoacanthoma, basal cell carcinoma, or melanoma. Talk with your health care provider about your risk for these cancers.

Please see additional Important Safety Information throughout this brochure and on [pages 17 to 19](#).

Please [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.



TAKING THE NEXT STEP IN TREATMENT

Moving forward after diagnosis

Finding out a loved one has cancer is life-altering news. As a caregiver of a child diagnosed with *BRAF* V600E+ LGG, you are probably experiencing many emotions. It may be overwhelming to go through all the information that's available.



This brochure can help you better understand the disease, how it's treated, and other important topics, including:

- [The *BRAF* V600E+ LGG disease](#)
- [How TAFINLAR + MEKINIST works](#)
- [Potential side effects](#)
- [How to administer this medication](#)
- [Additional resources for you](#)



Knowing how TAFINLAR + MEKINIST can treat this type of cancer can help you better support your child throughout their treatment journey



Not an actual patient.

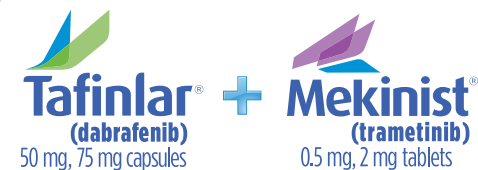
IMPORTANT SAFETY INFORMATION (continued)

Risk of new skin cancers (continued). Check your skin and tell your health care provider right away about any skin changes, including a new wart, skin sore, or reddish bump that bleeds or does not heal, or a change in size or color of a mole.

Your health care provider should check your skin before you start treatment, and every 2 months while on treatment, to look for any new skin cancers. Your health care provider should continue to check your skin for 6 months after you stop taking TAFINLAR and MEKINIST.

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UNDERSTANDING BRAF V600E+ LGG

What is BRAF V600E+ LGG?

Low-grade glioma, or LGG, is a slow-growing brain cancer. LGG is the most common type of brain tumor diagnosed in children.

Some children may have a damaged *BRAF* gene—known as a **mutation**—that may cause the LGG tumor to act more aggressively. The *BRAF* mutation damages the cell-growth pathway and causes cells to grow out of control.



UP TO 1 IN 5 PATIENTS
WITH LGG HAVE THE *BRAF* V600E MUTATION

IMPORTANT SAFETY INFORMATION (continued)

Risk of new skin cancers (continued). Your health care provider should also check for cancers that may not occur on the skin. Tell your health care provider about any new symptoms that have developed while taking TAFINLAR and MEKINIST in combination.

Bleeding problems. TAFINLAR and MEKINIST in combination can cause serious bleeding problems, especially in your brain or stomach, that can lead to death. Call your health care provider and get medical help right away if you have any signs of bleeding, including:

- headaches, dizziness, or feeling weak
- coughing up blood or blood clots
- vomiting blood or your vomit looks like “coffee grounds”
- red or black stools that look like tar

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KNOWING MUTATION STATUS CAN HELP DETERMINE TREATMENT

Why are *BRAF* V600E mutations important and how are they found?

LGG tumors with a *BRAF* V600E mutation are typically removed with surgery, but sometimes surgery might not be possible. These tumors are stubborn and often return and continue to grow (or **progress**), even after successful surgery, and some may respond poorly to chemotherapy.

BRAF mutations are found when a sample of the tumor is sent to a laboratory for genetic testing. A positive result means that the *BRAF* V600E mutation is present—this is why it's called *BRAF* V600E+ (the plus sign indicates the mutation status is positive).



Knowing a tumor's mutation status matters because children with *BRAF* V600E+ LGG may have access to a targeted treatment designed specifically for their type of cancer



Ask your child's health care provider if they have been tested for *BRAF* mutations

IMPORTANT SAFETY INFORMATION (continued)

Inflammation of the intestines or tears (perforation) of the stomach or intestines. MEKINIST, alone or in combination with TAFINLAR, can cause inflammation of your intestines, or tears in the stomach or intestines that can lead to death. Tell your health care provider right away if you have any of the following symptoms:

- bleeding (see "Bleeding problems")
- diarrhea (loose stools) or more bowel movements than usual
- stomach-area (abdomen) pain or tenderness
- fever
- nausea

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Not an actual patient.



TAFINLAR + MEKINIST FOR BRAF V600E+ LGG

What is TAFINLAR + MEKINIST?

TAFINLAR + MEKINIST is a targeted therapy (or treatment).

This means that it is designed to specifically control the abnormal *BRAF* V600E mutation and slow the growth of cancerous cells. TAFINLAR + MEKINIST is a combination therapy of 2 medications that work together to target and treat the tumor.



For children with *BRAF* V600E+ LGG, TAFINLAR + MEKINIST could transform their lives

How does TAFINLAR + MEKINIST work?

As a targeted combination therapy, TAFINLAR + MEKINIST helps control cancer cell growth by blocking cell-growth signals associated with the *BRAF* gene. **TAFINLAR and MEKINIST each target a different point in the cell-signaling process.**

BRAF V600E+ LGG cancer cells can grow uncontrollably



TAFINLAR + MEKINIST may help slow the growth of *BRAF* V600E+ LGG

IMPORTANT SAFETY INFORMATION (continued)

Blood clots. TAFINLAR and MEKINIST in combination can cause blood clots in your arms or legs, which can travel to your lungs and lead to death. Get medical help right away if you have the following symptoms:

- chest pain
- sudden shortness of breath or trouble breathing
- pain in your legs with or without swelling
- swelling in your arms or legs
- a cool, pale arm or leg

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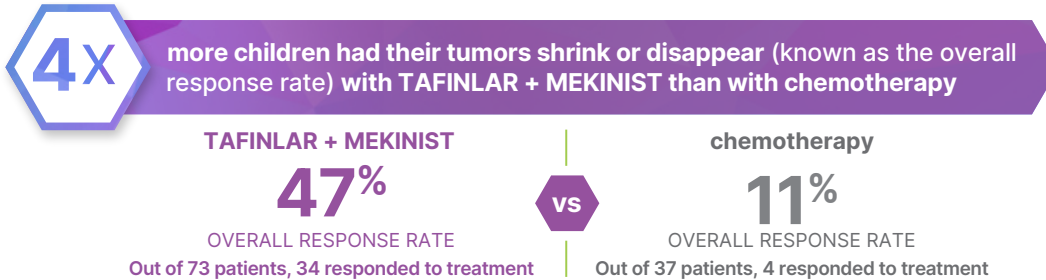


HOW TAFINLAR + MEKINIST CAN HELP

Benefits of TAFINLAR + MEKINIST for *BRAF* V600E+ LGG

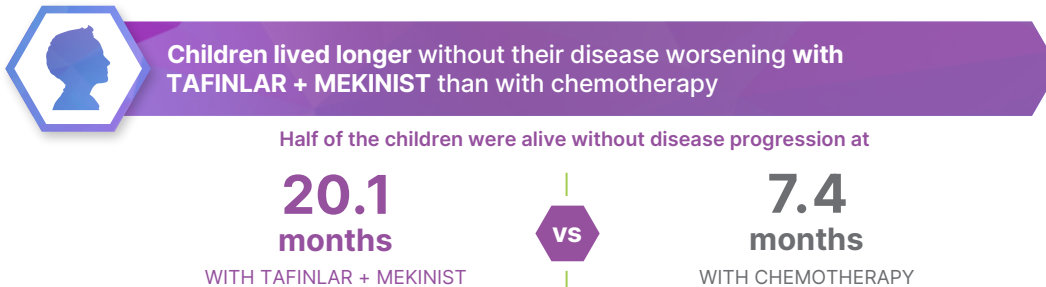
TAFINLAR + MEKINIST is an FDA-approved treatment that was researched in 110 children with *BRAF* V600E+ LGG whose cancer returned after surgery or was not able to be removed by surgery.

- 110 children → 73 treated with TAFINLAR + MEKINIST, 37 treated with chemotherapy (vincristine and carboplatin)



TAFINLAR + MEKINIST helps inhibit cancer growth so children can live longer without their disease worsening

- Tumors disappeared completely in 3% (2 out of 73) of patients treated with TAFINLAR + MEKINIST and 3% (1 out of 37) of patients treated with chemotherapy
- Tumors shrank in 44% (32 out of 73) of patients treated with TAFINLAR + MEKINIST and 8% (3 out of 37) of patients treated with chemotherapy



Ask your child's health care provider about TAFINLAR + MEKINIST for *BRAF* V600E+ LGG

IMPORTANT SAFETY INFORMATION (continued)

Heart problems, including heart failure. Your health care provider should check your heart function before you start taking TAFINLAR and MEKINIST in combination, and during treatment. Call your health care provider right away if you have any of the following signs and symptoms of a heart problem:

- feeling like your heart is pounding or racing
- shortness of breath
- swelling of your ankles and feet
- feeling lightheaded

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UNDERSTANDING POSSIBLE SIDE EFFECTS OF TAFINLAR + MEKINIST

Does TAFINLAR + MEKINIST have side effects?

Serious side effects

For a complete list of potential side effects, please see "Important Safety Information" on [pages 17 to 19](#). Serious side effects associated with TAFINLAR + MEKINIST include risk of new skin cancers, bleeding problems, inflammation of the intestines or tears (perforation) of the stomach or intestines, blood clots, heart problems, eye problems, lung or breathing problems, fever, serious skin reactions, increased blood sugar, a type of anemia called hemolytic anemia, and hemophagocytic lymphohistiocytosis.

Talk to your child's health care provider right away if they experience any side effects. Your child's health care provider may choose to modify, interrupt, or discontinue treatment.

TAFINLAR + MEKINIST has side effects that you should be aware of.

The most common side effects seen when using TAFINLAR + MEKINIST in children with LGG are:

- Fever
- Rash
- Headache
- Vomiting
- Muscle and bone pain
- Tiredness
- Dry skin
- Diarrhea
- Nausea
- Bleeding
- Stomach-area (abdomen) pain
- Acne



Take note of other medications

When starting treatment with TAFINLAR + MEKINIST, keep a list of all other medications your child is taking and share it with their health care provider; certain medicines may affect each other, resulting in side effects.



Report side effects

Keep track of your child's side effects and talk to their health care provider right away about any side effects that are tough to deal with or do not go away. Your child's health care provider may change the dose, temporarily stop, or completely stop treatment with TAFINLAR + MEKINIST if your child develops certain side effects.

IMPORTANT SAFETY INFORMATION (continued)

Eye problems. TAFINLAR and MEKINIST, in combination, can cause severe eye problems that can lead to blindness. Call your health care provider right away if you get these symptoms of eye problems:

- blurred vision, loss of vision, or other vision changes
- seeing color dots
- halo (seeing blurred outline around objects)
- eye pain, swelling, or redness

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MANAGING POSSIBLE SIDE EFFECTS OF TAFINLAR + MEKINIST

How are side effects managed?

It's important to talk to your child's health care provider about any side effects that might happen.

Here are some helpful tips on how to manage the most commonly seen side effects:

| Side Effects | Management Tips |
|---|---|
| Fever | <ul style="list-style-type: none">• Contact your child's health care provider right away if your child gets a fever• Give your child plenty of liquids (for example, water, soups, or ice pops)• Place a cold cloth on your child's forehead if it feels warm |
| Dry skin, rash, or acne | <p>For dry skin, consider:</p> <ul style="list-style-type: none">• Moisturizing skin, especially after bathing• Using extra protection from cold, wind, and dry heat <p>Contact your child's health care provider if your child gets a skin rash or acne that bothers them or worsens. For mild rash or acne, consider:</p> <ul style="list-style-type: none">• Protecting skin from the sun• Choosing a mild soap or shampoo• Using a hypoallergenic moisturizer and avoiding anti-acne skin products with alcohol or retinoids• Stopping your child from picking at pimples or scratching their skin to prevent infection |
| Headache | <ul style="list-style-type: none">• Use over-the-counter headache medication to reduce pain |
| Upset stomach (including nausea, vomiting, diarrhea, or stomach pain) | <ul style="list-style-type: none">• Contact your child's health care provider if your child has severe diarrhea• Give your child cool water to drink between meals• Offer smaller meals and bland foods (for example, dry crackers, cereal, or toast)• Reduce the number of greasy foods and foods containing dairy in your child's diet |

See next page for additional possible side effects and management tips.

IMPORTANT SAFETY INFORMATION (continued)

Lung or breathing problems. TAFINLAR and MEKINIST, in combination, can cause lung or breathing problems. Tell your health care provider if you have any new or worsening symptoms of lung or breathing problems, including:

- shortness of breath
- cough

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MANAGING POSSIBLE SIDE EFFECTS OF TAFINLAR + MEKINIST (CONTINUED)

How are side effects managed? (continued)

| Side Effects | Management Tips |
|----------------------|--|
| Muscle and bone pain | <ul style="list-style-type: none">• Use over-the-counter medication to reduce pain• Encourage gentle exercise, stretching, and breathing techniques• Give a simple massage at home and try using hot or cold compresses |
| Tiredness | <ul style="list-style-type: none">• Encourage extra sleep• Provide a healthy diet• Recommend exercising when possible |
| Bleeding | <p>This is a serious problem that requires immediate medical help. Call your child's health care provider right away if you see any signs of bleeding, including:</p> <ul style="list-style-type: none">• Headaches, dizziness, or feeling weak• Coughing up blood or blood clots• Vomiting blood or vomit that looks like "coffee grounds"• Red or black stool that looks like tar |

IMPORTANT SAFETY INFORMATION (continued)

Fever. Fever is common during treatment with TAFINLAR and MEKINIST, but it may also be serious. When taking TAFINLAR and MEKINIST, in combination, fever may happen often or may be severe. In some cases, chills or shaking chills, too much fluid loss (dehydration), low blood pressure, dizziness, or kidney problems may happen with the fever. Call your health care provider right away if you get a fever while taking TAFINLAR or MEKINIST.

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GETTING STARTED WITH TREATMENT

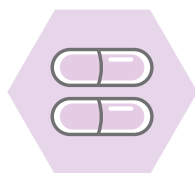
What should I know before starting TAFINLAR + MEKINIST?

TAFINLAR + MEKINIST is the first and only medicine for *BRAF* V600E+ LGG that can be given to your child at home.

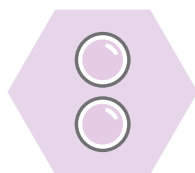
TAFINLAR + MEKINIST for children with *BRAF* V600E+ LGG is available in 2 forms:

1 Capsule + tablet medicine (pills)

If your health care provider prescribes pills for your child, [learn more about taking pills](#)



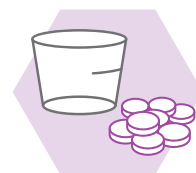
TAFINLAR Capsules



MEKINIST Tablets

2 Liquid medicine (for children who have difficulty swallowing pills)

If your health care provider prescribes liquid medicine for your child, [learn more about taking liquid medicine](#)



Dissolvable TAFINLAR Tablets
for Oral Suspension
(prepared by you)



MEKINIST Oral Solution
(prepared by your pharmacist)



Learn more about [when to take TAFINLAR + MEKINIST](#)

The recommended dosage for TAFINLAR + MEKINIST is based on the weight of your child. Your health care provider will determine the appropriate dose and prescribe either the capsule + tablet medicine or liquid medicine for your child. Give TAFINLAR + MEKINIST to your child exactly as their health care provider tells you to. Do not change your child's dose or stop TAFINLAR + MEKINIST unless their health care provider tells you to do so.

See [TAFINLAR Instructions for Use](#) and [MEKINIST Instructions for Use](#) for complete dosing information.

IMPORTANT SAFETY INFORMATION (continued)

Fever (continued). Your health care provider may temporarily or permanently stop your treatment or change your dose of MEKINIST with TAFINLAR if you have fevers. Your health care provider will treat you as needed for your fever and any signs and symptoms of infection and should check your kidney function during and after you have had severe fever.

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WHEN TO TAKE TAFINLAR + MEKINIST

Note that the dosing schedule is the same for both pills and liquid medicine.

T TAFINLAR

Follow directions from your child's health care provider for the correct number of TAFINLAR capsules to give to your child or tablets to disperse into an oral suspension.



First dose: morning

TAFINLAR should be taken at least 1 hour before or 2 hours after a meal.

12-hour interval between TAFINLAR doses



Second dose: evening

TAFINLAR should be taken at least 1 hour before or 2 hours after a meal.

M MEKINIST

Follow directions from your child's health care provider for the correct number of MEKINIST tablets to give to your child or amount of oral solution to administer.



Once daily

MEKINIST should be taken at the same time each day with either the morning dose or evening dose of TAFINLAR. MEKINIST should be taken at least 1 hour before or 2 hours after a meal (about every 24 hours).

What if your child misses a dose?

If your child misses a dose of TAFINLAR and/or MEKINIST, don't panic—it happens. Just make sure your child takes the missed dose as soon as you remember. **However, DO NOT make up for the missed dose if:**

- Your child has missed TAFINLAR and there are less than 6 hours until the next scheduled dose
- Your child has missed MEKINIST and there are less than 12 hours until the next scheduled dose, or
- Your child vomits after taking a dose of TAFINLAR or MEKINIST

IMPORTANT SAFETY INFORMATION (continued)

Serious skin reactions. Skin rash is a common side effect of TAFINLAR and MEKINIST. In some cases, these rashes and other skin reactions can be severe or serious, may need to be treated in a hospital, or lead to death.

Please see additional Important Safety Information throughout this brochure and on [pages 17 to 19](#).

Please [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.



Tip:

Develop a routine for giving your child medicine that fits your daily schedules. For example, your child can take TAFINLAR and MEKINIST in the morning, an hour before breakfast, and then take TAFINLAR again in the evening, 2 hours after dinner.



If you have any questions about how to prepare and give a dose of TAFINLAR + MEKINIST, **talk to your child's health care provider or pharmacist.**



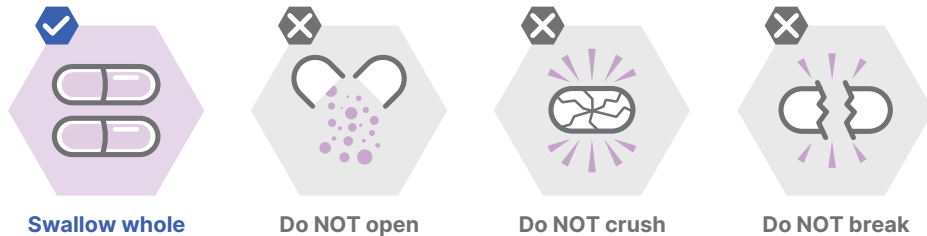
If your child's health care provider prescribes

PILLS: TAFINLAR CAPSULES + MEKINIST TABLETS

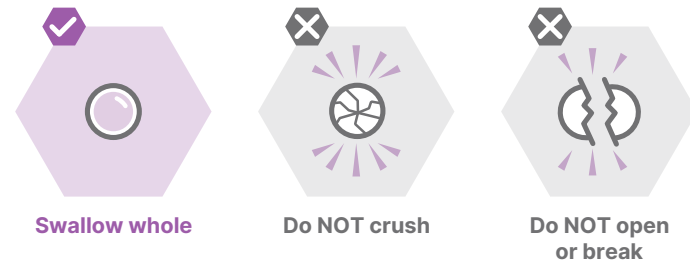
Your child's health care provider will determine the appropriate weight-based dose for your child and give you the exact dosing information you need to administer the TAFINLAR and MEKINIST pills correctly. If TAFINLAR capsules and MEKINIST tablets are prescribed for your child (age 1 or older), their health care provider will adjust their dose as they grow.

It is important that you understand and follow directions from your child's health care provider for taking TAFINLAR + MEKINIST.

TAFINLAR capsules need to be swallowed whole



MEKINIST tablets need to be swallowed whole



Tell your child's health care provider if your child is not able to swallow TAFINLAR capsules or MEKINIST tablets whole.

How should TAFINLAR and MEKINIST pills be stored?

Storing TAFINLAR capsules

- Store TAFINLAR capsules at room temperature, between 68 °F to 77 °F
- Keep TAFINLAR capsules in the original bottle
- The bottle of TAFINLAR capsules contains a cannister with a drying agent (desiccant) to help keep your medicine dry. Do not throw away the desiccant cannister

Storing MEKINIST tablets

- Store MEKINIST in the refrigerator, between 36 °F to 46 °F
- Keep MEKINIST dry and away from moisture and light
- The bottle of MEKINIST contains a drying agent (desiccant packet) to help keep your medicine dry. Do not throw away this packet
- Keep MEKINIST in its original bottle. Do not place tablets in a pill box
- Safely throw away MEKINIST that is out of date or no longer needed



Keep this medicine out of the reach of children

IMPORTANT SAFETY INFORMATION (continued)

Serious skin reactions (continued).

- tell your health care provider if you get a skin rash or acne that bothers you or worsens

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If your child's health care provider prescribes

LIQUID MEDICINE: TAFINLAR ORAL SUSPENSION + MEKINIST ORAL SOLUTION

If your child has difficulty swallowing pills, TAFINLAR and MEKINIST can be given as liquid medicines. Your child's health care provider will determine the appropriate weight-based dose of liquid medicine for your child and give you the exact dosing information you need to administer TAFINLAR + MEKINIST correctly. If TAFINLAR tablets for oral suspension and MEKINIST oral solution are prescribed for your child (age 1 or older), their health care provider will adjust their dose as they grow.

It is important that you understand and follow directions from your child's health care provider for taking TAFINLAR + MEKINIST.

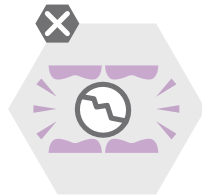
TAFINLAR tablets need to be mixed in water by you as an oral suspension and given as a liquid medicine (via dosing cup, oral syringe, or feeding tube).



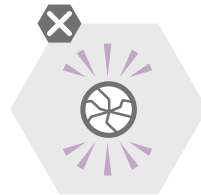
Mix in water



Do NOT swallow tablets whole



Do NOT chew



Do NOT crush

MEKINIST oral solution is provided as a premixed solution by your child's pharmacy.

This should be given as a liquid medicine (via oral syringe or feeding tube).



Give as a liquid medicine

IMPORTANT SAFETY INFORMATION (continued)

Serious skin reactions (continued).

- tell your health care provider right away if you develop any of the following signs or symptoms of a severe skin reaction, including:
 - blisters or peeling of your skin
 - mouth sores
 - high fever or flu-like symptoms
 - blisters on your lips, or around your mouth or eyes
 - enlarged lymph nodes

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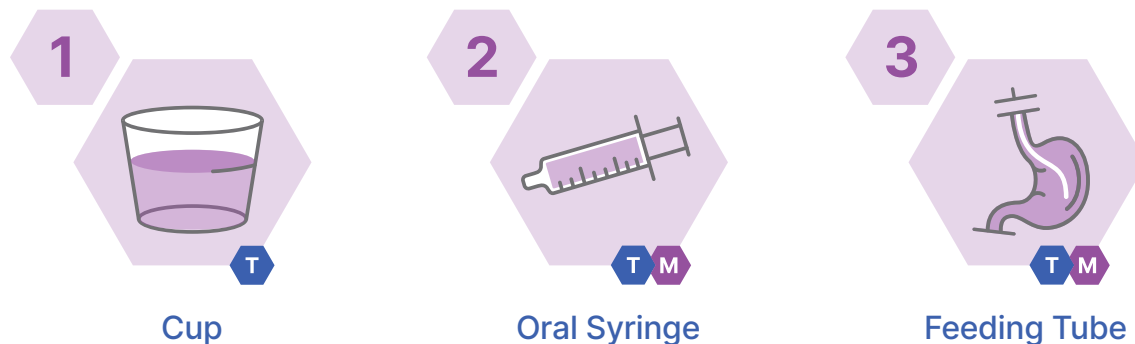
LIQUID MEDICINE: TAFINLAR ORAL SUSPENSION + MEKINIST ORAL SOLUTION (CONTINUED)

How should the liquid medicine be given?

Full instructions are available in the [TAFINLAR Instructions for Use](#), including [Medication Guide](#), and [MEKINIST Instructions for Use](#), [including Patient Information](#). Your health care provider or pharmacist should show you how to measure and give your child a dose of TAFINLAR and a dose of MEKINIST correctly. **Always give TAFINLAR and/or MEKINIST exactly as instructed.**

If you have any questions about how to give a dose of TAFINLAR or MEKINIST, talk to your child's health care provider or pharmacist.

As a liquid, there are 3 ways to give TAFINLAR + MEKINIST to your child:



See Instructions for Use for how to administer TAFINLAR oral suspension and MEKINIST oral solution.



IMPORTANT SAFETY INFORMATION (continued)

Increased blood sugar (hyperglycemia). Some people may develop high blood sugar or worsening diabetes during treatment with TAFINLAR and MEKINIST in combination. If you are diabetic, your health care provider should check your blood sugar levels closely during treatment with TAFINLAR and MEKINIST. Your diabetes medicine may need to be changed. Tell your health care provider if you have any of the following symptoms of severe high blood sugar:

- increased thirst
- urinating more often than normal, or urinating an increased amount of urine

TAFINLAR may cause healthy red blood cells to break down too early in people with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

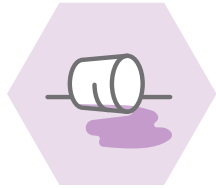
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LIQUID MEDICINE: TAFINLAR ORAL SUSPENSION + MEKINIST ORAL SOLUTION (CONTINUED)

What should I do if I spill TAFINLAR or MEKINIST liquid medicine, or if it gets on the skin or in the eyes?



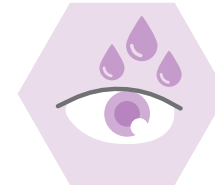
Spills

See Instructions for Use for how to clean a spill of [TAFINLAR](#) or [MEKINIST](#) liquid medicine.



Gets on skin

Wash the area well with soap and water.



Gets in eyes

Rinse the eyes well with cool water.

How should TAFINLAR and MEKINIST liquid medicines be stored?

Storing TAFINLAR dissolvable tablets for oral suspension

- Store the bottle of TAFINLAR tablets for oral suspension at room temperature, between 68 °F to 77 °F
- Store the bottle of TAFINLAR tablets for oral suspension, along with the 2 plastic cannisters inside the original packaging, with the cap tightly closed. The cannisters contain a drying agent (desiccant) to help keep your medicine dry
- TAFINLAR tablets for oral suspension come in a bottle with a child-resistant cap
- Throw away any mixed oral suspension if it is not given within 30 minutes after it is prepared



Keep this medicine out of the reach of children

Storing MEKINIST oral solution

- Store MEKINIST oral solution in the original bottle at room temperature, below 77 °F. **Do not freeze the oral solution**
- Throw away unused MEKINIST oral solution after the “discard after” date written on the bottle label

IMPORTANT SAFETY INFORMATION (continued)

This may lead to a type of anemia called hemolytic anemia, where the body does not have enough healthy red blood cells. Tell your health care provider if you have any of the following signs or symptoms:

- yellow skin (jaundice)
- weakness or dizziness
- shortness of breath

Hemophagocytic Lymphohistiocytosis (HLH). TAFINLAR when taken with MEKINIST may increase the risk of a type of overactivity of the immune system (hemophagocytic lymphohistiocytosis) that can cause fever, swollen glands, bruising, or skin rash. If you experience a combination of these symptoms, call your health care provider right away.

Please see additional Important Safety Information throughout this brochure and on [pages 17 to 19](#).

Please [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.



SUPPORT DESIGNED FOR PATIENTS AND CAREGIVERS

We're here to help you and your child throughout your treatment journey with TAFINLAR + MEKINIST. Educational resources are available online, and below you'll find some information about our financial aid and access programs.

Novartis Oncology Universal Co-pay Program

You may be eligible for immediate co-pay savings on your next prescription.

- Eligible patients with private insurance may pay \$25 per month
- Novartis will pay the remaining co-pay, up to \$15,000 per calendar year, per product*

*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit [Copay.NovartisOncology.com](https://www.copay.novartis.com) or call 1-877-577-7756.



To find out if you are eligible for the Universal Co-pay Program, call 1-877-577-7756 or visit [Copay.NovartisOncology.com](https://www.copay.novartis.com)

Patient Assistance Now Oncology

Our Patient Assistance Now Oncology (PANO) program was created to assist you with accessing your child's Novartis medicine(s)—from insurance verification to financial assistance—all through a knowledgeable and supportive call center.

With the Free Trial and Access Program, you can receive a free supply of TAFINLAR + MEKINIST for a US Food and Drug Administration–approved indication. The supply can be shipped directly to your home or another convenient location so your child can start treatment immediately. Program rules may vary by product.



To learn more, call 1-800-282-7630 or visit [Patient.NovartisOncology.com](https://www.patient.novartis.com)



Ask your child's health care provider to help you apply for the PANO Free Trial and Access Program

IMPORTANT SAFETY INFORMATION (continued)

TAFINLAR and MEKINIST, in combination, can harm your unborn baby.

Your health care provider will do a test to see if you are pregnant before starting treatment with TAFINLAR and MEKINIST in combination.

Women who are able to become pregnant should use effective birth control (contraception) during treatment with TAFINLAR and MEKINIST in combination, and for 4 months after stopping treatment with TAFINLAR and MEKINIST.

Please see additional Important Safety Information throughout this brochure and on [pages 17 to 19](#).

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IMPORTANT SAFETY INFORMATION

APPROVED USE

TAFINLAR and MEKINIST are prescription medicines that can be used in combination to treat a type of brain tumor called glioma in children 1 year of age and older

- that is low-grade glioma (LGG), **and**
- that have a certain type of abnormal “*BRAF*” gene, **and**
- who require a medicine by mouth or injection (systemic therapy)

TAFINLAR, in combination with MEKINIST, is not for use in treating people with wild-type *BRAF* solid tumors.

Your health care provider will perform a test to make sure that TAFINLAR and MEKINIST in combination is right for you.

It is not known if TAFINLAR, in combination with MEKINIST, is safe and effective in children younger than 1 years of age. It is not known if TAFINLAR used alone is safe and effective in children.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TAFINLAR in combination with MEKINIST? TAFINLAR and MEKINIST may cause serious side effects, including:

Risk of new skin cancers. TAFINLAR, when used in combination with MEKINIST, may cause a type of skin cancer called cutaneous squamous cell carcinoma, keratoacanthoma, basal cell carcinoma, or melanoma. Talk with your health care provider about your risk for these cancers.

Check your skin and tell your health care provider right away about any skin changes, including a new wart, skin sore, or reddish bump that bleeds or does not heal, or a change in size or color of a mole.

Your health care provider should check your skin before you start treatment, and every 2 months while on treatment, to look for any new skin cancers. Your health care provider should continue to check your skin for 6 months after you stop taking TAFINLAR and MEKINIST.

Your health care provider should also check for cancers that may not occur on the skin. Tell your health care provider about any new symptoms that have developed while taking TAFINLAR and MEKINIST in combination.

Bleeding problems. TAFINLAR and MEKINIST in combination can cause serious bleeding problems, especially in your brain or stomach, that can lead to death. Call your health care provider and get medical help right away if you

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have any signs of bleeding, including:

- headaches, dizziness, or feeling weak
- coughing up blood or blood clots
- vomiting blood or your vomit looks like “coffee grounds”
- red or black stools that look like tar

Inflammation of the intestines or tears (perforation) of the stomach or intestines. MEKINIST, alone or in combination with TAFINLAR, can cause inflammation of your intestines, or tears in the stomach or intestines that can lead to death. Tell your health care provider right away if you have any of the following symptoms:

- bleeding (see “Bleeding problems”)
- diarrhea (loose stools) or more bowel movements than usual
- stomach-area (abdomen) pain or tenderness
- fever
- nausea

Blood clots. TAFINLAR and MEKINIST in combination can cause blood clots in your arms or legs, which can travel to your lungs and lead to death. Get medical help right away if you have the following symptoms:

- chest pain
- sudden shortness of breath or trouble breathing
- pain in your legs with or without swelling
- swelling in your arms or legs
- a cool, pale arm or leg

Heart problems, including heart failure. Your health care provider should check your heart function before you start taking TAFINLAR and MEKINIST in combination, and during treatment. Call your health care provider right away if you have any of the following signs and symptoms of a heart problem:

- feeling like your heart is pounding or racing
- shortness of breath
- swelling of your ankles and feet
- feeling lightheaded



IMPORTANT SAFETY INFORMATION (CONTINUED)

Eye problems. TAFINLAR and MEKINIST, in combination, can cause severe eye problems that can lead to blindness. Call your health care provider right away if you get these symptoms of eye problems:

- blurred vision, loss of vision, or other vision changes
- seeing color dots
- halo (seeing blurred outline around objects)
- eye pain, swelling, or redness

Lung or breathing problems. TAFINLAR and MEKINIST, in combination, can cause lung or breathing problems. Tell your health care provider if you have any new or worsening symptoms of lung or breathing problems, including:

- shortness of breath
- cough

Fever. Fever is common during treatment with TAFINLAR and MEKINIST, but it may also be serious. When taking TAFINLAR and MEKINIST, in combination, fever may happen often or may be severe. In some cases, chills or shaking chills, too much fluid loss (dehydration), low blood pressure, dizziness, or kidney problems may happen with the fever. Call your health care provider right away if you get a fever while taking TAFINLAR or MEKINIST.

Your health care provider may temporarily or permanently stop your treatment or change your dose of MEKINIST with TAFINLAR if you have fevers. Your health care provider will treat you as needed for your fever and any signs and symptoms of infection and should check your kidney function during and after you have had severe fever.

Serious skin reactions. Skin rash is a common side effect of TAFINLAR and MEKINIST. In some cases, these rashes and other skin reactions can be severe or serious, may need to be treated in a hospital, or lead to death.

- tell your health care provider if you get a skin rash or acne that bothers you or worsens
- **tell your health care provider right away if you develop any of the following signs or symptoms of a severe skin reaction, including:**
 - blisters or peeling of your skin
 - mouth sores
 - high fever or flu-like symptoms
 - blisters on your lips, or around your mouth or eyes
 - enlarged lymph nodes

Please see additional Important Safety Information throughout this brochure. Please [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.

Increased blood sugar (hyperglycemia). Some people may develop high blood sugar or worsening diabetes during treatment with TAFINLAR and MEKINIST in combination. If you are diabetic, your health care provider should check your blood sugar levels closely during treatment with TAFINLAR and MEKINIST. Your diabetes medicine may need to be changed. Tell your health care provider if you have any of the following symptoms of severe high blood sugar:

- increased thirst
- urinating more often than normal, or urinating an increased amount of urine

TAFINLAR may cause healthy red blood cells to break down too early in people with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

This may lead to a type of anemia called hemolytic anemia, where the body does not have enough healthy red blood cells. Tell your health care provider if you have any of the following signs or symptoms:

- yellow skin (jaundice)
- weakness or dizziness
- shortness of breath

Hemophagocytic Lymphohistiocytosis (HLH). TAFINLAR when taken with MEKINIST may increase the risk of a type of overactivity of the immune system (hemophagocytic lymphohistiocytosis) that can cause fever, swollen glands, bruising, or skin rash. If you experience a combination of these symptoms, call your health care provider right away.

TAFINLAR and MEKINIST, in combination, can harm your unborn baby.

Your health care provider will do a test to see if you are pregnant before starting treatment with TAFINLAR and MEKINIST in combination.

Women who are able to become pregnant should use effective birth control (contraception) during treatment with TAFINLAR and MEKINIST in combination, and for 4 months after stopping treatment with TAFINLAR and MEKINIST.

Birth control using hormones (such as birth control pills, injections, or transdermal systems) may not work as well while you are taking TAFINLAR and MEKINIST in combination. You should use another effective method of birth control while taking TAFINLAR and MEKINIST in combination.



IMPORTANT SAFETY INFORMATION (CONTINUED)

Talk to your health care provider about birth control methods that may be right for you during this time.

Tell your health care provider right away if you become pregnant, or think you might be pregnant, during treatment with TAFINLAR and MEKINIST in combination.

Men (including those who have had a vasectomy) with a female partner who is able to become pregnant should use condoms during sexual intercourse during treatment with TAFINLAR and MEKINIST for at least 4 months after your last dose of TAFINLAR and MEKINIST in combination.

The most common side effects of TAFINLAR when taken with MEKINIST in children 1 year of age and older with low-grade glioma include:

- fever
- rash
- headache
- vomiting
- muscle and bone pain
- tiredness
- dry skin
- diarrhea
- nausea
- bleeding
- stomach-area (abdomen) pain
- acne

New or worsening high blood pressure (hypertension). Your health care provider should check your blood pressure during treatment with MEKINIST. Call your health care provider right away if you develop high blood pressure, your blood pressure worsens, or you have severe headache, lightheadedness, blurry vision, or dizziness.

Fertility problems. TAFINLAR and MEKINIST, in combination, may cause fertility problems in women. This could affect the ability to become pregnant. Talk to your health care provider if this is a concern for you.

Low sperm counts. TAFINLAR may cause lower sperm counts in men. This could affect the ability to father a child. Talk to your health care provider if this is a concern for you.

Please see additional Important Safety Information throughout this brochure. Please [click here](#) for full Prescribing Information for TAFINLAR, including Medication Guide, and [click here](#) for full Prescribing Information for MEKINIST, including Patient Information.

Nursing mothers. It is not known if TAFINLAR and/or MEKINIST pass into breast milk. Do not breastfeed during treatment, and for 4 months after your last dose of TAFINLAR and MEKINIST. Talk to your health care provider about the best way to feed your baby during this time.

These are not all the possible side effects of TAFINLAR and MEKINIST. For more information about side effects, ask your health care provider or pharmacist.

Before you take TAFINLAR and MEKINIST in combination, tell your health care provider about all your medical conditions, including if you:

- have had bleeding problems or blood clots
- have stomach problems
- have inflammation of the colon
- have heart problems
- have eye problems
- have lung or breathing problems
- have high blood pressure (hypertension)
- have liver or kidney problems
- have diabetes
- plan to have surgery, dental, or other medical procedures
- have a deficiency of the G6PD enzyme
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your health care provider and pharmacist when you get a new medicine.

Please read the Medication Guide for TAFINLAR and the Patient Information for MEKINIST and discuss any questions you have with your health care provider.

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.



WE'RE HERE FOR YOU



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Not an actual patient.



IMPORTANT SAFETY INFORMATION (continued)

Birth control using hormones (such as birth control pills, injections, or transdermal systems) may not work as well while you are taking TAFINLAR and MEKINIST in combination. You should use another effective method of birth control while taking TAFINLAR and MEKINIST in combination.

Talk to your health care provider about birth control methods that may be right for you during this time.

Tell your health care provider right away if you become pregnant, or think you might be pregnant, during treatment with TAFINLAR and MEKINIST in combination.

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