



Not actual patient. BRAFTOVI is approved for the treatment of adult patients only.

Discover BRAFTOVI + cetuximab + a specific type of chemotherapy (mFOLFOX6)

BRAFTOVI (encorafenib) is a prescription medicine used in combination with medicines called cetuximab and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin) to treat people with cancer of the colon or rectum (colorectal cancer) that has spread to other parts of the body and that has a certain type of abnormal "BRAF" gene.

BRAFTOVI in combination with cetuximab and mFOLFOX6 was approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of BRAFTOVI in combination with cetuximab and mFOLFOX6.

BRAFTOVI should not be used to treat people with wild-type BRAF colorectal cancer. Your healthcare provider will perform a test to make sure that BRAFTOVI is right for you.

It is not known if BRAFTOVI is safe and effective in children.

SELECTED IMPORTANT SAFETY INFORMATION

BRAFTOVI (encorafenib) may cause serious side effects, including:

• **Risk of new skin cancers.** BRAFTOVI combination therapy may cause skin cancers called cutaneous squamous cell carcinoma or basal cell carcinoma. Talk to your healthcare provider about your risk for these cancers.

Check your skin and tell your healthcare provider right away about any skin changes, including a:

o new o skin sore or reddish bump o change in size or wart that bleeds or does not heal color of a mole

Your healthcare provider should check your skin before treatment, every 2 months during treatment, and for up to 6 months after you stop treatment to look for any new skin cancers.

Your healthcare provider should also check for cancers that may not occur on the skin. Tell your healthcare provider about any new symptoms that develop during treatment.



The BRAFTOVI combination therapy is FDA approved

BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6) is a combination therapy that can be taken when first diagnosed with BRAF+ (V600E) metastatic colorectal cancer (mCRC).

Remember, this brochure is being provided for your information only and does not replace the medical advice of your doctor.

Be sure to consult your doctor regarding any questions or concerns you may have about your specific medical condition or treatment plan.

What is **BRAFTOVI**?

BRAFTOVI is a prescription medicine used in combination with medicines called cetuximab and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin) to treat people with cancer of the colon or rectum (colorectal cancer):

- that has spread to other parts of the body, and
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BRAFTOVI is a prescription medicine used in combination with a medicine called cetuximab to treat adults with cancer of the colon or rectum (colorectal cancer) after past treatment:

- that has spread to other parts of the body, and
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Selected Important Safety Information

- Heart problems, including heart failure. Your healthcare provider will check your heart function before and during treatment. Tell your healthcare provider right away if you have any of the following signs and symptoms of a heart problem:
- o feeling like your heart is pounding or racing o shortness of breath
- o swelling in your hands, ankles, legs, or feet o feeling faint or light-headed



Learn about the BRAFTOVI combination therapy

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- Liver problems. Your healthcare provider will perform blood tests to check your liver function before and during treatment. Tell your healthcare provider if you have any of the following signs and symptoms of a liver problem:
 - o yellowing of your skin or your eyes o dark or brown (tea-colored) urine
- o loss of appetite o tiredness
- o bruising o bleeding

o nausea or vomiting

About metastatic colorectal cancer

Colorectal cancer (CRC) is a type of cancer that starts in the colon or rectum. When you were diagnosed, your doctor may have referred to your type of cancer as either colon or rectal cancer—that's because these cancers, which start in the large intestine, share similar features.

When the cancer has spread outside the colon or rectum to other distant parts of the body, it is called metastatic colorectal cancer (mCRC).

Did you know? About 70% of colorectal cancers will eventually become metastatic.

What are biomarkers?

There are **certain characteristics that may be specific to someone's diagnosis**. One of these specific characteristics can be identified by something called a "biomarker," which can be found by testing tissue from the tumor or a sample of blood.

Biomarker testing may be used to help doctors know if the cancer has an abnormal gene that can cause cancer to grow and spread faster. Knowing if your cancer has abnormal genes from biomarker testing can help your doctor recommend treatment options.

What is BRAF?

BRAF+

One type of biomarker is called "BRAF." If your metastatic CRC tested BRAF positive (BRAF+), that means it may have a certain type of abnormal BRAF (V600E) gene. Your doctor may recommend a treatment combination based on your test results and diagnosis.

Know your biomarker status

Knowing what biomarkers your metastatic CRC has can help your doctor recommend treatment options. Ask your doctor about the results of your biomarker test.

The BRAFTOVI combination therapy





BRAFTOVI is a targeted treatment, which works to target cancer cells with the BRAF+ (V600E) mutation. However, it may also affect healthy cells.

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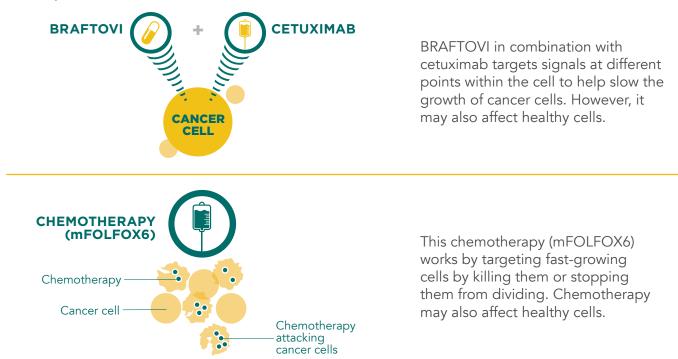
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How the different treatments are thought to work

In BRAF+ (V600E) metastatic CRC, signals are sent within the cancer cells, telling the cancer to grow and spread. How BRAFTOVI and cetuximab work in combination with chemotherapy (mFOLFOX6) is not currently known.



Selected Important Safety Information

- Bleeding problems. BRAFTOVI combination therapy can cause serious bleeding problems, including in your stomach or brain, that can lead to death. Tell your healthcare provider and get medical help right away if you develop any signs of bleeding, including:
 - o headaches, dizziness, or feeling weak
 - o cough up blood or blood clots
 - o vomit blood or your vomit looks like "coffee grounds"
- o red or black stools that look like tar o nose bleeds

BRAFTOVI (encorafenib) 75 mg capsules

How the BRAFTOVI combination therapy may help

BRAFTOVI in combination with cetuximab and a specific type of chemotherapy called mFOLFOX6 was studied in adults with BRAF+ (V600E) metastatic colorectal cancer (mCRC) that had never been treated for mCRC.

Of those people who took part in the trial:

236

were given BRAFTOVI in combination with cetuximab and a specific type of chemotherapy called mFOLFOX6.



were given a specific type of chemotherapy with or without a medicine called bevacizumab. Doctors chose one of the following types of chemotherapy: mFOLFOX6, FOLFOXIRI, or CAPOX. This was the control group of the trial.

Selected Important Safety Information

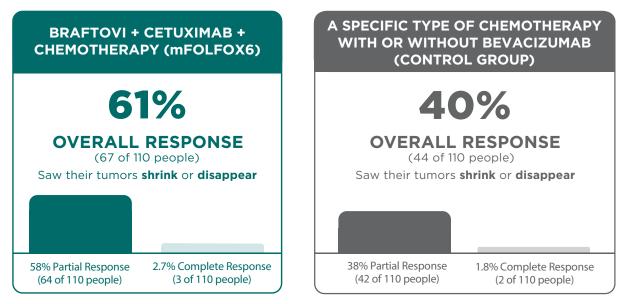
- **Eye problems.** Your healthcare provider should perform an eye exam regularly during treatment. Tell your healthcare provider right away if you develop any new or worsening symptoms of eye problems, including:
 - o blurred vision, loss of vision, or other vision changes
 - o see colored dots
 - o see halos (blurred outline around objects)
 - o eye pain, swelling, or redness

How the BRAFTOVI combination therapy may help (continued)



People saw their tumors shrink

The primary measure in the trial looked at how many people with BRAF+ (V600E) mCRC saw their tumors shrink or disappear. This measure is based on the first 110 of the 236 people who were treated with BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6) and the first 110 of 243 people who were treated with the control group (a specific type of chemotherapy called mFOLFOX6, FOLFOXIRI, or CAPOX with or without bevacizumab).



- **Overall response** rate is the percentage of people whose cancer shrinks or disappears after treatment
- **Tumors shrink**, or "partial response," means that the amount of cancer in the body, or the size of the tumor, decreased after treatment
- **Tumors disappear**, or "complete response," means that all signs of cancer were gone after treatment. This doesn't mean that the cancer was cured

BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6) will not work for everyone. Individual results may vary.

Selected Important Safety Information

• Changes in the electrical activity of your heart called QT prolongation. QT prolongation can cause irregular heartbeats that can be life-threatening. Your healthcare provider should do tests before you start taking BRAFTOVI combination therapy and during your treatment to check your body salts (electrolytes). Tell your healthcare provider right away if you feel faint, light-headed, dizzy, or if you feel your heart beating irregularly or fast during treatment with BRAFTOVI combination therapy. These symptoms may be related to QT prolongation

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with BRAFTOVI if you have certain side effects.

How the BRAFTOVI combination therapy may help (continued)



How long were people responding to treatment?

Another outcome that was measured in the clinical trial in people who responded to treatment was the **duration of response (DOR)**. This is the length of time that tumors continued to respond to treatment. The clinical trial also measured the median DOR. **Median** is defined as the middle number in a group of numbers arranged from lowest to highest.

For the 67 of 110 people who responded to **BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6)** in the clinical trial:



For the 44 of 110 people in the control group who responded to **chemotherapy (doctors chose either mFOLFOX6, FOLFOXIRI, or CAPOX)** with or without bevacizumab in the clinical trial:

The median DOR was 11.1 months



34% of people were still responding at 6 months (15 of 44 people)



11% of people were still responding at 12 months (5 of 44 people)

BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6) will not work for everyone. Individual results may vary.

Selected Important Safety Information

Tell your healthcare team if you are pregnant or plan to become pregnant. BRAFTOVI can harm your unborn baby.

- Females who are able to become pregnant should use effective non-hormonal birth control (contraception) during treatment with BRAFTOVI and for 2 weeks after the last dose of BRAFTOVI
- Birth control methods that contain hormones (such as birth control pills, injections, or transdermal systems) may not work as well during treatment with BRAFTOVI
- Your healthcare provider will do a pregnancy test before you start taking BRAFTOVI. Tell your healthcare provider right away if you become pregnant or think you might become pregnant during treatment



Learn about possible serious side effects

Each person responds differently to treatment, so make sure to talk to your doctor about how you're feeling. This is a summary of important risk information about BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6). If you have any of these symptoms while taking BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6), call your doctor immediately. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with BRAFTOVI if you have certain side effects.

Risk of new skin cancers	Symptoms included new warts; skin sores or reddish bumps that bleed or do not heal; change in size or color of a mole.		
Heart problems, including heart failure	Symptoms included feeling like your heart is pounding or racing; shortness of breath; swelling in your hands, ankles, legs, or feet; feeling faint or light-headed.		
Liver problems	Symptoms included yellowing of your skin or your eyes; dark or brown (tea-colored) urine; nausea or vomiting; loss of appetite; tiredness; bruising; bleeding.		
Bleeding problems	Can lead to death. Symptoms included 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; nose bleeds.		
Eye problems	Symptoms included blurred vision, loss of vision, or other vision changes; seeing colored dots; seeing halos (blurred outline around objects); eye pain, swelling, or redness.		
Changes in the electrical activity of your heart (QT prolongation)	Can be life-threatening. Symptoms included feeling faint, light-headed, dizzy, or if you feel your heart beating irregularly or fast.		
Risk of harm to unborn babies	Tell your doctor if you are pregnant or plan to become pregnant. BRAFTOVI can harm your unborn baby.		



These are not all of the possible side effects of BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6). Call your doctor for medical advice about side effects. You may report side effects to the FDA at <u>1-800-FDA-1088</u> or visit <u>www.fda.gov/medwatch</u>. You may also report side effects to Pfizer Inc. at <u>1-800-438-1985</u>.

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The most common side effects



In this section, you will find the most common side effects that people experienced in the clinical trial when taking BRAFTOVI in combination with cetuximab and chemotherapy (mFOLFOX6). **Remember, the information below does not replace directions from your doctor. Always talk to your doctor about side effects and ways you may be able to manage them.** Your doctor may change your dose or stop treatment temporarily or completely. Before taking any medicines, speak with your doctor.

Numbness, tingling, or burning in your hands or feet (peripheral neuropathy)	Talk to your doctor if you experience any symptoms related to peripheral neuropathy (nerve pain). Your doctor may suggest pain medicine or recommend some practices, such as acupuncture, massage, physical therapy, or yoga.
Nausea	Nausea may be worse if your stomach is empty, so discuss your eating habits with your doctor. They may also suggest an anti-nausea medicine.
Fatigue	Talk to your doctor if you experience fatigue (tiredness or lack of energy). They may recommend daily exercise or other activities that may help reduce fatigue.
Rash	Tell your doctor about any rashes right away. They may recommend soaps, creams, or lotions to soothe it.
Diarrhea	Your doctor may suggest you take over-the-counter anti-diarrheal medicine to help, but it's also always important to stay hydrated. Sports drinks are often recommended, as they can help replace electrolytes and salts. Report diarrhea to your doctor right away.
Decreased appetite	Discuss with your doctor different ways you could increase your appetite. These may include eating balanced, nutritious meals and eating small, frequent meals or snacks 6 to 8 times daily.
Vomiting	It's important to stay hydrated throughout treatment. Talk to your doctor about liquids and over-the-counter medicines that may help. Fruit juices, ginger ale, water, and sports drinks are often recommended, as they can help prevent dehydration.



The most common side effects (continued)

Bleeding (hemorrhage)	Talk with your doctor about different ways to manage bleeding and possibly prevent it. They may recommend not taking certain over-the- counter medicines that can increase your risk of bleeding. They may also suggest using a very soft toothbrush and wearing shoes, even when you're indoors.
Stomach-area (abdominal) pain	Talk to your doctor about your eating habits and how you can make adjustments. They may suggest avoiding foods that commonly cause abdominal pain and eating smaller meals throughout the day.
Fever	Usually, a temperature at or above 100.4°F for at least 1 hour is considered a fever. Talk to your doctor about what temperature they consider a fever and how to manage it. If you have a fever, your doctor may recommend certain over-the-counter medicines to treat it.

BRAFTOVI may cause fertility problems in males. This may affect your ability to father a child. Talk to your doctor if this is a concern for you.

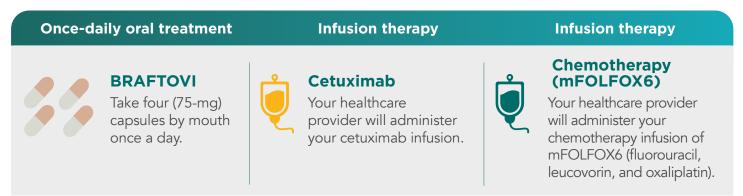


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Taking the BRAFTOVI combination therapy

BRAFTOVI® (encorafenib) 75 mg capsules

BRAFTOVI is a medicine you take by mouth one time per day. Cetuximab and chemotherapy (mFOLFOX6) are infusions administered by a healthcare provider. Take BRAFTOVI exactly as your healthcare provider tells you. Do not change your dose or stop taking it unless your healthcare provider tells you to.



If you stop treatment with cetuximab or chemotherapy (mFOLFOX6), talk to your healthcare provider about your BRAFTOVI treatment. Your BRAFTOVI dose may need to be changed or stopped.

What to do if you miss a dose

If you miss a dose of BRAFTOVI, take your dose as soon as you remember. If it is within 12 hours of your next scheduled dose, take your next dose at your regular time. Do not make up for the missed dose.



Do not take an extra dose if you vomit after taking your scheduled dose. Take your next dose at the regular time.

Before taking BRAFTOVI

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

- Have had bleeding problems
- Have eye problems
- Have heart problems, including a condition called long QT syndrome
- Have been told that you have low blood levels of potassium, calcium, or magnesium
- Have liver or kidney problems
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed

Selected Important Safety Information

Talk to your healthcare team if you are breastfeeding or plan to breastfeed. It is not known if BRAFTOVI passes into your breast milk. Do not breastfeed during treatment with BRAFTOVI and for 2 weeks after the last dose of BRAFTOVI.

BRAFTOVI may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if this is a concern for you.



Not actual patients.

If you develop side effects

Your doctor may change your dose or stop treatment temporarily or completely. Talk to your doctor if you experience side effects to help determine what your next steps may be.

Selected Important Safety Information

The most common side effects of BRAFTOVI when taken in combination with cetuximab and mFOLFOX6 include: numbness, tingling, or burning in your hands or feet (peripheral neuropathy), nausea, fatigue, rash, diarrhea, decreased appetite, vomiting, bleeding (hemorrhage), stomach-area (abdominal) pain, and fever.

Taking the BRAFTOVI combination therapy (continued)



Important things to remember when taking BRAFTOVI + cetuximab + chemotherapy (mFOLFOX6)

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BRAFTOVI and certain other medicines can affect each other, causing side effects or affecting how BRAFTOVI or other medicines work. When starting a new treatment, it can be helpful to make it part of your daily routine.



Set treatment reminders

Make it a habit by setting an alarm on your phone or watch to remind you to take your BRAFTOVI at the same time every day.



Take with or without food

Take BRAFTOVI with or without a meal or snack. **There is no need to fast.**

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Avoid grapefruit

Avoid consuming grapefruit when taking BRAFTOVI. Grapefruit products may increase the amount of BRAFTOVI in your body.

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Store in a dry place

Store BRAFTOVI in its original bottle and in a dry place at a room temperature. Keep the bottle closed tightly to protect it from moisture. It does not need to be refrigerated. That means you can take it at home or on the go.

Staying hydrated is important, especially for people living with cancer. Talk with your doctor about how much water you should drink daily.

Drink enough water

Selected Important Safety Information

The most common side effects of BRAFTOVI when taken in combination with cetuximab include: fatigue, nausea, diarrhea, acne-like rash (dermatitis acneiform), stomach-area (abdominal) pain, decreased appetite, pain or swelling of your joints (arthralgia), and rash.



Important Safety Information and Indications

What is the most important information I should know about BRAFTOVI?

BRAFTOVI (encorafenib) may cause serious side effects, including:

• **Risk of new skin cancers.** BRAFTOVI combination therapy may cause skin cancers called cutaneous squamous cell carcinoma or basal cell carcinoma. Talk to your healthcare provider about your risk for these cancers.

Check your skin and tell your healthcare provider right away about any skin changes, including a:

- o new wart
- o skin sore or reddish bump that bleeds or does not heal o change in size or color of a mole

Your healthcare provider should check your skin before treatment, every 2 months during treatment, and for up to 6 months after you stop treatment to look for any new skin cancers.

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 - o feeling like your heart is pounding or racing
 - o shortness of breath
 - o swelling in your hands, ankles, legs, or feet
 - o feeling faint or light-headed
- Liver problems. Your healthcare provider will perform blood tests to check your liver function before and during treatment. Tell your healthcare provider if you have any of the following signs and symptoms of a liver problem:
 - o yellowing of your skin or your eyes
 - o dark or brown (tea-colored) urine
 - o nausea or vomiting
 - o loss of appetite
 - o tiredness
 - o bruising
 - o bleeding

- **Bleeding problems.** BRAFTOVI combination therapy can cause serious bleeding problems, including in your stomach or brain, that can lead to death. Tell your healthcare provider and get medical help right away if you develop any signs of bleeding, including:
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Important Safety Information and Indications (continued)



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It is not known if BRAFTOVI is safe and effective in children.

Financial assistance



Pfizer Oncology together™

If needed, we'll help you find financial assistance options for your prescribed BRAFTOVI (encorafenib), regardless of your insurance coverage.

Commercially insured

Resources for eligible patients with commercial, private, employer, or state health insurance marketplace coverage:

• **Co-pay assistance:** Eligible, commercially insured patients may pay as little as \$0 per month for their Pfizer Oncology treatment. Limits, terms, and conditions apply.* Patients may receive up to \$10,000 per product in savings annually

*Patients are not eligible to use this card if they are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico.



Medicare/government insured

Help identifying resources for eligible patients with Medicare/Medicare Part D, Medicaid, or other government insurance plans who express a financial need:

- We can assist patients with searching for financial support from alternate funding resources, which may include financial assistance through Extra Help, a Medicare Part D Low-Income Subsidy (LIS) program
- If support from alternate funding resources or Medicare Extra Help is not available, Pfizer Oncology Together will see if patients are eligible for the Pfizer Patient Assistance Program,[†] which can provide prescribed Pfizer Oncology medicines for free

Uninsured

Help identifying resources for eligible patients without any form of healthcare coverage:

- We can check patient eligibility for Medicaid and help them understand how to apply
- Patients who do not qualify for Medicaid may receive free medicine through the Pfizer Patient Assistance Program. Patients must be eligible and reapply as needed

[†]The Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation[™]. Free medicines from Pfizer are provided through the Pfizer Patient Assistance Foundation[™]. The Pfizer Patient Assistance Foundation[™] is a separate legal entity from Pfizer Inc. with distinct legal restrictions.

Not actual patients.

Call 1-877-744-5675 (Monday-Friday 8 AM-8 PM ET)

VISIT PfizerOncologyTogether.com

Personalized assistance



THIS IS **LIVING WITH** CANCER[™]



This Is Living With Cancer[™] is a free online resource developed by Pfizer Oncology for all people living with cancer, regardless of age, income, race, location, cancer type, or stage of disease. This comprehensive program is available to anyone in the United States, whether they're on a Pfizer treatment or not, with a growing focus on those facing challenges accessing care.

Visit <u>ThisIsLivingWithCancer.com</u> to learn more

The free resources offered through **This Is Living With Cancer™** and **LivingWith®** are available to anyone living with cancer and their loved ones, and are not specific to BRAFTOVI (encorafenib).

Support for caregivers



Taking good care means caring for yourself, too

There are many ways to show care for your loved one, like providing emotional care and practical help in their time of need. But try to remember that doing your best means caring for yourself, too. Below are 4 ways to help you find a better balance.



Every day, set aside some time for yourself

Maybe it's the peace and quiet of reading a book, the fresh air you breathe while taking a walk, or the enjoyment you get from seeing a movie. Whatever it is, take time to recharge so you have the energy to take better care of your loved one.



Ask to adjust your work schedule

If you need to dedicate more time to your caregiving responsibilities, your employer may be able to adjust your work schedule or workload. Ask if your company has a family leave, elder care, or other employee benefit policy that can help.



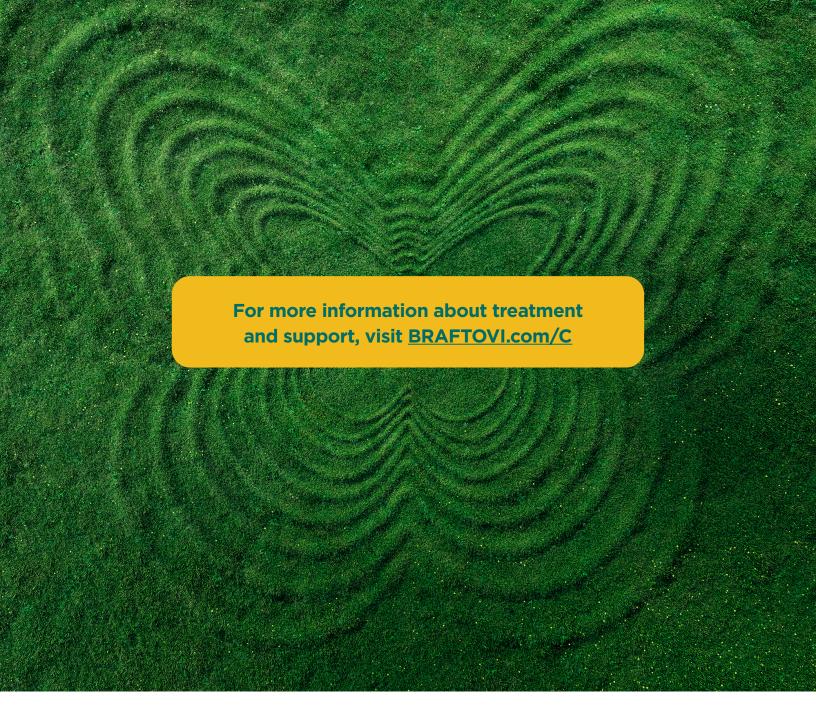
Don't be afraid to delegate

When you feel overwhelmed, ask family, friends, neighbors, and even coworkers for help. Some people will say no, and that's okay. But many will say yes again and again. Think of tasks that may take time but don't require a lot of skill, such as laundry or grocery shopping.



Talk to other caregivers

It may feel like you're the only one in the world facing these challenges. But you're not alone. Through local support groups, you can connect with other people who share the same feelings and are experiencing similar struggles.





Please see Important Safety Information and Indications on pages 15-16 and BRAFTOVI full Prescribing Information, including Medication Guide, for additional information.



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