



AIM FOR A DAY OF POSSIBILITIES

Understanding treatment with TIBSOVO®

Please see Important Safety Information on pages 20 to 22 and [Full Prescribing Information](#), including BOXED WARNING and Medication Guide.

 **TIBSOVO®**  
ivosidenib tablets 250mg



About this brochure

TIBSOVO®: A TARGETED TREATMENT OPTION

When the diagnosis of acute myeloid leukemia (AML) came, you rose to meet the challenge. Now, you and your healthcare provider have decided on TIBSOVO, **which is a personalized treatment option because it works to target a specific type of genetic mutation known as IDH1**. TIBSOVO is an oral medication you can take at home.

This brochure explains how TIBSOVO works, what can be expected during treatment, and how to find support. **Together, we can aim for a day of possibilities.**

TIBSOVO is the **first-in-class targeted therapy** that inhibits mutated IDH1.

TIBSOVO is a prescription medicine used to treat acute myeloid leukemia (AML) with an isocitrate dehydrogenase-1 (IDH1) mutation in:

- adults with newly diagnosed AML who are 75 years or older or who have health problems that prevent the use of certain chemotherapy treatments.
- adults with AML when the disease has come back or has not improved after previous treatment(s).

Your healthcare provider will perform a test to make sure that TIBSOVO is right for you. It is not known if TIBSOVO is safe and effective in children.

**TIBSOVO may cause serious side effects, including differentiation syndrome.** Differentiation syndrome is a condition that affects your blood cells and may be life-threatening or lead to death if not treated. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the symptoms of differentiation syndrome while taking TIBSOVO. For a list of these symptoms, see page 13 in this booklet.

WHAT YOU CAN FIND IN THIS BROCHURE

ABOUT AML

What is AML? .....	4	Types of remission.....	5
Types of AML .....	4		

HOW TREATMENT WITH TIBSOVO WORKS

Genetic mutations and targeted treatments .....	6	The TIBSOVO clinical study.....	7
How TIBSOVO works against your AML.....	7	Benefits of TIBSOVO .....	8

TAKING AND STORING TIBSOVO

How to take TIBSOVO .....	10	Differentiation syndrome .....	12
How to store TIBSOVO .....	11	Possible side effects of TIBSOVO .....	14
What to expect with TIBSOVO .....	12	What to do if you experience side effects .....	15

ADDITIONAL RESOURCES

Important questions to ask your healthcare provider .....	16	Additional support resources for you.....	18
myAgios™ Patient Support Services .....	17	TIBSOVO dosing calendar.....	19

IMPORTANT SAFETY INFORMATION

Important Safety Information .....	20
Differentiation Syndrome Reference Card .....	23

To find more information about TIBSOVO and to uncover additional resources, visit [TIBSOVO.com](https://www.tibsovo.com)



# ABOUT AML

## What is AML?

In healthy bone marrow, essential cells such as red blood cells, white blood cells, and platelets are produced. These specialized cells transport oxygen, help fight infections, and assist in blood clotting.

AML is a cancer that disrupts this important process. AML affects a type of white blood cell in the bone marrow called a myeloblast. In people with AML, the myeloblasts are immature and abnormal. These cells do not mature or work like they should. As more and more myeloblasts are produced, they prevent healthy cells from forming and working. When there are too many myeloblasts and not enough healthy cells, the symptoms of AML begin to occur.

## Types of AML

**Newly diagnosed AML** means you've never had AML before and don't have a clinical history of myelodysplastic syndrome (MDS).

**Secondary AML (sAML)** may occur in individuals who have previously experienced a hematological disorder or developed AML as a result of certain cytotoxic treatments.

**Relapsed AML** means you have experienced remission of AML after initial treatment, but the signs and symptoms of the disease, including higher myeloblast counts and low blood counts, have returned.

**Refractory AML** means your AML has not responded to treatment.

**Monitor your health.** No matter what stage of treatment or remission you are in, it is important to have regular follow-up visits with your healthcare provider.

## Types of remission

The goal of all cancer treatments is to help get people with cancer into remission. With AML and other blood cancers, there are a few types of remission, including:

### Complete remission (CR)

No signs of cancer are seen, and bone marrow and blood counts have returned to normal.

### Complete remission with partial hematologic recovery (CRh)

No signs of cancer are seen, but certain blood counts have not completely returned to normal.



# HOW TREATMENT WITH TIBSOVO® WORKS

## Genetic mutations and targeted treatments

Genetic mutations are changes in the DNA (deoxyribonucleic acid) of a cell. Mutations can play a role in the development of AML. That is why it's important to get tested for genetic mutations to help your healthcare team understand which AML treatments may work best for you.

TIBSOVO is a targeted therapy that works against a mutation called the IDH1 mutation. The IDH1 mutation plays an important role in the development of AML because it prevents myeloblasts from becoming healthy white blood cells.



About 1 in 10 people with AML has an IDH1 mutation.

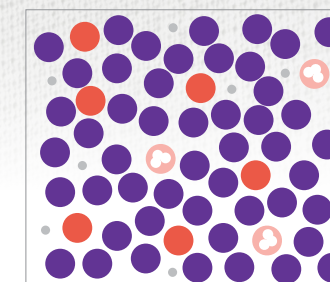
As a targeted therapy, TIBSOVO works differently from traditional chemotherapy. Chemotherapy kills cells that divide quickly, including cells in healthy tissues. It is typically given by infusion, usually in the hospital.

**TIBSOVO is an oral treatment** that can help myeloblasts grow into healthy blood cells by inhibiting IDH1.

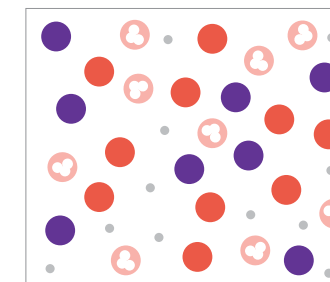
Because personalized, targeted therapies can only be used on specific mutations, not all targeted therapies can be used for every patient.

## How TIBSOVO works against your AML

**TIBSOVO is a targeted therapy.** TIBSOVO works on cells with a mutation called an IDH1 mutation. In IDH1-mutated AML, myeloblasts do not develop into fully formed, healthy white blood cells.



**Bone marrow after treatment with TIBSOVO.** TIBSOVO targets the mutation causing myeloblasts to remain immature. By targeting the IDH1 mutation, TIBSOVO helps the body return to normal blood cell counts.



- Young blood cell (myeloblast)
- White blood cell
- Red blood cell
- Platelet

**TIBSOVO is a nonmyelosuppressive therapy.** This means that TIBSOVO does not attack normal, healthy blood cells.

## The TIBSOVO clinical study

TIBSOVO was studied in the following patients:

- 28 adults with newly diagnosed AML who were 75 years or older or had health problems that prevented the use of certain chemotherapy treatments
- 179 adults with relapsed or refractory AML

All patients received TIBSOVO 500 mg orally to start. They were treated with TIBSOVO until:

- Their AML progressed or
- They had certain side effects so their healthcare provider decided to stop treatment or
- They received a stem cell transplant

## HOW TREATMENT WITH TIBSOVO® WORKS

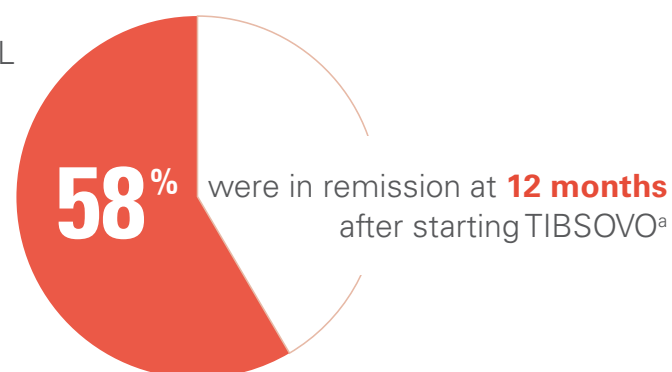
### Benefits seen with TIBSOVO in the clinical study: newly diagnosed AML

Some patients with newly diagnosed AML who received TIBSOVO were able to achieve remission.



In the TIBSOVO clinical study, **3 in 7 people** (12 out of 28) achieved complete remission (CR) or complete remission with partial hematologic recovery (CRh).

Of the 12 people with newly diagnosed AML who achieved CR or CRh:



### TIBSOVO also helped reduce the need for red blood cell or platelet transfusions.



**41%** of people (7 out of 17) became **transfusion free**. This means that people who needed transfusions when the study began were able to stop receiving transfusions for a period of at least 8 weeks.

**55%** of people (6 out of 11) who were **transfusion free** when they started TIBSOVO remained so for a period of at least 8 weeks.

<sup>a</sup>The median length of time that people stayed in remission could not be estimated in the study.

### SELECT IMPORTANT SAFETY INFORMATION

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

- **Changes in the electrical activity of your heart called QTc prolongation. QTc prolongation can cause irregular heartbeats that can be life-threatening.** Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) during treatment with TIBSOVO. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint.

### Benefits seen with TIBSOVO in the clinical study: relapsed or refractory AML

Some people with relapsed or refractory AML who received TIBSOVO were able to achieve remission.



In the clinical study, about **1 in 3 people** (57 out of 174) achieved CR or CRh with TIBSOVO.

Of the 57 people with relapsed or refractory AML who achieved CR or CRh:



Half did so within **2 months** of starting TIBSOVO (range 0.9–5.6 months)

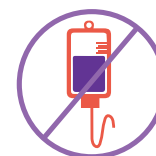


All did so within **6 months** of starting TIBSOVO



It is estimated that **1 in 3** were in remission for **1 year** after starting TIBSOVO

### TIBSOVO also helped reduce the need for red blood cell or platelet transfusions.



**37%** of people (41 out of 110) became **transfusion free**. This means that people who needed transfusions when the study began were able to stop receiving transfusions for a period of at least 8 weeks.

**59%** of people (38 out of 64) who were **transfusion free** when they started TIBSOVO remained so for a period of at least 8 weeks.



# TAKING AND STORING TIBSOVO®

## Before you take TIBSOVO

Tell your healthcare provider about all of your medical conditions, including if you have any heart problems, have problems with abnormal electrolytes, have nervous system problems, have problems with your kidneys or are on dialysis, or have any liver disorders including cirrhosis.

Tell your healthcare provider if you are pregnant or plan to become pregnant. TIBSOVO may cause harm to your unborn baby. You should avoid becoming pregnant during treatment with TIBSOVO. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with TIBSOVO. Tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if TIBSOVO passes into your breast milk. Do not breastfeed during your treatment with TIBSOVO and for at least 1 month after your last dose of TIBSOVO.

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

Especially tell your healthcare provider if you take hormonal contraceptives. TIBSOVO may affect how hormonal contraceptives work and may cause them to not work as well.

## How to take TIBSOVO

TIBSOVO is an oral medication you can take at home. Take TIBSOVO exactly as your healthcare provider tells you to.



Tablets not shown at actual size.



**Take 2 tablets orally, once a day.** Taking TIBSOVO at the same time as another daily activity, like when you brush your teeth, can help you remember.



**Take TIBSOVO with or without food.**  
**Do not** take TIBSOVO with a high-fat meal (about 1000 calories and 58 grams of fat).



**Swallow TIBSOVO tablets whole.**  
**Do not** split, crush, or chew the tablets.



**If you miss a dose of TIBSOVO** or did not take it at the usual time, take your dose as soon as possible and at least 12 hours before your next dose. Return to your normal schedule the following day. **Do not** take 2 doses of TIBSOVO within 12 hours.

**If you vomit after taking a dose of TIBSOVO, do not** take an additional dose. Take your next dose at your usual time.



## Information about the safe use of TIBSOVO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take TIBSOVO for conditions for which it was not prescribed. Do not give TIBSOVO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TIBSOVO that is written for healthcare professionals.

## How you should store TIBSOVO

- Store TIBSOVO at room temperature between 68 °F to 77 °F (20 °C to 25 °C)
- Keep TIBSOVO in the original container
- Keep the container tightly closed with the desiccant canister (drying agent) inside to protect the tablets from moisture
- Keep TIBSOVO and all medicines out of reach of children





## What to expect with TIBSOVO

Remember that TIBSOVO works differently than traditional chemotherapy. **Because of this, there are some important things to remember during treatment:**

- Take TIBSOVO exactly as your healthcare provider tells you to. TIBSOVO can take time to work. So if your AML does not progress and you do not have side effects you cannot tolerate, your healthcare provider may keep you on TIBSOVO for at least 6 months
- TIBSOVO may cause serious side effects, including differentiation syndrome.** Learn more below.

### How long will I stay on TIBSOVO?

Responses and relapses occur at different times for different people, so it's hard to say exactly how long you'll be on TIBSOVO. Your healthcare provider may **keep you on TIBSOVO for at least 6 months** if your AML doesn't progress or you don't have side effects you cannot tolerate. Wherever your treatment journey takes you, it's important to keep talking with your healthcare provider about your treatment plan.

## Differentiation syndrome

### Learn more about differentiation syndrome

Blood cells form through a process called differentiation. Some treatments for AML, including TIBSOVO, can cause cellular differentiation to happen too fast. This is called differentiation syndrome.

Differentiation syndrome is serious and may be life-threatening if not treated. Differentiation syndrome has happened as early as the first day and up to 3 months after starting TIBSOVO.

Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the symptoms of differentiation syndrome listed on the facing page.

In the clinical study, 1 in 4 people with newly diagnosed AML who took TIBSOVO (7 out of 28) experienced differentiation syndrome.

In the clinical study, about 1 in 5 people with relapsed or refractory AML who took TIBSOVO (34 out of 179) experienced differentiation syndrome.



Contact your healthcare provider right away if you have any of the following symptoms of differentiation syndrome:



Fever



Cough



Trouble breathing



Rash



Decreased urination



Dizziness or lightheadedness



Rapid weight gain



Swelling of the arms or legs

If you have differentiation syndrome, your healthcare provider may give you steroids or other medications and monitor you in the hospital.

**It is important to let all of your healthcare providers know that you are taking a medication that can cause differentiation syndrome. The Differentiation Syndrome Reference Card can help.**

### Differentiation Syndrome Reference Card

Remember to carry this card with you at all times.

- Download the card
- Fill it out
- Keep it with you at all times
- Show it to any person involved in your medical care

Possible side effects of TIBSOVO

TIBSOVO may cause serious side effects, including:

- Differentiation syndrome, which may be life-threatening or lead to death if not treated
- Changes in the electrical activity of your heart called QTc prolongation. QTc prolongation can cause irregular heartbeats and can be life-threatening. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint
- Guillain-Barré syndrome. Tell your healthcare provider right away if you develop any signs or symptoms of Guillain-Barré syndrome, including weakness or a tingling feeling in your legs, arms, or upper body; numbness and pain on one side or both sides of your body; any changes in your ability to see, touch, hear, or taste; burning or prickling sensation; or difficulty breathing

Your healthcare provider will do blood tests before you start and during treatment with TIBSOVO.

Be sure to tell your healthcare provider right away about any side effects you have. Your healthcare provider may decrease, temporarily hold, or permanently stop your treatment with TIBSOVO if you develop certain side effects.

To study the safety of TIBSOVO, 213 adults with AML with an IDH1 mutation were assigned to receive TIBSOVO 500 mg every day and were monitored for the occurrence of side effects.

The most common side effects of TIBSOVO include:

- |                               |  |   |
|-------------------------------|--|---|
| • Fatigue                     | • Pain or sores in your mouth or throat                  | • Constipation                                  |
| • Joint pain                  |  | • Fever   |
| • High white blood cell count | • Irregular heart rhythm or heartbeat (QTc prolongation) | • Decreased hemoglobin levels (anemia)          |
| • Diarrhea                    | • Rash   | • Changes in liver or kidney function tests     |
| • Swelling of arms or legs    | • Cough  | • Decreased levels of electrolytes in the blood |
| • Nausea                      | • Decreased appetite                                     |   |
| • Shortness of breath         | • Muscle pain  |   |

These are not all the possible side effects of TIBSOVO. Call your healthcare provider for medical advice about side effects. You may also report side effects to FDA (U.S. Food & Drug Administration) at 1-800-FDA-1088.



What to do if you experience side effects

Always tell your healthcare provider about any side effects you experience. They may be able to prescribe medicines to help you manage them. However, there are some things you can do on your own that may help as well.

If you experience a rash

- Avoid the sun (especially between 10 AM and 4 PM), wear a broad-brimmed hat, and use sunscreen with an SPF of 15 or higher
  - If the sunscreen stings or burns, try one with zinc oxide or titanium dioxide
- Shower with lukewarm (not hot) water and use a mild soap
- Apply a cream-based moisturizer to all skin within 5 minutes of showering or bathing
  - Use a hypoallergenic moisturizer that does not have perfumes or preservatives
- Avoid skin products containing alcohol or retinoids, which can dry out your skin
- Avoid laundry detergent with strong perfumes

**Rash may be a symptom of differentiation syndrome, so it is important to speak with your healthcare provider right away if you have a rash.**

If you experience nausea

- If nausea only happens between meals, eat frequent small meals and have a snack at bedtime
- Drink clear liquids served cold and sipped slowly
- Eat bland foods (dry toast and crackers)
- Eat food cold or at room temperature
- Avoid fatty, fried, spicy, or very sweet foods
- Rest quietly while sitting upright for at least an hour after each meal
- Distract yourself with music, TV, or company

If you experience diarrhea

- Eat small meals often
- Avoid acidic drinks (tomato or citrus juices, fizzy soft drinks); hot, spicy, or greasy foods; bran; raw fruits and vegetables; pastries; candies; rich desserts; jellies; preserves; and nuts
- Avoid caffeine, alcohol, and tobacco
- Avoid milk and milk products if they make diarrhea worse
- Try a clear liquid diet as soon as diarrhea starts or when you feel it’s going to start
- When diarrhea starts to improve, try eating small amounts of foods that are easy to digest (rice, bananas, applesauce, yogurt, mashed potatoes, low-fat cottage cheese, dry toast). If diarrhea continues to improve after a day or two, start to eat small, regular meals



Important questions to ask your healthcare provider

It is important to take an active role in your treatment. One of the best ways you can do this is to talk with your healthcare providers. This can help you feel more confident about your treatment with TIBSOVO®. Some important questions to ask are:

<i>What makes TIBSOVO right for me?</i>	<i>What should I expect while taking TIBSOVO?</i>
<i>Is there anything I should avoid while taking TIBSOVO?</i>	<i>How do I take TIBSOVO, and what if I miss a dose?</i>
<i>Is it safe for me to take TIBSOVO while on other medications?</i>	<i>How should I store TIBSOVO?</i>

**Ask every question.** Talk with your healthcare provider so you can understand any questions regarding your diagnosis and treatment.

myAgios™ Patient Support Services

myAgios Patient Support Services will work with you, your caregiver, and your healthcare provider(s) to help you get treatment after you've been prescribed TIBSOVO.

**Financial assistance may be available, no matter your insurance type or status.<sup>a</sup>**

Your healthcare provider or myAgios Patient Support Services can help figure out which finance assistance program is right for you.

TYPES OF INSURANCE	WHAT DOES IT MEAN?	THE PROGRAM(S) FOR YOU
<b>Commercial/private</b>	You get your health insurance through your work or your spouse's work, or you purchase it yourself.	<b>Commercial \$25 Co-Pay Program</b>  You may pay no more than \$25 for each prescription of TIBSOVO regardless of how much you make. You can get a maximum benefit of \$25,000 per calendar year. Talk to your healthcare provider about applying if you've been prescribed TIBSOVO. For more information on the co-pay program, go to <a href="https://www.myagios-copay.com">www.myagios-copay.com</a> .  <b>Note:</b> If you have government insurance, you are not eligible for this program.
<b>Government</b>	You have federal or state-funded insurance, including Medicare, Medicaid, Medigap, Tricare, Veterans Affairs (VA), or Department of Defense (DoD).	<b>Independent foundations<sup>b</sup></b>  Independent foundations may be available to help you pay for TIBSOVO. One of our specialty pharmacies or myAgios can provide a referral to these foundations.
<b>Uninsured or underinsured</b>  <i>(may apply to commercial or government insurance)</i>	You do not have insurance, or your insurance plan does not cover TIBSOVO.	<b>Patient Assistance Program (PAP)</b>  The PAP may help you get access to TIBSOVO. Income requirements apply. You and your healthcare provider can reach out to myAgios to learn more.

Please see [myAgios.com](https://myAgios.com) for full Terms and Conditions for each program.  
<sup>a</sup> If you are waiting for or have a gap in coverage, you may be eligible for a free product program. Contact myAgios for more information.  
<sup>b</sup> Eligibility is determined by the individual foundation. Servier Pharmaceuticals is not affiliated with these organizations.



# ADDITIONAL RESOURCES

## More information about TIBSOVO® and Servier Pharmaceuticals

**TIBSOVO**  
[TIBSOVO.com](https://tibsovo.com)

**Servier Pharmaceuticals**  
[Servier.us](https://servier.us)

## General cancer resources<sup>a</sup>

**American Cancer Society®**  
1-800-227-2345  
[cancer.org/cancer/leukemia](https://cancer.org/cancer/leukemia)

**Leukemia & Lymphoma Society®**  
1-800-955-4572  
[lls.org/support/support-groups](https://lls.org/support/support-groups)

## Support groups and services for you and your caregiver<sup>a</sup>

**CancerCare®**  
1-800-813-HOPE (1-800-813-4673)  
[cancercare.org](https://cancercare.org)

**MyLifeLine**  
1-888-793-9355  
[mylifeline.org](https://mylifeline.org)

**Cancer Support Community**  
1-888-793-9355  
[cancersupportcommunity.org](https://cancersupportcommunity.org)

**PAN Foundation**  
1-866-316-7263  
[panfoundation.org](https://panfoundation.org)

**Good Days®**  
1-972-608-7141  
[mygooddays.org](https://mygooddays.org)

**Patient Advocate Foundation**  
1-800-532-5274  
[patientadvocate.org](https://patientadvocate.org)

**HealthWell Foundation®**  
1-800-675-8416  
[healthwellfoundation.org](https://healthwellfoundation.org)

<sup>a</sup>These are independent resources. Servier Pharmaceuticals is not affiliated with these organizations.

## TIBSOVO dosing calendar

Use this TIBSOVO dosing calendar to ensure you are taking every dose.

Date of first TIBSOVO dose:  Month:

Time of dose  
(2 tablets, orally once per day):

My notes:

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
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# IMPORTANT SAFETY INFORMATION

## WHAT IS TIBSOVO®?

- TIBSOVO is a prescription medicine used to treat acute myeloid leukemia (AML) with an isocitrate dehydrogenase-1 (IDH1) mutation in:
- adults with newly diagnosed AML who are 75 years or older or who have health problems that prevent the use of certain chemotherapy treatments.
  - adults with AML when the disease has come back or has not improved after previous treatment(s).

Your healthcare provider will perform a test to make sure that TIBSOVO is right for you. It is not known if TIBSOVO is safe and effective in children.

## IMPORTANT SAFETY INFORMATION

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

- Differentiation Syndrome.** Differentiation syndrome is a condition that affects your blood cells and may be life-threatening or lead to death if not treated. Differentiation syndrome has happened as early as 1 day and up to 3 months after starting TIBSOVO. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following symptoms of differentiation syndrome during treatment with TIBSOVO:
  - fever
  - cough
  - trouble breathing
  - rash
  - decreased urination
  - dizziness or lightheadedness
  - rapid weight gain
  - swelling of your arms and legs
- If you develop signs and symptoms of differentiation syndrome, your healthcare provider may treat you with a corticosteroid medicine or a medicine called hydroxyurea and may monitor you in the hospital.
- Changes in the electrical activity of your heart called QTc prolongation. QTc prolongation can cause irregular heartbeats that can be life-threatening.** Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) during treatment with TIBSOVO. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint.
- Guillain-Barré Syndrome.** Guillain-Barré syndrome has happened in people treated with TIBSOVO. Your healthcare provider will monitor you for nervous system problems and will permanently stop your treatment with TIBSOVO if you develop Guillain-Barré syndrome. Tell your healthcare provider right away if you develop any signs or symptoms of Guillain-Barré syndrome, including:
  - weakness or tingling feeling in your legs, arms, or upper body
  - numbness and pain on one side or both sides of your body
  - any changes in your ability to see, touch, hear, or taste
  - burning or prickling sensation
  - difficulty breathing

### The most common side effects of TIBSOVO include:

- fatigue
- joint pain
- high white blood cell count
- diarrhea
- swelling of arms or legs
- nausea
- shortness of breath
- pain or sores in your mouth or throat
- irregular heart rhythm or heartbeat (QTc prolongation)
- rash
- cough
- decreased appetite
- muscle pain
- constipation
- fever
- hemoglobin decreased (anemia)
- decreased levels of electrolytes in the blood
- changes in liver or kidney function tests

Your healthcare provider will do blood tests before you start and during treatment with TIBSOVO. Your healthcare provider may decrease, temporarily hold, or permanently stop your treatment with TIBSOVO if you develop side effects.

TIBSOVO may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of TIBSOVO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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

- have any heart problems, including a condition called long QT syndrome.
- have problems with abnormal electrolytes such as sodium, potassium, calcium, or magnesium levels.
- have nervous system problems.
- have problems with your kidneys or are on dialysis.
- have any liver disorders, including cirrhosis.
- are pregnant or plan to become pregnant. TIBSOVO can cause harm to your unborn baby. You should avoid becoming pregnant during treatment with TIBSOVO. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with TIBSOVO.
- are breastfeeding or plan to breastfeed. It is not known if TIBSOVO passes into your breast milk. Do not breastfeed during your treatment with TIBSOVO and for at least 1 month after your last dose of TIBSOVO.



# IMPORTANT SAFETY INFORMATION

## IMPORTANT SAFETY INFORMATION (cont'd)

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **Especially tell your doctor if you take hormonal contraceptives.** TIBSOVO® may affect how hormonal contraceptives work and may cause them to not work as well.

### Taking TIBSOVO

- Take TIBSOVO exactly as your healthcare provider tells you to.
- Do not change your dose or stop taking TIBSOVO without talking to your healthcare provider.
- Take TIBSOVO 1 time a day about the same time each day.
- Swallow TIBSOVO tablets whole. Do not split, crush, or chew the tablet.
- TIBSOVO can be taken with or without food. Do not take TIBSOVO with a high-fat meal.
- If you vomit after taking a dose of TIBSOVO, do not take an additional dose. Take your next dose at your usual time.
- If you miss a dose of TIBSOVO or did not take it at the usual time, take your dose as soon as possible and at least 12 hours before your next dose. Return to your normal schedule the following day. Do not take 2 doses of TIBSOVO within 12 hours.

### General information about the safe and effective use of TIBSOVO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take TIBSOVO for conditions for which it was not prescribed. Do not give TIBSOVO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TIBSOVO that is written for healthcare professionals.

## Notes

## Differentiation Syndrome Reference Card

### Differentiation Syndrome Reference Card

This card can help you let your healthcare providers know that you are taking a medication that can cause differentiation syndrome.

- Download the card
- Fill it out
- Keep it with you at all times
- Show it to any person involved in your medical care

Please see additional information about differentiation syndrome on pages 12 and 13 of this booklet and in the Medication Guide.



# TIBSOVO®: A TARGETED TREATMENT OPTION

To find more information about TIBSOVO and to uncover additional resources, visit [www.TIBSOVO.com](http://www.TIBSOVO.com)

*myAgios™ Patient Support Services is here for you.  
Visit [myAgios.com](http://myAgios.com) to find assistance for you and your caregiver.*

**Please see Important Safety Information on pages 20 to 22 and Full Prescribing Information, including BOXED WARNING and Medication Guide.**



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