



AIM FOR A DAY OF POSSIBILITIES

Understanding treatment with TIBSOVO® for AML

**TIBSOVO may cause serious side effects, including Differentiation Syndrome in AML patients.** Differentiation syndrome is a condition that affects your blood cells and may be life-threatening or lead to death. Differentiation syndrome in adults with acute myeloid leukemia (AML) 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 symptoms of differentiation syndrome during treatment with TIBSOVO. For a list of these symptoms, see page 15 in this brochure.

Please see Important Safety Information on pages 20 and 21 and [Full Prescribing Information](#), including **BOXED WARNING** for AML patients and [Medication Guide](#).

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## 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 treated in combination with TIBSOVO and azacitidine who are 75 years or older or who have health problems that prevent the use of certain chemotherapy treatments
- 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 in AML patients.**

Differentiation syndrome is a serious condition that affects your blood cells and may be life-threatening or lead to death. Differentiation syndrome in adults with AML 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 symptoms of differentiation syndrome during treatment with TIBSOVO. For a list of these symptoms, see page 15 in this brochure.

Please see additional Important Safety Information on pages 20 and 21 and [Full Prescribing Information](#), including **BOXED WARNING** for AML patients and [Medication Guide](#).

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

Please see additional Important Safety Information on pages 20 and 21 and **Full Prescribing Information**, including **BOXED WARNING** for AML patients and **Medication Guide**.

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# 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.

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## ABOUT AML (cont'd)

### 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.

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# 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 mutated IDH1.***

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

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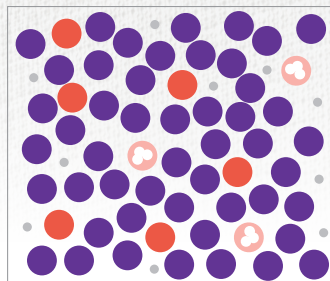


# HOW TREATMENT WITH TIBSOVO WORKS (cont'd)

## How TIBSOVO works against your AML

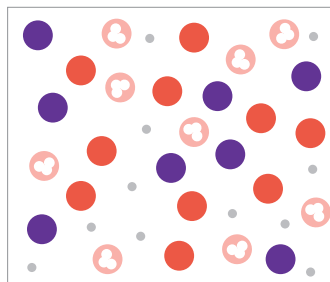
### **TIBSOVO is a targeted therapy.**





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 works differently from chemotherapy***  
*in that it does not attack normal, healthy blood cells.*

## TIBSOVO + azacitidine: better together



Your doctor may prescribe TIBSOVO in combination with azacitidine to treat newly diagnosed AML patients who are 75 years or older or who have health problems that prevent the use of certain chemotherapy treatments. The two treatments work together to **extend survival**.

Azacitidine is administered by your healthcare provider in an office setting. Please consult your doctor to learn more about this combination regimen.

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## HOW TREATMENT WITH TIBSOVO WORKS (cont'd)

### The TIBSOVO + azacitidine clinical study

TIBSOVO was studied in the following patients:

- 146 adult patients with newly diagnosed AML with an isocitrate dehydrogenase-1 (IDH1) mutation who were 75 years or older or had health problems that prevented the use of certain chemotherapy treatments

All patients received azacitidine for 7 days every 4 weeks, along with either:

- 500 mg of TIBSOVO taken orally once a day, or
- A daily oral placebo

Patients receiving TIBSOVO + azacitidine or placebo + azacitidine were treated for at least 6 four-week treatment cycles unless:

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

**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.**

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# HOW TREATMENT WITH TIBSOVO WORKS (cont'd)

## Benefits seen with TIBSOVO in combination with azacitidine in newly diagnosed AML

More people with newly diagnosed AML who received TIBSOVO + azacitidine were able to live longer and achieve remission.

### Median overall survival<sup>a</sup>

**24**  
months

TIBSOVO + azacitidine

**7.9**  
months

Placebo +  
azacitidine

TIBSOVO + azacitidine was proven to help more people **live longer** than those treated with azacitidine alone

<sup>a</sup>Median overall survival is defined as the length of time from the start of treatment in a clinical trial to the time when half of the patients are still alive.

In the clinical study, **51%** of people (37 out of 72) achieved complete remission (CR) or complete remission with partial hematologic recovery (CRh) compared with **18%** of people (13 out of 74) on azacitidine alone.

Of the 37 people with newly diagnosed AML who achieved **CR or CRh**:

**80.5%**

were in remission at **12 months** after starting TIBSOVO + azacitidine<sup>b</sup>

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

**TIBSOVO + azacitidine also helped reduce the need for red blood cell or platelet transfusions.**



**46%** of people became **transfusion free** when they were treated with TIBSOVO and azacitidine. 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.

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# HOW TREATMENT WITH TIBSOVO WORKS (cont'd)

## 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

## Benefits seen with TIBSOVO alone in newly diagnosed AML

**Some people 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**:

**58%**

were in remission at **12 months** after starting TIBSOVO<sup>a</sup>

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

**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.

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# HOW TREATMENT WITH TIBSOVO WORKS (cont'd)

## Benefits seen with TIBSOVO in 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.

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# 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.

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## TAKING AND STORING TIBSOVO (cont'd)

### 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 and 77 °F (20-25 °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



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# TAKING TIBSOVO

## 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

### *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.*

- **TIBSOVO may cause serious side effects, including differentiation syndrome**

## 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. Differentiation syndrome in adults with AML 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 7 people with **newly diagnosed AML who took TIBSOVO in combination with azacitidine** (11 out of 71) experienced differentiation syndrome.

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

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

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## TAKING TIBSOVO (cont'd)



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



Fever



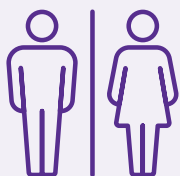
Cough



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 in the back of this brochure 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

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# TAKING TIBSOVO (cont'd)

## Possible side effects of TIBSOVO

TIBSOVO may cause serious side effects, including:

- Differentiation syndrome, which may be life-threatening or lead to death
- 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.

## The most common side effects of TIBSOVO when used in combination with azacitidine or alone in adults with AML include:

- |   |  |   |
|---|--|---|
| • Changes in certain blood cell counts          | • Nausea                                   | • Pain or sores in your mouth or throat                 |
| • Diarrhea                                      | • Vomiting                                 | • Rash  |
| • Increased blood sugar                         | • Decreased appetite                       | • Irregular heart rhythm or heartbeat (QT prolongation) |
| • Fatigue                                       | • Joint pain                               | • Differentiation syndrome                              |
| • Changes in certain liver function tests       | • Shortness of breath                      | • Muscle pain   |
| • Swelling of arms or legs                      | • Uric acid increased                      |   |
| • Decreased levels of electrolytes in the blood | • Stomach (abdominal) pain                 |   |
|   | • Changes in certain kidney function tests |   |

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 the FDA (U.S. Food & Drug Administration) at 1-800-FDA-1088.

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# ADDITIONAL RESOURCES

## 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.

*What makes TIBSOVO right for me?*

*What should I expect while taking TIBSOVO?*

*Is there anything I should avoid while taking TIBSOVO?*

*How do I take TIBSOVO, and what if I miss a dose?*

*Is it safe for me to take TIBSOVO while on other medications?*

*How should I store TIBSOVO?*

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

If you have any questions, please visit [ServierONE.com](https://www.servierone.com)  
or call 1-800-813-5905, Monday through Friday, from 8 AM to 6 PM ET.

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# ADDITIONAL RESOURCES (cont'd)

## ServierONE Patient Support Services

ServierONE 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 ServierONE Patient Support Services can help figure out which financial assistance program is right for you.

TYPE 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 Co-Pay Program</b> This program can help lower out-of-pocket costs. There are no income restrictions, and it is available to eligible patients with commercial/private insurance. For more information on the co-pay program, go to <a href="https://www.servierone-copay.com">ServierONE-copay.com</a> . <b>Note:</b> If you have government insurance, you are not eligible for this program.
<b>Government</b>	You get your health insurance through a government healthcare insurance program such as Medicare, Medicaid, Medigap, Tricare, Veterans Affairs (VA), Department of Defense (DOD), or any state-funded programs.	<b>Independent foundations<sup>b</sup></b> Independent foundations may be available to help you pay for TIBSOVO. One of our specialty pharmacies or ServierONE can provide a referral to these foundations.
<b>Uninsured or underinsured</b> <i>(may apply to commercial or government insurance)</i>	You have no insurance coverage or lack coverage for your prescribed therapy.	<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 ServierONE to learn more.

Please see [ServierONE.com](https://www.servierone.com) for full Terms and Conditions for each program.

Visit [ServierONE.com](https://www.servierone.com) to find assistance for you and your caregiver.

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# ADDITIONAL RESOURCES (cont'd)

## More information about TIBSOVO and Servier Pharmaceuticals

### **TIBSOVO**

[TIBSOVO.com/AML](https://TIBSOVO.com/AML)

### **Servier Pharmaceuticals**

[Servier.us](https://Servier.us)

## Patient advocacy, support, and assistance<sup>c</sup>

### **American Cancer Society<sup>®</sup>**

1-800-227-2345

[cancer.org/cancer/leukemia](https://cancer.org/cancer/leukemia)

### **Leukemia & Lymphoma Society<sup>®</sup>**

1-800-955-4572

[lls.org/support/support-groups](https://lls.org/support/support-groups)

### **MDS Foundation**

1-800-637-0839

[mds-foundation.org](https://mds-foundation.org)

### **AA.MDS International Foundation (AAMDSIF)**

1-800-747-2820

[aamds.org](https://aamds.org)

### **CancerCare<sup>®</sup>**

1-800-813-HOPE (1-800-813-4673)

[cancercare.org](https://cancercare.org)

### **Cancer Support Community**

1-888-793-9355

[cancersupportcommunity.org](https://cancersupportcommunity.org)

### **Good Days<sup>®</sup>**

1-972-608-7141

[mygooddays.org](https://mygooddays.org)

### **Patient Advocate Foundation**

1-800-532-5274

[patientadvocate.org](https://patientadvocate.org)

### **HealthWell Foundation<sup>®</sup>**

1-800-675-8416

[healthwellfoundation.org](https://healthwellfoundation.org)

***Independent foundations may also provide support to patients.***  
*Your ServierONE care manager team can provide more information.*

<sup>a</sup> If you are waiting for coverage, you may be eligible for a free-product program. Contact ServierONE for more information.

<sup>b</sup> Eligibility is determined by the individual foundation. Servier Pharmaceuticals is not affiliated with these organizations.

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

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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 treated in combination with TIBSOVO and azacitidine who are 75 years or older or who have health problems that prevent the use of certain chemotherapy treatments
- 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 in AML Patients.** Differentiation syndrome is a serious condition that affects your blood cells and may be life-threatening or lead to death. Differentiation syndrome in adults with acute myeloid leukemia (AML) 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             | - rash                         | - rapid weight gain              |
| - cough             | - decreased urination          | - swelling of your arms and legs |
| - trouble breathing | - dizziness or lightheadedness |                                  |

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	- burning or prickling sensation
	- any changes in your ability to see, touch, hear, or taste	- difficulty breathing

Please see [Full Prescribing Information](#), including **BOXED WARNING** for AML patients and [Medication Guide](#).

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# IMPORTANT SAFETY INFORMATION (cont'd)

**The most common side effects of TIBSOVO when used in combination with azacitidine or alone in adults with AML include:**

- changes in certain blood cell counts
- diarrhea
- increased blood sugar
- fatigue
- changes in certain liver function tests
- swelling of arms or legs
- decreased levels of electrolytes in the blood
- nausea
- vomiting
- decreased appetite
- joint pain
- shortness of breath
- uric acid increased
- stomach (abdominal) pain
- changes in certain kidney function tests
- pain or sores in your mouth or throat
- rash
- irregular heart rhythm or heartbeat (QTc prolongation)
- differentiation syndrome
- muscle pain

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 of the possible side effects of TIBSOVO. Call your doctor for medical advice about side effects. You may report side effects to the 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 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 doctor if you take hormonal contraceptives.** TIBSOVO may affect how hormonal contraceptives work and may cause them to not work as well.

Please see [Full Prescribing Information](#), including **BOXED WARNING** for AML patients and [Medication Guide](#).

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# ADDITIONAL RESOURCES

## TIBSOVO Dosing Calendar

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

Date of first TIBSOVO dose: \_\_\_\_\_ Month: \_\_\_\_\_

Time of dose (2 tablets orally once a day): \_\_\_\_\_

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY

Please see additional Important Safety Information on pages 20 and 21 and [Full Prescribing Information](#), including BOXED WARNING for AML patients and [Medication Guide](#).

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Differentiation Syndrome Reference Card

Differentiation Syndrome Reference Card

This card can help 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 14 and 15 of this brochure and in the [Medication Guide](#).

### Differentiation Syndrome Reference Card



Remember to carry this card with you at all times.

Scan here to save a copy to your phone.



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TIBSOVO + AZACITIDINE  
IN NEWLY DIAGNOSED AML

PROVEN TO HELP MORE  
PATIENTS LIVE LONGER

Please see the full TIBSOVO + azacitidine  
clinical study information and  
results on pages 8 and 9.

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



TIBSOVO is a prescription medicine used to treat AML with an 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.

**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.**

**Please see Important Safety Information on pages 20 and 21 and [Full Prescribing Information](#), including BOXED WARNING for AML patients and [Medication Guide](#).**



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