

AIM FOR A DAY OF POSSIBILITIES



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 11 in this booklet.

Please see additional Important Safety Information on pages 18-20 and full [Prescribing Information](#), including **Boxed WARNING** and Medication Guide.

 **TIBSOVO®**
ivosidenib tablets 250mg

About this booklet

This booklet is intended for people who have been prescribed TIBSOVO®. TIBSOVO is a treatment option for the specific type of AML that you have. Talk with your healthcare provider about any questions or concerns you have before starting treatment with TIBSOVO.



TIBSOVO is:

- Personalized for you because it targets the IDH1 mutation. Learn more on page 5
- Taken orally, once a day, with or without food, and can be taken at home. Learn more on page 8
 - Do not take TIBSOVO with a high-fat meal (about 1000 calories and 58 grams of fat)
- Shown to be effective and safe in a clinical study. Learn more on pages 6 and 7

Please see Important Safety Information on pages 18-20 and full [Prescribing Information](#), including Boxed WARNING and Medication Guide.

Here's what you'll find inside this booklet:

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About AML and TIBSOVO®

About AML

AML is a cancer that affects a type of white blood cell in the bone marrow called a myeloblast. Healthy myeloblasts grow into other kinds of white blood cells.

In people with AML, the myeloblasts are immature and abnormal. This means they do not grow or work like they should. Sometimes, red blood cells and platelets are abnormal too.

All of these abnormal blood cells (called blasts) can build up in the body. They crowd out healthy white blood cells, red blood cells, and platelets. When there are too many blasts and not enough healthy cells, the symptoms of AML begin to occur.

Newly diagnosed

You have not had treatment for AML. In the past, you may have had treatment for another disease of the bone marrow, such as myelodysplastic syndrome (MDS).

Relapsed

You were symptom free for a time after initial treatment, but the signs and symptoms of AML have returned.

Refractory

Your AML did not respond to initial treatment.

Types of remission

As you know, the goal of many cancer treatments is to put people with cancer into remission. With AML and other blood cancers, there are a few types of remission. Two important ones to know about are:

Complete remission (CR)

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

Complete remission with partial hematological recovery (CRh)

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

Please see Important Safety Information on pages 18-20 and full [Prescribing Information](#), including Boxed WARNING and Medication Guide.

Targeted treatment

Mutations are changes in the DNA (deoxyribonucleic acid) of a cell. Mutations can play a role in the development of AML. That's why testing for mutations helps your healthcare team understand which AML treatments may work for you.

TIBSOVO is a type of treatment called targeted therapy. It works on cells with a mutation called an IDH1 mutation. An IDH1 mutation can cause AML because it keeps myeloblasts from becoming healthy white blood cells. Because TIBSOVO targets this mutation, it can be used to treat adults with AML with an IDH1 mutation. About 1 in 10 people with AML have an IDH1 mutation.

Because TIBSOVO is a targeted therapy, it works differently from traditional chemotherapy. Chemotherapy kills cells that divide quickly, including blast cells. Chemotherapy can affect many types of cells in the body and is typically given by infusion, usually in the hospital.



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

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 doctor decided to stop treatment, **or**
- They received a stem cell transplant

Benefits seen with TIBSOVO® in the clinical study

Newly diagnosed AML

Some people with newly diagnosed AML who had health problems that prevented the use of certain chemotherapy treatments and who received TIBSOVO were able to achieve remission



In the clinical study, about **2 in 5 people** (12 out of 28) achieved CR or CRh with TIBSOVO.

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



58% were in remission at **12 months** after starting TIBSOVO*



Another benefit of TIBSOVO was a reduction in 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 started were able to stop getting them 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.

*The median length of time that people stayed in remission could not be estimated in the study.

SELECTED 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.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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 to 5.6 months)



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

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



Another benefit of TIBSOVO was a reduction in 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 started were able to stop getting them 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.

Understanding treatment with TIBSOVO®

How to take TIBSOVO



Tablets not shown at actual size.

Take 2 tablets orally, once a day

- Do not adjust your dose or stop taking TIBSOVO without talking to your healthcare provider

Before taking 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, have any liver disorders, including cirrhosis, are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed
- 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

While taking TIBSOVO



Take TIBSOVO 1 time a day at about the same time each day. Taking it at the same time as another daily activity, like brushing 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).



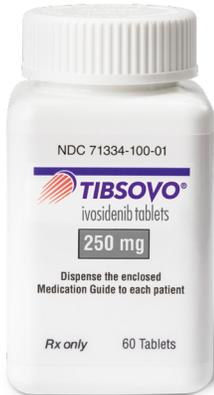
Swallow TIBSOVO tablets whole. **Do not** split, crush, or chew the tablets.



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.

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including Boxed WARNING and Medication Guide.

How to store TIBSOVO



- Store TIBSOVO at room temperature (68°F to 77°F)
- Keep TIBSOVO in the original container
- Keep TIBSOVO and all medicines out of reach of children

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.

What to expect with TIBSOVO

Remember that TIBSOVO works differently than traditional chemotherapy. Because of this, there are some important things to be aware of 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.** 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 11 in this booklet

Differentiation syndrome



Learn more: Differentiation syndrome

Blood cells form through a process called differentiation. Some treatments for AML, including TIBSOVO®, can cause 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 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 listed on page 11.

1 in 4 people with **newly diagnosed AML** who took TIBSOVO (7 out of 28) experienced differentiation syndrome.

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 your 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.

Differentiation Syndrome Reference Card

Remember to carry this card with you at all times.



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The **Differentiation Syndrome Reference Card** in the back of this booklet can help.

- Remove the card from page 21
- 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 doctor 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 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 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 appearance of side effects.



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

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

What to do if you experience side effects

You should always tell your healthcare provider about any side effects you have. 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, too.

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.

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

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 or 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 2, start small, regular meals



Talk with your healthcare provider about ways to manage any side effects you may experience with TIBSOVO®.

Additional support

Finding the right support can make a big difference in your experience with AML. The resources listed here can help with many aspects of AML, from assistance paying for treatment to making contact with others facing the challenges of AML.

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^a

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

Types of insurance	What does it mean?	The program(s) for you
<p>Commercial/ private</p>	<p>You get your health insurance through your work or your spouse's work, or you purchase it yourself.</p>	<p>Commercial \$25 Co-Pay Program</p> <p>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 doctor about applying if you've been prescribed TIBSOVO.</p> <p>Note: If you have government insurance, you are not eligible for this program.</p>
<p>Government or commercial</p>	<p>You have commercial or private insurance or insurance through a government program.</p>	<p>Independent foundations^b</p> <p>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.</p>
<p>Uninsured or underinsured (may apply to commercial or government insurance)</p>	<p>You do not have insurance or your insurance plan does not cover TIBSOVO.</p>	<p>Patient Assistance Program (PAP)</p> <p>The PAP can help you get access to TIBSOVO. Income requirements apply. You and your healthcare provider can reach out to myAgios to learn more.</p>

Please see myAgios.com for full Terms and Conditions for each program.

If you have questions, please visit myAgios.com or call 1-844-409-1141, Monday through Friday, 8 AM to 6 PM ET

Please see Important Safety Information on pages 18-20 and full Prescribing Information, including Boxed WARNING and Medication Guide.

Other resources that can help

More information about TIBSOVO and Agios

TIBSOVO

Tibsovo.com

Agios

Agios.com

General cancer resources^c

American Cancer Society[®]

1-800-227-2345

cancer.org/cancer/leukemia

Leukemia & Lymphoma Society[®]

1-800-955-4572

lls.org/support/support-groups

Support groups and services for you and your caregiver^c

CancerCare[®]

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

cancercares.org

MyLifeLine

1-888-793-9355

mylifeline.org

Cancer Support Community

1-888-793-9355

cancersupportcommunity.org

Patient Access Network Foundation

1-866-316-7263

panfoundation.org

Good Days

1-972-608-7141

mygooddays.org

Patient Advocate Foundation

1-800-532-5274

patientadvocate.org

HealthWell Foundation[®]

1-800-675-8416

healthwellfoundation.org

^a 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.

^b Eligibility is determined by the individual foundation. Agios is not affiliated with these organizations.

^c These are independent resources. Agios is not affiliated with these organizations.

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
- decreased urination
- cough
- dizziness or lightheadedness
- trouble breathing
- rapid weight gain
- rash
- 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
 - any changes in your ability to see, touch, hear, or taste
 - numbness and pain on one side or both sides of your body
 - burning or prickling sensation
 - difficulty breathing

Please see additional Important Safety Information on page 20 and full [Prescribing Information](#), including **Boxed WARNING** and **Medication Guide**.

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.

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 (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.

Please see additional Important Safety Information on pages 18 and 19 and full [Prescribing Information](#), including **Boxed WARNING and **Medication Guide**.**



Learn more
about TIBSOVO® at
Tibsovo.com

Get support at
myAgiOS.com



**Please see Important Safety Information on pages 18-20 and full
Prescribing Information, including Boxed WARNING and Medication Guide.**



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