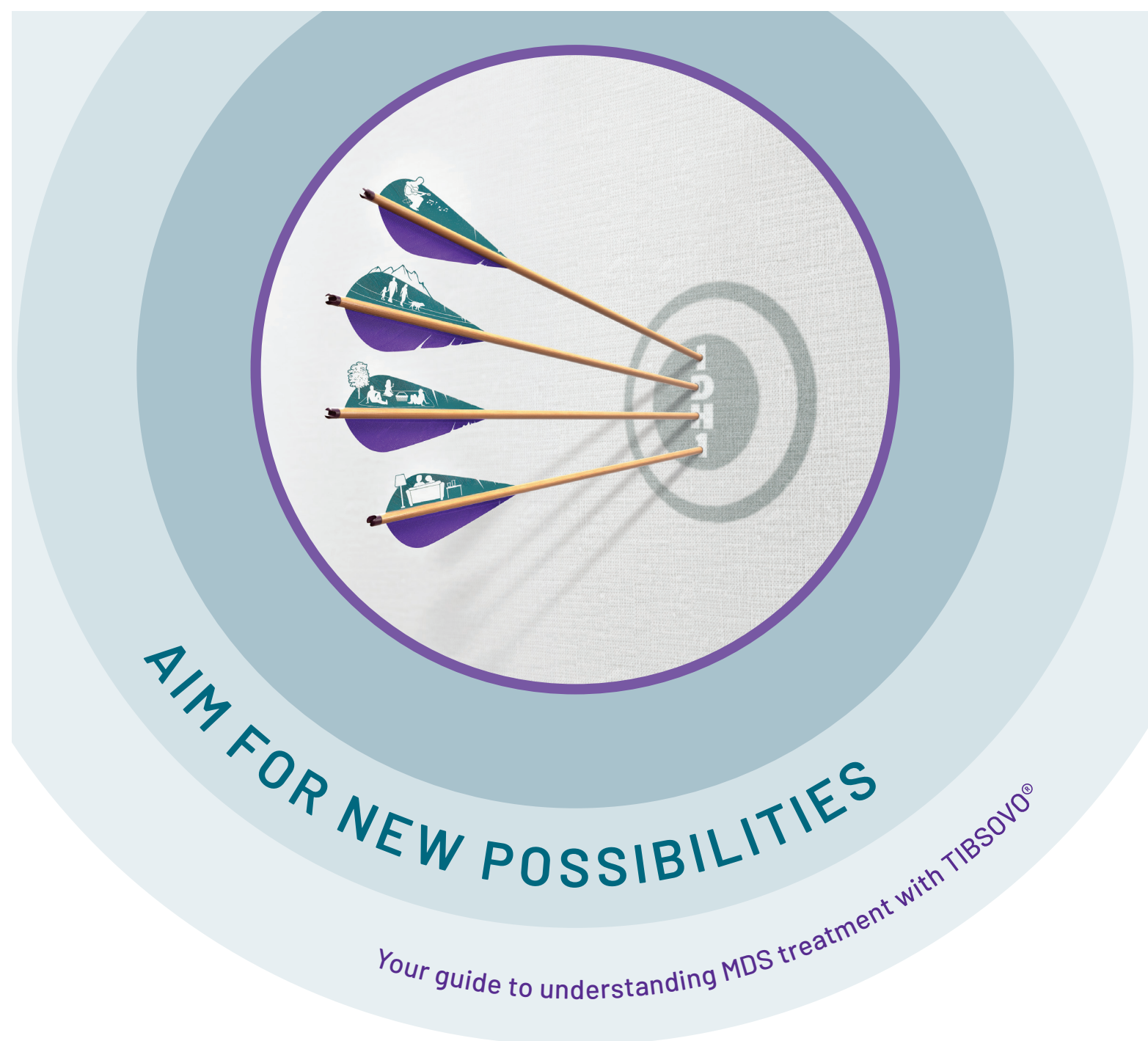




SELECTED IMPORTANT SAFETY INFORMATION

TIBSOVO may cause serious side effects, including differentiation syndrome—
a condition that affects your blood cells and may be life-threatening or lead to death.

Please see Important Safety Information on pages
16 and 17 and Full Prescribing Information, including
BOXED WARNING for MDS patients and Medication Guide,
accompanying this document or at [Tibsovo.com](https://www.tibsovo.com).

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ivosidenib tablets 250mg

WHAT YOU'LL FIND IN THIS GUIDE

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What are the signs and symptoms of MDS

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What is TIBSOVO?

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Important Safety Information

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TIBSOVO is the **#1 prescribed, first-in-class targeted therapy** that inhibits mutated isocitrate dehydrogenase-1 (IDH1).

2 Please see Important Safety Information on pages 16 and 17 and Full Prescribing Information, including BOXED WARNING for MDS patients and Medication Guide, accompanying this document or at Tibsovo.com.



UNDERSTANDING MDS

What is myelodysplastic syndromes (MDS)?

The bone marrow is responsible for producing immature blood cells that mature into specialized cells such as red blood cells, white blood cells, and platelets. These specialized cells transport oxygen, help fight infections, and assist in blood clotting, respectively.

Myelodysplastic syndromes (mai•uh•low•dis•pla•stik sin•dromes) are a group of blood cancers that disrupt this important process. In patients with MDS, immature blood cells do not mature into healthy red blood cells, white blood cells, or platelets like they should. As more and more immature blood cells are produced, they prevent healthy cells from forming. This leads to the signs and symptoms of MDS.

MDS is closely related to acute myeloid leukemia (AML), a more serious type of cancer that about 1 in 3 MDS patients can progress to. That's why it's so important to treat MDS when it appears.

What are the signs and symptoms of MDS?



Feeling tired, dizzy, or weak



Shortness of breath



Skin that is paler than normal
(which may be harder to see on darker skin tones)



Easy bruising or bleeding



Tiny purple spots on the skin



Frequent infections

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TREATMENT WITH TIBSOVO

TIBSOVO is the first and only FDA-approved treatment for people with relapsed or refractory MDS with IDH1 mutations

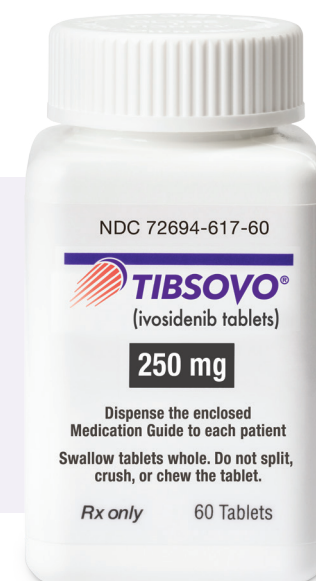
Historically, for people who relapse from or do not respond to MDS treatment, options have been limited.

TIBSOVO fills this gap by providing a treatment option.

500 mg
(2 x 250-mg film-coated tablets)



Tablets not shown at actual size.



Doctors may use terms like “relapsed” or “refractory” to describe the type of MDS that TIBSOVO is used for



Relapsed MDS means that after reaching remission with initial treatment, the signs and symptoms of MDS have returned.



Refractory MDS means that the disease has not responded to treatment.

What are isocitrate dehydrogenase-1 (IDH1) mutations?



Mutations are changes in the DNA (deoxyribonucleic acid) of a cell. **Isocitrate dehydrogenase-1** (eye•so•si•trate de•hi•dro•jen•ace one) mutations play an important role in the development of MDS because they may prevent immature blood cells from becoming healthy, mature ones.

IDH1 mutations can appear at any time during the course of MDS.
Ask your doctor to get retested if your disease worsens or relapses.

4 | Please see Important Safety Information on pages 16 and 17 and Full Prescribing Information, including BOXED WARNING for MDS patients and Medication Guide, accompanying this document or at [Tibsovo.com](https://www.tibsovo.com).

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TREATMENT WITH TIBSOVO

How was TIBSOVO studied?

A clinical trial studied efficacy in 18 adults with relapsed or refractory MDS who were given 500 mg of TIBSOVO orally. The goal of this trial was to determine how effective and safe TIBSOVO is. Treatment continued as long as it remained effective and side effects were manageable, unless patients went on to a stem cell transplant or had another reason to stop.

Some people with relapsed or refractory MDS who received TIBSOVO were able to achieve complete remission



Complete remission is an important treatment goal that occurs when the signs and symptoms of MDS cannot be detected.

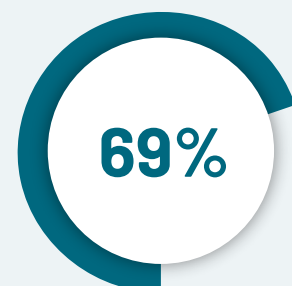


At the time of the clinical trial, **39%** of people (7 out of 18) reached **complete remission** with TIBSOVO

For the people who reached complete remission:



The average time to reach remission was **1.9 months**



were estimated to remain in remission for **6 years**^a

^aThe number of people who remained in remission was estimated. The median length of time that people stayed in remission could not be estimated in the study, because patients were still in remission at the end of the study.

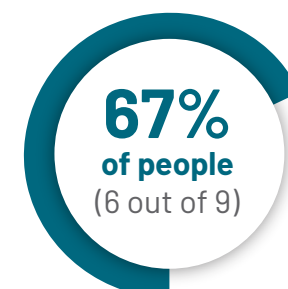
Please see Important Safety Information on pages 16 and 17 and Full Prescribing Information, including **BOXED WARNING** for MDS patients and Medication Guide, accompanying this document or at [Tibsovo.com](https://www.tibsovo.com).



TIBSOVO helped people become or stay transfusion-free



Transfusion-free means that people who needed transfusions when the study began stopped receiving them for at least 8 weeks.



who needed red blood cell or platelet transfusions became **transfusion-free** after taking TIBSOVO



who were **transfusion-free** when they started taking TIBSOVO remained so

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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 that can be taken at home. Take TIBSOVO exactly as your healthcare provider tells you to.



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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Actor portrayal.

How you should store TIBSOVO

- Store TIBSOVO at room temperature between 68 and 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



How long will I stay on TIBSOVO?

The average amount of time that people stayed on TIBSOVO was about 8 months. It's important to remember that responses and relapses occur at different times for different people, so the amount of time that someone will be on TIBSOVO may vary.

Your healthcare provider may **keep you on TIBSOVO for at least 6 months** if your disease doesn't progress, unless you have side effects that you can't tolerate.

Wherever your treatment journey takes you, it's important to keep talking with your doctor about your treatment plan.

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POSSIBLE SIDE EFFECTS OF TIBSOVO

What to expect when taking TIBSOVO

Some people may experience differentiation syndrome.

Blood cells form through a process called differentiation. Some treatments for MDS, 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 MDS has happened as early as the first day and up to 3 months after starting TIBSOVO.

Your Differentiation Syndrome Reference Card

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

It is important to let all 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 booklet can help.

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

Differentiation Syndrome Reference Card

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

- Scan the QR code to download the card or use the card in the back of this booklet
- 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 10 and 11 of this booklet and in the Medication Guide accompanying this document or at Tibsovo.com.



POSSIBLE SIDE EFFECTS OF TIBSOVO

Possible side effects of TIBSOVO

TIBSOVO may cause serious side effects, including:

- **Differentiation syndrome:** Differentiation syndrome may be life-threatening or lead to death. See more information on pages 10 and 11
- **QTc prolongation:** QTc prolongations are changes in the electrical activity of your heart that 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 adults with MDS include:

- changes in certain kidney function tests
- changes in certain blood cell counts
- joint pain, back pain, or neck pain
- decreased levels of albumin in the blood
- changes in liver function tests
- fatigue
- diarrhea
- cough
- decreased levels of sodium in the blood
- pain or sores in your mouth or throat
- decreased appetite
- muscle pain
- decreased levels of phosphorus in the blood
- itchy skin
- rash

Please see Important Safety Information on pages 16 and 17 and Full Prescribing Information, including BOXED WARNING for MDS patients and Medication Guide, accompanying this document or at [Tibsovo.com](https://tibsovo.com).



Actor portrayal.

SUPPORT AND RESOURCES

These questions can help guide a conversation between you and your doctor to determine if TIBSOVO may be right for you

What makes TIBSOVO right for me?

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

What impact could TIBSOVO have on my MDS?

What should I expect while taking TIBSOVO?

Is there anything I should avoid while taking TIBSOVO?

If TIBSOVO is the right choice for me, how soon can I expect to start?

Always feel empowered to ask your doctor questions. Talking with your doctor can help you better understand your diagnosis and treatment.



If you have any questions, please visit ServierONE.com or call 1-800-813-5905, Monday through Friday, from 8 AM to 6 PM ET.



SUPPORT AND RESOURCES

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.^a 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
Commercial/ Private	You get your health insurance through your work or your spouse's work, or you purchase it yourself.	Commercial Co-Pay Program This program can help lower out-of-pocket costs to as little as \$0 per prescription. 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 ServierONE-copay.com. Note: If you have government insurance, you are not eligible for this program.
Government	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.	Independent foundations^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.
Uninsured or underinsured (may apply to commercial or government insurance)	You have no insurance coverage or lack coverage for your prescribed therapy.	Patient Assistance Program (PAP) 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 for full Terms and Conditions for each program.

Please see Important Safety Information on pages 16 and 17 and Full Prescribing Information, including BOXED WARNING for MDS patients and Medication Guide, accompanying this document or at Tibsovo.com.

Visit our websites to learn more about TIBSOVO and Servier Pharmaceuticals

TIBSOVO

TIBSOVO.com/MDS

Servier Pharmaceuticals

Servier.us

Discover patient advocacy groups, support, and assistance to help you on your MDS treatment journey^c

American Cancer Society[®]

1-800-227-2345
cancer.org/cancer/leukemia

Leukemia & Lymphoma Society[®]

1-800-955-4572
lls.org/support/support-groups

MDS Foundation

1-800-637-0839
mds-foundation.org

Aplastic Anemia and MDS International Foundation

1-800-747-2820
aamds.org

CancerCare[®]

1-800-813-4673
cancercare.org

Cancer Support Community

1-888-793-9355
cancersupportcommunity.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

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

^aIf you are waiting for coverage, you may be eligible for a free-product program. Contact ServierONE for more information.

^bEligibility is determined by the individual foundation. Servier Pharmaceuticals is not affiliated with these organizations.

^cThese are independent resources. Servier Pharmaceuticals is not affiliated with these organizations.



IMPORTANT SAFETY INFORMATION

What is TIBSOVO?

TIBSOVO is a prescription medicine used to treat adults with an isocitrate dehydrogenase-1 (IDH1) mutation with myelodysplastic syndromes (MDS) 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 common condition that affects your blood cells and may be life-threatening or lead to death. Differentiation syndrome in adults with MDS 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** 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 when used in adults with MDS:

- changes in certain kidney function tests
- changes in certain blood cell counts
- joint pain, back pain, or neck pain
- decreased levels of albumin in the blood
- changes in liver function tests
- fatigue
- diarrhea
- cough
- decreased levels of sodium in the blood
- pain or sores in your mouth or throat
- decreased appetite
- muscle pain
- decreased levels of phosphorus in the blood
- itchy skin
- rash

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 certain 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.

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

ADDITIONAL RESOURCES

TIBSOVO Dosing Calendar

Use this dosing calendar to help you stay on track with TIBSOVO.

Date of first TIBSOVO dose: _____ Month: _____

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

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY

18 Please see Important Safety Information on pages 16 and 17 and Full Prescribing Information, including **BOXED WARNING** for MDS patients and Medication Guide, accompanying this document or at Tibsovo.com.

My notes

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.

- Remove 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 10 and 11 of this booklet and in the Medication Guide accompanying this document or at Tibsovo.com

TIBSOVO IN RELAPSED OR REFRACTORY MDS

TARGETED TREATMENT

TIBSOVO can help the body return to normal blood counts by targeting the IDH1 mutation

POWERFUL RESULTS

With TIBSOVO, some people achieved complete remission and became transfusion-free

CONVENIENT DOSING

TIBSOVO is an oral medication that you can take at home

See more information inside.

Aim for new possibilities with TIBSOVO.
Visit [TIBSOVO.com/MDS](https://tibsovo.com/MDS) to learn more



What is TIBSOVO?

TIBSOVO is a prescription medicine used to treat adults with an isocitrate dehydrogenase-1 (IDH1) mutation with myelodysplastic syndromes (MDS) when the disease has come back or has not improved after previous treatment(s).

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TIBSOVO is a registered trademark of SERVIER PHARMACEUTICALS LLC, a wholly owned, indirect subsidiary of LES LABORATOIRES SERVIER.
US-02757 v2 09/2025

