

# Differentiation Syndrome Reference Card

Remember to carry this card with you at all times.



## Information for Patients

There are serious risks associated with your acute myeloid leukemia (AML) therapy, including a condition called differentiation syndrome which may be life-threatening or lead to death if not treated.

If you have any of the symptoms to the right while taking treatment, you should call your doctor and seek emergency medical care right away.

## These symptoms include:

- Fever
- Cough
- Trouble breathing
- Rash
- Decreased urination
- Dizziness or light-headedness
- Rapid weight gain
- Swelling of arms and legs



## REMEMBER!

**Call your doctor and get emergency medical care right away if you have any of these symptoms.** Show this card in the emergency room and to any healthcare provider involved in your care.

Patient name

Prescriber name

Prescriber phone number

Current medication(s)

## Information for Healthcare Providers



This patient is taking a medication for the treatment of acute myeloid leukemia (AML) that can cause differentiation syndrome.

Differentiation syndrome may be life-threatening or fatal if untreated.

If this patient presents with signs or symptoms of differentiation syndrome:

- Evaluate urgently
- Provide all supportive care
- Contact the prescribing physician (see information at left) as soon as possible to coordinate care

If differentiation syndrome is suspected:

- Administer systemic corticosteroids and initiate hemodynamic monitoring until symptom resolution and for a minimum of 3 days
- Interrupt the AML medication if severe signs and/or symptoms persist for more than 48 hours after initiation of systemic corticosteroids
- Resume the AML medication when signs and symptoms improve to Grade 2 or lower

For additional management information, visit **[understand-ds.com](http://understand-ds.com)**.

To report adverse events, call Agios Medical Information at 1-833-228-8474.

Please see Important Safety Information on following pages and [full Prescribing Information](#), including Boxed WARNING and [Medication Guide](#), available at [Tibsovo.com](http://Tibsovo.com).

## What is TIBSOVO?

TIBSOVO (ivosidenib) 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.

Please see additional Important Safety Information on next page and [full Prescribing Information](#), including **Boxed WARNING** and [Medication Guide](#), available at [Tibsovo.com](http://Tibsovo.com).

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.

**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.

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