

TIBSOVO®

Consumer Medicine Information (CMI) summary

This medicine is new or being used differently. Please report side effects. The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using TIBSOVO?

TIBSOVO contains the active ingredient ivosidenib. TIBSOVO is used to **treat specific cancers (bile duct cancer and Acute myeloid leukaemia (AML)) that contain a particular mutated (abnormal) form of the isocitrate dehydrogenase 1 (IDH1) enzyme.** For more information, see Section [1. Why am I using TIBSOVO?](#) in the full CMI.

2. What should I know before I use TIBSOVO?

WARNING: DIFFERENTIATION SYNDROME AND QTc INTERVAL PROLONGATION.

TIBSOVO can cause Differentiation Syndrome in patients with AML, which is a severe reaction to medicines used to treat leukaemia . Symptoms may include: fever; cough; trouble breathing; weight

gain; rash; decreased urination; dizziness or light-headedness; rapid weight gain; and swelling of the arms, legs, and neck. TIBSOVO can also cause QTc Interval Prolongation, regardless of the type of cancer a person has, which can cause life-threatening irregular heartbeats. Symptoms may include feeling dizzy, light-headed or faint. These conditions can be life-threatening or lead to death if not treated. Seek urgent medical attention or go straight to the Emergency Department at your nearest hospital if you notice any of these symptoms.

Do not use if you have ever had an allergic reaction to TIBSOVO or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use TIBSOVO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TIBSOVO and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use TIBSOVO?

The usual dose of TIBSOVO is two tablets to be taken once daily at approximately the same time each day. In some cases your doctor may tell you to take a reduced dose if you are taking some other medicines or to help you better tolerate some possible side effects. It is important to follow the instructions provided and use TIBSOVO until your doctor tells you to stop. More instructions can be found in Section [4. How do I use TIBSOVO?](#) in the full CMI.

5. What should I know while using TIBSOVO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using TIBSOVO.• Continue regular monitoring (e.g. echocardiogram and/or blood tests) as directed by your doctor.
Things you should not do	<ul style="list-style-type: none">• Do not take TIBSOVO along with a high-fat meal.• Do not have grapefruit or grapefruit juice during treatment with TIBSOVO

	<p>as it can affect how this medicine works.</p> <ul style="list-style-type: none"> • You should not take TIBSOVO together with certain medications including dabigatran, St. John's wort, rifampicin or certain medicines used to treat epilepsy (e.g. carbamazepine, phenobarbital, phenytoin).
Looking after your medicine	<ul style="list-style-type: none"> • Store in a cool dry place away from moisture, heat, and sunlight. Keep out of reach of children. • Close the bottle lid tightly to prevent moisture.

For more information, see Section [5. What should I know while using TIBSOVO?](#) in the full CMI.

6. Are there any side effects?

TIBSOVO is usually well tolerated, however all medications may have unwanted effects in some people. Always tell your healthcare provider about any side effects that you experience. For more information,

including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems

TIBSOVO®

Active ingredient(s): *ivosidenib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TIBSOVO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TIBSOVO.**

Where to find information in this leaflet:

- [1. Why am I using TIBSOVO?](#)
- [2. What should I know before I use TIBSOVO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use TIBSOVO?](#)
- [5. What should I know while using TIBSOVO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using TIBSOVO?

TIBSOVO contains the active substance ivosidenib.

TIBSOVO is used to treat specific cancers (bile duct cancer and acute myeloid leukaemia) that contain a particular mutated (abnormal) form of the IDH1 enzyme.

When the IDH1 enzyme is mutated, metabolic changes in the cell can lead to the development of cancer. TIBSOVO blocks the effects of the mutated enzyme and helps to slow or stop the cancer from growing.

TIBSOVO can be used to treat adults with bile duct cancer (also known as 'cholangiocarcinoma'). It is used to treat patients whose bile duct cancer has spread to other parts of the body and when therapy with other anti-cancer medicines are no longer working.

TIBSOVO can also be used alone or in combination with another anti-cancer medicine called azacitidine, to treat adults with acute myeloid leukaemia (AML) who are not eligible to receive intensive chemotherapy.

TIBSOVO can also be used alone in adults with AML when the disease has come back or has not improved after previous treatment(s).

TIBSOVO is only used in patients whose cancer is related to a particular mutation (called R132) in the IDH1 enzyme.

Your doctor will have performed a test confirming the cancer contains the R132-mutated IDH1 enzyme before deciding that this medicine is the right treatment for you.

Speak to your doctor if you have any questions about this test and the results.

2. What should I know before I use TIBSOVO?

There are some people who shouldn't take TIBSOVO. Please read the list below. If you think any of these situations apply to you or you have any questions, please see your doctor.

Warnings

Do not use TIBSOVO if:

- you are allergic to ivosidenib or any of the other ingredients of this medicine (listed in section 3); or
- you are already taking medicines such as dabigatran, St. John's wort, rifampicin or certain medicines used to treat epilepsy (e.g. carbamazepine, phenobarbital, phenytoin).

Precautions when taking TIBSOVO:

- If you have AML, and if your cancer responds to treatment, TIBSOVO can cause a serious condition known as Differentiation Syndrome, which can be life-threatening if not treated. Seek urgent medical attention if you develop fever; cough; trouble breathing; weight gain; rash; swelling of the arms, legs, and neck; build-up of excess fluid around the

heart and lungs; or low blood pressure (see "Serious side effects" in Section 6. Are there any side effects?).

- TIBSOVO can cause a serious condition known as QTc interval prolongation, which can cause life-threatening irregular heartbeats. Seek urgent medical attention if you feel dizzy, light-headed or faint (see also Section 6. Are there any side effects?) after taking TIBSOVO.
- Guillain-Barré syndrome has happened in patients treated with TIBSOVO. Your doctor will monitor you for nervous system problems. Tell your doctor if you develop 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.

If you get any of the above serious side effects, your doctor may give you other medicines to treat them and they may tell you to stop taking TIBSOVO for a while or stop taking it altogether.

Check with your doctor if:

- you have heart problems including a condition called long QT syndrome or have problems with abnormal electrolyte levels (such as sodium, potassium, calcium or magnesium);
- you are taking certain medicines that can affect the heart (e.g. those used to prevent arrhythmia called anti-arrhythmics, some antibiotics, some antifungals and those used to prevent nausea and vomiting - see also Section [3. What if I am taking other medicines?](#));

- you have kidney problems; and/or
- you have liver problems.

Other side effects that could happen during treatment are described under Section 7. It is important you understand these risks and how to look out for them.

Pregnancy and breastfeeding

It is important to tell your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

Pregnancy

TIBSOVO is not recommended for use during pregnancy as it may harm the unborn baby. People of child-bearing age should have a pregnancy test prior to starting treatment with TIBSOVO and should avoid becoming pregnant during therapy.

If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Contact your doctor or nurse immediately if you become pregnant whilst taking TIBSOVO.

As TIBSOVO may affect an unborn developing baby, it is important for women not to become pregnant for at least 1 month after treatment discontinuation.

Contraception

People who might become pregnant, and people who have partners who might become pregnant, should use effective contraception during treatment with TIBSOVO and for at least 1 month after the last dose.

TIBSOVO may stop hormonal contraceptives from working properly. If you or your partner use a hormonal contraceptive (e.g. birth control pills, or contraceptive patches or implants), you should also use a barrier method (e.g. condoms or a diaphragm) to avoid pregnancy. Talk to your doctor or nurse about the right contraceptive method for you.

Breastfeeding

It is not known if TIBSOVO passes into breast milk. Do not breastfeed your baby during treatment with TIBSOVO and for at least 1 month after the last dose.

Fertility

It is not known if TIBSOVO affects fertility. If you are concerned about your fertility whilst taking TIBSOVO talk to your doctor.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years old because there is no information about its use in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

This is because they may reduce how well TIBSOVO works or increase the risk of side effects, or TIBSOVO may affect the way these other medicines work.

In particular, tell your doctor if you are taking any of the following medications:

- **antibiotics** used for bacterial infections (e.g. erythromycin, clarithromycin, benzylpenicillin, ciprofloxacin, levofloxacin);
- **warfarin** (used to stop blood clots);
- **medicines used for fungal infections** (e.g. itraconazole, ketoconazole, fluconazole, isavuconazole, posaconazole, voriconazole);
- **medicines that affect your heartbeat** known as anti-arrhythmics (e.g. diltiazem, verapamil, quinidine);
- **medicines used to stop nausea and vomiting** known as anti-emetics (e.g. aprepitant, ondansetron, tropisetron, granisetron);
- **medicines used after organ transplants** known as immunosuppressants (e.g. ciclosporin, everolimus, sirolimus, tacrolimus);
- **medicines used for HIV** (e.g. raltegravir, ritonavir);
- **alfentanil** (used for anaesthesia in surgery);
- **fentanyl** (used for severe pain);

- **pimozide** (used for schizophrenia);
- **medicines used for cancer** (e.g. cyclophosphamide, ifosfamide, paclitaxel);
- **methadone** (used for morphine or heroin addiction, or severe pain);
- **medicines used for type 2 diabetes** (e.g. pioglitazone, repaglinide);
- **omeprazole** (used for stomach ulcers and acid reflux);
- **furosemide** (used for fluid build-up known as oedema);
- **medicines used for high cholesterol** known as statins (e.g. atorvastatin, pravastatin, rosuvastatin); and/or
- **lamotrigine** (used for epilepsy).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TIBSOVO.

4. How do I use TIBSOVO?

How much to take / use

Always take this medicine exactly as your doctor has instructed. Check with your doctor if you are unsure.

The recommended dose is **2 tablets** (500 mg ivosidenib) to be taken once daily at approximately the **same time each day**.

Your doctor may tell you to take **1 tablet** (250 mg ivosidenib) if you are **taking some other medicines** or to help you **better tolerate some possible side effects**. Follow the dosage instructions from your doctor.

The tablets can be taken with or without food, but do not take it with fatty foods (e.g. high fat breakfast).

Swallow the tablets whole with water.

Do not swallow the silica gel desiccant found in the bottle. The silica gel desiccant helps protect the tablets from moisture. (See Section [5. What should I know while using TIBSOVO?](#).)

If you vomit after taking your usual dose, do not take additional tablets. Take your next dose as usual the following day.

It is important to follow the instructions provided and use TIBSOVO until your doctor tells you to stop.

When to take / use TIBSOVO

TIBSOVO should be taken **once daily** at approximately the **same time each day**.

If you forget to take TIBSOVO

If a dose is missed or not taken at the usual time, take the tablets as soon as possible unless the next dose is due within 12 hours.

Do not take two doses within 12 hours.

Take the next dose as usual the following day.

If you use too much TIBSOVO

If you think that you have used too much TIBSOVO you may need urgent medical attention.

You should immediately do one of the following:

- phone the Poisons Information Centre (**by calling 13 11 26**);
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do one of the above even if there are no signs of discomfort or poisoning.

TIBSOVO with food and drink

- **Do not** have grapefruit or grapefruit juice during treatment with TIBSOVO as it can affect how this medicine works.
- **Do not take** the tablets with fatty foods (e.g., high fat breakfast), as it can affect how this medicine works

5. What should I know while using TIBSOVO?

Things you should do

Regular Tests

You will be monitored closely by your doctor before and during treatment with TIBSOVO.

You will need to have regular electrocardiograms (ECGs) to monitor your heartbeat, in a hospital. An ECG is a recording of the electrical activity in your heart. You will be given an ECG before you start treatment with TIBSOVO, once a week for the first three weeks of treatment, and then once monthly thereafter.

Call your doctor straight away or go straight to the Emergency Department if you experience any serious side effects.

More information about serious side effects can be found in Section [6. Are there any side effects?](#).

Things you should not do

Do not stop using this medicine without consulting your doctor.

Driving or using machines

This medicine is not likely to affect your ability to drive or use any tools or machines, but if you feel unwell after taking TIBSOVO, do not drive or use any tools or machines until you feel well again.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol could worsen certain side effects that you may have with TIBSOVO.

Looking after your medicine

Store it in a cool dry place away from moisture, heat or sunlight (e.g. high on a pantry shelf away from the stove).

Do not store it in the refrigerator, bathroom, near a sink, in the car, or on windowsills.

Keep the bottle tightly closed in order to protect from moisture.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

Do not use this medicine after the expiry date which is printed on the bottle label and box after EXP.

The expiry date is the last day of the printed month.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, please take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. Some side effects may need medical attention.

Ask your doctor or pharmacist if you have any further questions about side effects after reading the below information.

Less serious side effects

Less serious side effects	What to do
<p>Stomach</p> <ul style="list-style-type: none"> • feeling sick, nausea, vomiting, diarrhoea, abdominal pain. • fluid and swelling in your stomach area. <p>Liver related</p> <ul style="list-style-type: none"> • yellowing of the skin or eyes (jaundice) which is a sign of reduced flow of bile from the liver. • changes in liver function tests. <p>Respiratory</p> <ul style="list-style-type: none"> • cough <p>Blood</p> <ul style="list-style-type: none"> • lower number of red blood cells (anaemia). Symptoms may include tiredness, headaches, being short of breath when exercising, 	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you or if you don't understand something in this list.</p>


Less serious side effects	What to do
<p>dizziness and looking pale.</p> <ul style="list-style-type: none"> • abnormal white blood cell counts. Symptoms may include chills, fever, sweating or other signs of infection (sore throat). • abnormal platelet counts. Symptoms may include unusual bruising or bleeding. <p>Nervous system</p> <ul style="list-style-type: none"> • headache • changes to the peripheral nerves (peripheral neuropathy). Symptoms may include weakness, pain, numbness, pins and needles in the fingers and toes (paraesthesia). <p>Skin</p> <ul style="list-style-type: none"> • rash <p>Musculoskeletal and connective tissue disorders</p> <ul style="list-style-type: none"> • back pain • joint pain 	

Less serious side effects	What to do
General <ul style="list-style-type: none"> • decreased appetite • fatigue • falls 	

Serious side effects

Serious side effects	What to do
<p>Differentiation Syndrome (see Precautions when taking TIBSOVO):</p> <p>Differentiation syndrome in adults with AML occurred from one day and up to 3 months after starting treatment with TIBSOVO.</p> <p>Signs and symptoms of Differentiation Syndrome include fever; cough; trouble breathing; weight gain; rash; swelling of the arms, legs, and neck; build-up of excess fluid around the heart and lungs; low blood pressure.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Changes to the interval between the heart contracting and relaxing (called QTc interval prolongation).</p> <p>Some or all of these symptoms could be due to a serious condition known as QTc interval prolongation, which can be life-threatening:</p> <ul style="list-style-type: none"> • experience a fast or irregular heart rhythm or heartbeat (QTc prolongation) and/or • feel dizzy, lightheaded, or faint <p>If you are taking TIBSOVO, please show this information to all healthcare providers involved in your care, because this is a new type of medicine and not everyone will be familiar with it.</p> <p>Alternatively, you can scan the QR code below to access a Patient Alert</p>	

Serious side effects	What to do
<p>Card which can be saved to your phone or printed.</p> <p>Keep this information leaflet, or the Patient Alert Card, with you at all times.</p> 	

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What TIBSOVO contains

Active ingredient (main ingredient)	Ivosidenib
Other ingredients (inactive ingredients)	Microcrystalline cellulose Croscarmellose sodium Hypromellose acetate succinate Colloidal anhydrous silica Magnesium stearate Sodium lauryl sulfate Hypromellose Titanium dioxide Lactose monohydrate Triacetin Indigo carmine aluminium lake

Do not take this medicine if you are allergic to any of these ingredients.

What TIBSOVO looks like

TIBSOVO tablets are blue, oval shaped, film-coated tablets approximately 18 mm in length, debossed with 'IVO' on one side and '250' on the other side.



(Tablet image not actual size)

TIBSOVO is available in plastic bottles containing 60 tablets and a silica gel desiccant. The bottles are packaged in a cardboard box; each box contains 1 bottle.

(AUST R 391874).

Who distributes TIBSOVO

Servier Laboratories (Aust.) Pty. Ltd.

www.servier.com.au

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588A Swan Street,

Burnley, 3121, Victoria

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