

Package leaflet: Information for the patient

TIBSOVO® 250 mg film-coated tablets

ivosidenib

▼ 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. See the end of section 4 for how to report side effects.

The name of your medicine is TIBSOVO 250 mg film-coated tablets but will be referred to as Tibsovo throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tibsovo is and what it is used for
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1. What Tibsovo is and what it is used for

What Tibsovo is

Tibsovo contains the active substance ivosidenib.

It is a medicine used to treat specific cancers that contain a mutated (changed) gene that makes a protein known as IDH1, which plays an important role in making energy for cells. When the IDH1 gene is mutated, the IDH1 protein is changed and does not function properly, and this results in changes in the cell which can lead to the development of cancer. Tibsovo blocks the mutated form of the IDH1 protein and helps to slow or stop the cancer from growing.

What Tibsovo is used for

Tibsovo is used to treat adults with:

- acute myeloid leukaemia (AML). When used for patients with AML, Tibsovo will be given in combination with another anti-cancer medicine called 'azacitidine'.
- bile duct cancer (also known as 'cholangiocarcinoma'). Tibsovo is used on its own to treat patients whose bile duct cancer has spread to other parts of the body and who have been treated with at least one prior therapy.

Tibsovo is only used in patients whose AML or bile duct cancer is related to a change (mutation) in the IDH1 protein.

2. What you need to know before you take Tibsovo

Your doctor will perform a test to check if you have a mutation in the IDH1 protein before deciding if this medicine is the right treatment for you.

Do not take Tibsovo

- if you are **allergic** to **ivosidenib** or any of the **other ingredients** of this medicine (listed in section 6);
- if you are already taking medicines such as dabigatran (a medicine used for preventing the formation of blood clots), St. John's wort (an herbal remedy used for depression and anxiety), rifampicin (a medicine used for treating bacterial infections) or certain medicines used to treat epilepsy (e.g. carbamazepine, phenobarbital, phenytoin);
- if you have a heart problem that you were born with called 'congenital long QTc syndrome';
- if you have a familial history of sudden death or an abnormal or irregular heartbeat in the lower chambers of the heart;
- if you have a severe abnormality of electrical activity of the heart that affects its rhythm called 'QTc prolongation'.

Do not take Tibsovo if any of the above applies to you. If you are not sure, talk to your doctor or nurse.

Warnings and precautions

Differentiation syndrome in patients with AML:

Tibsovo can cause a serious condition known as **differentiation syndrome** in patients with AML. This is a condition that affects your blood cells and may be life-threatening if not treated.

Seek urgent medical attention if you have any of the following symptoms after taking Tibsovo:

- fever,
- cough,
- trouble breathing,
- rash,
- decreased urination,
- dizziness or light-headedness,
- rapid weight gain,
- swelling of your arms or legs.

These may be signs of differentiation syndrome.

The pack contains a patient alert card to carry with you at all times. It contains important information for you and your healthcare professionals about what to do if you get any of the symptoms of differentiation syndrome (see section 4).

QTc interval prolongation:

Tibsovo can cause a serious condition known as **QTc interval prolongation** which can cause irregular heartbeats and life-threatening arrhythmias (abnormal electrical activity of the heart that affects its rhythm). Your doctor must check the electrical activity of your heart before and during treatment with Tibsovo (see 'Regular tests').

Seek urgent medical attention if you feel dizzy, light-headed, palpitations or faint (see also section 4) after taking Tibsovo.

During treatment, tell your doctors you are taking Tibsovo before starting any new medicine as these may increase the risk of an abnormal heart rhythm.

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.

Talk to your doctor **before taking** Tibsovo if:

- you have **heart problems** or have **problems with abnormal electrolytes 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 'Other medicines and Tibsovo');
- you have kidney problems;
- you have liver problems.

Regular tests

You will be monitored closely by your doctor before and during treatment with Tibsovo. You will need to have regular electrocardiograms (ECGs; a recording of the electrical activity in your heart) to monitor your heartbeat.

You will be given an ECG before you start treatment with Tibsovo, once a week for the first three weeks of treatment, and then monthly thereafter. Additional ECG may be given as instructed by your doctor. If you start taking certain medicines that can affect your heart, you will be given an ECG before starting and during treatment with the new medicine as needed.

You will also have a blood test before starting treatment with Tibsovo and then regularly thereafter.

If necessary, your doctor may reduce your dose of Tibsovo, interrupt it temporarily or stop it altogether.

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.

Other medicines and Tibsovo

Tell your doctor if you are taking, have recently taken or might take any other medicines. 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, you should **tell your doctor** if you are taking any of the following medicines so that they can decide if your treatment needs to change:

- **antibiotics** used for bacterial infections (e.g. erythromycin, clarithromycin, benzylpenicillin, ciprofloxacin, levofloxacin);
- **warfarin** (used to prevent 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).
- **lamotrigine** (used for epilepsy).

Tibsovo with food and drink

Do not have grapefruit or grapefruit juice during treatment with Tibsovo as it can affect how this medicine works.

Pregnancy, breast-feeding and fertility

Tibsovo is not recommended for use during pregnancy as it may harm the unborn baby.

Women 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.

Contraception

Tibsovo should not be used in pregnancy as it can harm the unborn baby. Women who might become pregnant or men with partners who might become pregnant must use effective contraception to avoid pregnancy 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 must **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.

Breast-feeding

It is not known if Tibsovo passes into breast milk. **Do not** breast-feed 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.

Driving and using machines

This medicine has minor influence on your ability to drive or use any tools or machines. If you feel unwell after taking Tibsovo, do not drive or use any tools or machines until you feel well again.

Tibsovo contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tibsovo

Always take this medicine exactly as your doctor has told you. Check with your doctor or nurse if you are not sure.

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**.

- Take the tablets **without food**. Do not eat anything for **2 hours before** through **1 hour after** taking the tablets.
- Swallow the tablets whole with water.
- **Do not** swallow the **desiccant** found in the bottle. The desiccant helps protect the tablets from moisture. (see section 5 and section 6.)
- If you vomit after taking your usual dose, **do not** take additional tablets. Take your next dose as usual the following day.

If you take more Tibsovo than you should

If you accidentally take more tablets than your doctor prescribed, **seek urgent medical attention** and take the medicine bottle with you.

If you forget to take Tibsovo

If you miss a dose or do not take it 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.

How long to take Tibsovo

You should keep taking this medicine until your doctor tells you to stop. **Do not** stop taking the tablets before discussing it with your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

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4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Seek urgent medical attention if you get any of the following side effects. The symptoms listed below could be due to serious conditions known as **differentiation syndrome** or **QTc interval prolongation**, which can both be life-threatening:

Differentiation syndrome

Contact your doctor straight away if you have any of the following symptoms:

- fever,
- cough,
- trouble breathing,
- rash,
- decreased urination,
- dizziness or light headedness,
- rapid weight gain,
- swelling of your arms or legs.

Some or all of these symptoms may be signs of a condition called differentiation syndrome (may affect more than 1 in 10 people). Differentiation syndrome in patients with AML happened up to 46 days after starting Tibsovo.

Heart rhythm problems (QTc interval prolongation)

Contact your doctor straight away if you have a change in your heartbeat, or if you feel: dizzy, lightheaded, or faint. These maybe signs of a heart problem called QT prolongation (may affect more than 1 in 10 people).

Other side effects

Tell your doctor if you notice any of the following side effects:

For patients with AML

Very common (may affect more than 1 in 10 people):

- vomiting;
- neutropenia (low levels of neutrophils, a type of white blood cell that fights infections);
- thrombocytopenia (low levels of blood platelets which can lead to bleeding and bruising);
- leukocytosis (high levels of white blood cells);
- insomnia (difficulty sleeping);
- pain in extremity, joint pain;
- headache;
- dizziness;
- back pain.

Common (may affect more than 1 in 100 people):

- pain in your mouth or throat;
- peripheral neuropathy (nerve damage in arms and legs causing pain or numbness, burning and tingling);
- leukopenia (low levels of white blood cells).

For patients with bile duct cancer

Very common (may affect more than 1 in 10 people):

- fatigue;
- nausea;
- abdominal pain;
- diarrhoea;
- decreased appetite;
- ascites (a build-up of fluid in the abdomen);
- vomiting;
- anaemia (low levels of red blood cells);
- headache;
- changes in liver function tests (Aspartate aminotransferase increased);
- peripheral neuropathy (nerve damage in arms and legs causing pain or numbness, burning and tingling);
- rash;
- blood bilirubin (a breakdown product of red blood cells) increased which can cause yellowing of the skin and eyes.

Common (may affect more than 1 in 100 people):

- white blood cell count decreased;
- platelet count decreased;
- changes in liver function tests (Alanine aminotransferase increased);
- falls;
- hyperbilirubinemia (high levels of blood bilirubin);
- jaundice cholestatic (build-up of bile causing yellowing of the skin or eyes).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tibsovo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and box after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Keep the bottle tightly closed in order to protect from moisture.

Keep the desiccant inside the bottle (see section 6).

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tibsovo contains

- The active substance is ivosidenib. Each tablet contains 250 milligrams of ivosidenib.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, hypromellose acetate succinate, colloidal silica anhydrous, magnesium stearate, sodium lauryl sulfate (E487), hypromellose, titanium dioxide (E171), lactose monohydrate, triacetin and indigo carmine aluminum lake (E132) (see section 2 'Tibsovo contains lactose and sodium').

What Tibsovo looks like and contents of the pack

- The film-coated tablets are blue, oval shaped with "IVO" on one side and "250" on the other side.
- Tibsovo is available in plastic bottles containing 60 film-coated tablets and a desiccant. The bottles are packaged in a cardboard box; each box contains 1 bottle.

Product Licence Holder and Manufacturer

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Tibsovo 250 mg film-coated tablets

PL 45985/1078

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Leaflet revision date: 14/10/2025

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