

TIBSOVO®

Active ingredient(s): ivosidenib

Consumer Medicine Information

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?
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6. Are there any side effects?
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1. Why am I using TIBSOVO?

TIBSOVO contains the active substance ivosidenib.

TIBSOVO is used to treat specific cancers (such as bile duct cancer) that contain a 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'). TIBSOVO 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 is only used in patients whose bile duct cancer is related to a mutation (change) in the IDH1 enzyme.

Your doctor will have performed a test confirming the change (mutation) in the 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).