



PATIENT CARD_ST_001#00

GENERAL INFORMATIONS	
DIMENSIONS (15)_TIBSOVO 250 MG_LGS_001 16/03/2023 7219_06.02 IRELAND (IRL)	92 x 249 mm ILLUSTRATOR CC Font size: 10 pts Line spacing: 12 pts Font type: Helvetica Neue LT Pro
PRINTABLE COLORS	NON PRINTABLE COLORS
 BLACK	



ivosidenib
film-coated tablets
TIBSOVO
250 mg

**PATIENT ALERT CARD
ACUTE MYELOID LEUKAEMIA**

▼ 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.

Information for healthcare professionals

- Patients treated with Tibsovo have experienced differentiation syndrome which may be life-threatening or fatal if not treated.
- Differentiation syndrome in patients with AML happened up to 46 days after starting treatment.
- Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells. Symptoms include:

Non-infectious leukocytosis, peripheral oedema, pyrexia, dyspnoea, pleural effusion, hypotension, hypoxia, pulmonary oedema, pneumonitis, pericardial effusion, rash, fluid overload, tumour lysis syndrome and creatinine increased.

- If differentiation syndrome is suspected, administer systemic corticosteroid and initiate haemodynamic monitoring until symptom resolution and for a minimum of 3 days.

See the Tibsovo Summary of Product Characteristics for more information.

Please complete this section

Name of patient: _____

Date of birth: _____

Tibsovo start date and dose:

Prescriber/Hospital emergency contact:

**Information for the patient
treated for acute myeloid leukaemia**

This Patient Alert Card contains important information for you and healthcare professionals about Tibsovo.

- Keep this card with you at all times.
- Tell any doctor, pharmacist or nurse that you are taking Tibsovo.

- Contact immediately a healthcare professional and show him the Patient Alert Card if you get any of the symptoms listed below.
- Make sure you use the latest version of this card. This will be the one found in your latest box of tablets.

About your treatment

- Tibsovo is used to treat adults with acute myeloid leukaemia (AML) and is given in combination with another anti-cancer medicine called 'azacitidine'. Tibsovo is only used in patients whose AML is related to a change (mutation) in the IDH1 protein.
- Tibsovo can cause **serious side effects** including a serious condition known as **differentiation syndrome**.

- Differentiation syndrome may be life-threatening if not treated.
- Differentiation syndrome in patients with AML happened up to 46 days after starting treatment.

Seek urgent medical attention if you get any of the following **symptoms** of differentiation syndrome:

- fever
- cough
- trouble breathing

- rash
- decreased urination
- dizziness or light-headedness
- rapid weight gain
- swelling of your arms or legs

See the Tibsovo Package Leaflet for more information.