



**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.

PC5366



**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.**