

CONTENT OF THE PATIENT ALERT CARD

PATIENT ALERT CARD – ACUTE MYELOID LEUKAEMIA

Tibsovo 250 mg film-coated tablets ivosidenib

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.

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: _____