Date: July 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION
Tibsovo▼ 250 mg filmcoated tablets: Interim Supply of Irish packs to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Servier Laboratories Limited is currently experiencing supply disruption with TIBSOVO▼ (ivosidenib) in Great Britain.

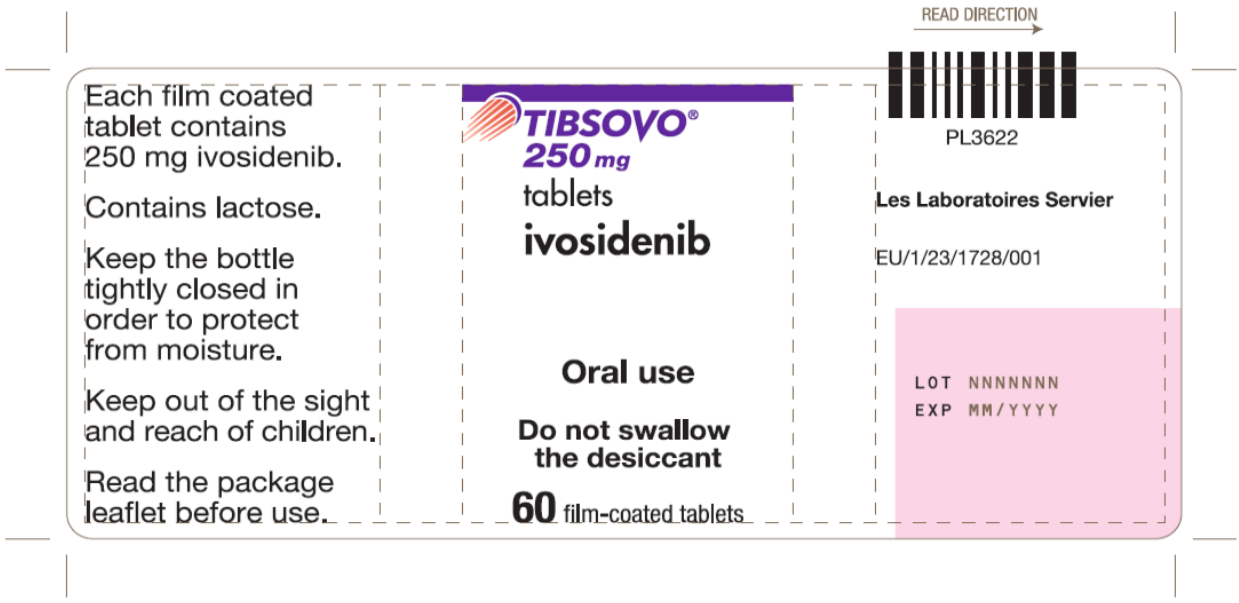
To ensure supply, Servier Laboratories Ltd has obtained approval from the MHRA to supply Irish packs (batch number W072782B, expiry date 09/2026) which is expected to be on the GB market from July 2023.

Please note the following:

- This product is considered licensed in the UK.
- The product from Ireland has the same formulation as the UK product.
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Irish packs and expected UK(GB) packs.
- Please ensure the UK(GB) Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please see on page 2 a mock-up of the Irish packs that will be provided.
- This DHPC will be supplied with each UK(GB) order of Irish packs.
- Tibsovo is indicated:
    - in combination with azacitidine is indicated for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive standard induction chemotherapy.
    - in monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with an IDH1 R132 mutation who were previously treated by at least one prior line of systemic therapy.
- Product Information for Tibsovo is available via The Electronic Medicines Compendium at http://www.medicines.org.uk/emc/product/14886
- For additional copies of the leaflet, please refer to http://www.medicines.org.uk/emc/product/14886/pil or contact the company contact point (see below).
- The MHRA has agreed to an exemption according to regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Tibsovo.

Please ensure all relevant staff are made aware of the content of this letter.


TIBSOVO®
250 mg
film-coated tablets
ivosidenib
Each film coated tablet contains 250 mg ivosidenib.
Contains lactose.
Read the package leaflet before use.
Oral use
Do not swallow the desiccant
60 film-coated tablets
Keep out of the sight and reach of children.
Keep the bottle tightly closed in order to protect from moisture.
SERVIER
Les Laboratoires Servier
50, rue Carnot
92284 Suresnes cedex – France
Ireland
United Kingdom (Northern Ireland)
Malta
POM
EU/1/23/1728/001
READ DIRECTION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PL3622
Les Laboratoires Servier
EU/1/23/1728/001
LOT NNNNNNN
EXP MM/YYYY

Call for reporting
Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Tibsovo ▼ is subject to additional monitoring identified by the black triangle. Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Company contact point

If you have any questions about this letter or wish more information about Tibsovo, please contact Servier Laboratories Limited Medical Information by

- Telephone: 01753 666409 or
- Email: Medical.Information-UK@Servier.com

Yours faithfully,

Florent TEXIER
Managing Director
Servier Laboratories Limited for Les Laboratoire Servier (MAH)

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