Recordati Netherlands B.V.
Beechavenue 54,
1119 PW Schiphol-Rijk
Netherlands

5th Sep 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Fotivda 890 mcg hard capsules (tivozanib), [EU/1/17/1215/001]. Interim Supply of Dutch Language Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Recordati Netherlands B.V. (*formerly EUSA Pharma Netherlands B.V.*) is currently experiencing supply disruption with Fotivda 890 mcg hard capsules (tivozanib).
To ensure continuity in supply, Recordati Netherlands B.V. has obtained approval from the MHRA to supply to Northern Ireland the following product:

- Dutch language: Fotivda 890 mcg hard capsules, Dutch pack [EU/1/17/1215/001] (batch number 4203045I; **import of 30 boxes**).

Please note the following:

- This product is considered licensed in the UK (Northern Ireland).
- The product from the Netherlands has the same formulation as the UK (NI) product.
- The product from the Netherlands is manufactured according to the same manufacturing process and quality controls as the UK (NI) product.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are referred to and followed. SPC and PIL will be provided electronically.
- Discard the Dutch PIL in the pack.
- For additional copies of the Package leaflet, please refer to eMC Northern Ireland website: https://www.emcmedicines.com/en-gb/northernireland/medicine?id=0c2d10fa-82e3-4600-9bd5-971d6d41ad72&type=pil
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Fotivda 890 mcg and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

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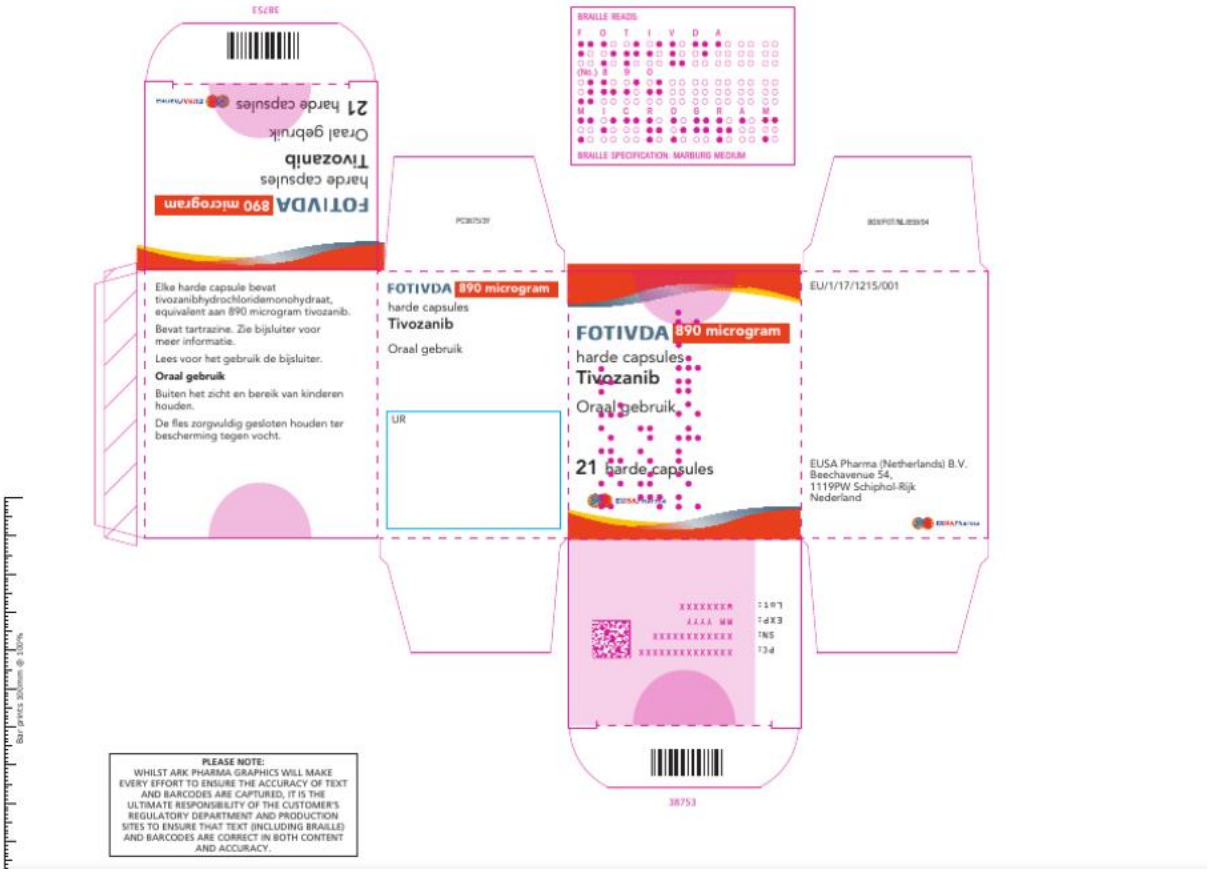
Mock-up of Fotivda 890 mcg hard capsules to be supplied (Dutch language pack)



Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

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You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

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

Company contact point
If you have any questions about this letter, or require more information about Fotivda, please contact Recordati Netherlands B.V. at www.recordatirarediseases.com/products/fotivda.

Yours faithfully

DocuSigned by:
Lucie Bock
EADDADA299FC4FD...

Lucie Bock
Associate Director Quality Assurance and UK RP for EUSA Pharma (UK) Limited

DocuSigned by:
Jean-Philippe Manin
852DF0C8411A4C5...

Jean-Philippe Manin
Head of Quality Oncology and Responsible Person Recordati Netherlands B.V.