Date: May 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Sirturo ▼100 mg (bedaquiline):
Interim Supply of IRISH Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: JANSSEN is currently experiencing supply disruption with Sirturo 100 mg tablets(Bedaquiline) in the UK.

To ensure continuity in supply during the current Covid-19 situation, Janssen has obtained approval from the MHRA to supply Irish product, batch number TMC18041E , Expiry date 30 November 2021, maximum 25 packs , which is expected to be on the UK market from 12th May to 22nd May 2020.

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.
- The product has a European licence there is no differences in Summary of Product Characteristics and the safety information in the Patient Information Leaflet (PIL).
- There are minor differences between the Irish and UK pack and product information. Key differences are:

	UK Current Pack 24 pack -	**Irish Pack 188 pack**
Carton	Local representative- Janssen -Cilag Ltd Tel: +44 1494 567444	Local representative – Janssen-Sciences Ireland UC Tel + 353 1 800 709 122
Label	Foil 4 x 6 tablets	Label, approved EU labelling English text
Leaflet- aligned with EU approved labelling	Adverse event reporting: You can also report side effects directly via the yellow card Scheme at: www.mhra.gov.uk/ yellowcard or search for Yellow Card in the Google Play or Apple App Store Local representative: Janssen -Cilag Ltd 50-100 Holmers Farm Way High Wycombe Buckinghamshire HP 12 4EG UK Tel : +44 1494 567444	Adverse event reporting: In Ireland you can also report d side effects directly via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie Local representative: Janssen-Sciences Ireland UC Barnahely Ringaskiddy IRL – Co. Cork P43 FA46 Tel + 353 1 800 709 122

Janssen-Cilag Ltd. 50–100 Holmers Farm Way
High Wycombe Buckinghamshire HP12 4EG England
Telephone: (01494) 567567 Fax: (01494) 567568
Website: www.janssen-cilag.co.uk
Registered in England 1027904

- Please refer to the UK approved PIL supplied with the Irish packs. Discard the leaflet in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/ or contact the company contact point (see below).

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

Call for reporting

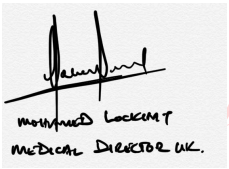
Sirturo▼ (bedaquiline) is subject to additional monitoring. This will allow quick identification of new safety information. All suspected ADRs associated with new drugs identified by the black triangle▼ should be reported.

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 effect 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, treatment dates, and product brand name.

Company contact point
If you have any questions about this letter or wish more information about Sirturo, please contact Janssen Medical Information Department: telephone 01494 567444 or medinfo@its.jnj.com .

Yours faithfully,



Digitally signed by Mohamed Lockhat
Date: 2020.05.14 14:28:35 +01'00'

Mohamed Lockhat

Interim Medical Director
Therapy Area Medical Director

Pulmonary Hypertension, Infectious Diseases & Vaccines, Early Products and Pioneer Portfolio

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