MEDICINES RECALL

CLASS 1 MEDICINES RECALL

Action Now – including out of hours Patient/Pharmacy/Wholesaler Level Recall

Date: 21 October 2022 NatPSA/2022/008/MHRA Our Ref: MDR 111-10/22

Dear Healthcare Professional.

Aventis Pharma Limited t/a Sanofi

Targocid 200mg powder for solution for injection/infusion or oral solution

PL 04425/0088

Batch Number	Expiry Date	Pack Size	First Distributed
0J25D1	30/04/2023	1 vial	28/07/2022
0J25D2	30/04/2023	1 vial	10/08/2022

Active Pharmaceutical Ingredients: Teicoplanin

Brief description of the problem

Sanofi UK is initiating an urgent recall of the above batches of Targocid 200mg powder for solution for injection/infusion or oral solution. This is due to out of specification results obtained for bacterial endotoxins, which has been confirmed through testing of retain samples. This issue was observed following a medical adverse event, which reported that four patients experienced high grade of fever approximately three hours post-administration of vials from the impacted batches. Due to the out of specification results observed there is a potential life threatening or serious risk to patient health.

Advice for healthcare professionals in primary care

- Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Pharmacists and homecare providers involved in dispensing this product should:
 - immediately contact all patients who have been issued the impacted batches and ask them to confirm if they have any affected stock within their possession. If batch traceability information is not available, all patients dispensed this product since 28 July 2022 should be contacted.
 - o appropriately counsel affected patients to contact their General Practitioners (GPs) or other relevant prescribers to arrange a new prescription.
- GPs and other prescribers involved in patient care should also actively seek to identify any
 patients who have been prescribed the impacted product/batches since 28 July 2022 to ensure
 that a new prescription is available for the patient when they return their medicine to the pharmacy.



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Advice for healthcare professionals in secondary care

- Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- In liaison with relevant colleagues, Pharmacy Procurement teams (NHS provider Trust and others) involved in dispensing this product should immediately identify patients who are currently using any impacted batches and source alternative supplies. The Department of Health and Social Care has confirmed that alternative unaffected batches of Targocid and non-proprietary teicoplanin preparations remain available.

Advice for all healthcare professionals

- Healthcare professionals should be aware of the following clinical symptoms related to the
 potential risk to patient health: a high temperature (fever) or low body temperature, chills and
 shivering, cold, clammy and pale or mottled skin, a fast heartbeat, fast breathing, severe
 breathlessness, severe muscle pain, feeling dizzy or faint, a change in mental state such as
 confusion or disorientation, loss of consciousness, slurred speech, nausea and vomiting and/or
 diarrhoea.
- In the event the affected batches have been administered to patients, appropriate clinical
 assessment should be performed, in addition to close monitoring for any adverse reactions. All
 suspected adverse events should also be reported via the MHRA's Yellow Card scheme
 immediately.

Advice for patients

- For most patients, this product is administered by healthcare professionals directly in hospitals. If you have concerns about a medicine you may be using, please contact your healthcare professional.
- If you have been prescribed this medicine to use at home (via intravenous injection/infusion or for use by preparing the solution for oral administration), check to see if you have any of the impacted batches listed above and return to your local pharmacy.
- If you have received an impacted batch and are currently undergoing medical treatment with an
 impacted batch, you should discontinue treatment and seek immediate medical advice on
 alternative supplies and/or monitoring. Alternative teicoplanin medicines can be sourced by
 speaking to your GP or pharmacist. If they have not contacted you within 24 hours, please contact
 them directly or an out-of-hours service to discuss.
- If you are being treated with Targocid 200mg currently and are concerned after experiencing any
 of the symptoms listed below, please seek medical assistance or visit the nearest accident and
 emergency centre:
 - o high temperature (fever) or low body temperature
 - chills and shivering
 - o cold, clammy and pale or mottled skin
 - o a fast heartbeat
 - fast breathing

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- o severe breathlessness
- o severe muscle pain
- o feeling dizzy or faint
- o a change in mental state such as confusion or disorientation
- loss of consciousness
- o slurred speech
- o nausea and vomiting
- o diarrhoea
- o feeling increasingly unwell

Further Information

For more information on licensed stock and resupply queries for the licensed presentation, please contact <u>GB-CustomerServices@sanofi.com</u>; phone number: 0800 854 430.

For medical information queries and all other enquiries, please contact <u>uk-medicalinformation@sanofi.com</u>; phone number: 0800 035 25 25.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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