

RECALL OF TARGOCID 200MG INJECTION IN UK

Date: 31st October, 2022.

Target Audience:

- Healthcare Professionals- Physicians, Pharmacists, and Nurses.
- General Public

Problem or Issue:

Sanofi UK is initiating an urgent recall of two batches of Targocid 200mg powder for solution for injection/infusion or oral solution (Batch Number 0J25D1 and Batch Number 0J25D2). Reason for recall is the out of specification results obtained for bacterial endotoxins in retain samples.

However, both of these batches are not imported or marketed in Pakistan by the authorized registration holder company, hence Pakistan market will not be affected by this recall operation.

Nonetheless, DRAP has directed registration holder company to test the retaining samples of batches supplied in Pakistan to ensure that problem is not extended beyond the identified two batches.

Advice for healthcare professional: -

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 diarrhea.

Adverse reactions or quality problems experienced with the use of this product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using <u>Adverse Event Reporting Form</u> or online through this <u>link</u>. Further information of reporting problems to DRAP is available on this <u>link</u>.

Advice for general public: -

Since, these affected batches have not been imported or supplied in Pakistan by the marketing authorization holder. These batches were supplied and being recalled in the UK market only. However, if any person has carried these batches for their personal use they are advised not to consume it, and consult their healthcare professional immediately.





