Drug Alert

CLASS 1 MEDICINES RECALL

Action Now - including out of hours

Date: 26th April 2017 Our Ref: MDR 7-04/2017

Dear Healthcare Professional,

Biotest Pharma Gmbh

Albiomin 20% Solution for Infusion 200g/l (50ml) MA008/00203
Albiomin 20% Solution for Infusion 200g/l (100ml MA008/00203

Batch Number	Expiry Date	Pack Size	First Distributed
B236356	31/07/19	x 1 vial	3rd November 2016
B236316	30/06/2019	x 1 vial	19th September 2016

Under the supervision of the Medicines Authority, Rodel Ltd. (the local wholesale distributor) in collaboration with Biotest Pharma GmbH is initialising a recall for the listed batches of Albiomin 20% solution for infusion 200g/l (50ml and 100ml).

Biotest recalls batches of Human Albumin due to contamination with ethylene glycol containing cooling liquid.

On April 13th 2017 Biotest requested that specified batches of Human Albumin are placed in quarantine due to a quality defect (see Manufacturer's Safety Notice). Biotest assumes that the affected batches have already been placed in quarantine.

From the two facilities available for the production of Human Albumin (Albiomin®), only one was affected. In this facility, ethylene glycol containing liquid got into the product due to a technical defect (hairline crack in the cooling system).

The cooling liquid is used for temperature control of the manufacturing process. It is considered to be non-cancerogenic, non-mutagenic, and non-reprotoxic.

Analytical data from drug product batches indicated contamination of final drug product batches. Preliminary data had suggested the potential for contamination free batches. Therefore initially a recall was not requested and Biotest communicated to customers the requirement to quarantine batches on April 13th 2017 and to refrain from their usage.

However, ongoing investigations substantiated the suspicion that all batches from the affected manufacturing facility will display a quality defect. In agreement with the relevant supervisory bodies (Paul-Ehrlich-Institute and Regierungspräsidium Darmstadt) Biotest decided to recall all affected batches as a precautionary measure. The batch certification of the affected batches has been withdrawn by the Paul-Ehrlich –Institute on 25 April 2017.

According to current knowledge occurrence of serious adverse reactions due to the contamination are not likely to be expected in exposed patients.

Symptoms of an acute poisoning known from oral ingestion range from mild central nervous symptoms like, somnolence, vertigo, through comatose conditions up to renal and multi organ failure. However these symptoms occur only after acute intake of large quantities of pure ethylene glycol. Under no circumstances have these quantities been reached in the affected and tested batches which are now the subject of this recall.

Yours faithfully

Clint Pace
Medicines Inspector