

Drug Alert

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Date: 24th March 2021

Our Ref: MDR010-03/2021

Dear Healthcare Professional,

Central Procurement & Supplies Unit (CPSU)

Diazepam 2mg/5ml Oral Solution Sugar Free, 100 ml

AA565/51301

Batch Number	Expiry Date	Pack Size	First Distributed
154655	31/07/2021	100ml	11/12/2019
154797	30/09/2021	100ml	17/03/2020
154798	30/09/2021	100ml	17/03/2020

Brief description of the problem

Medicines & Healthcare products Regulatory Agency of United Kingdom (MHRA) issued a Class 4 Medicines Defect Information on 9th March 2021 (Ref. No.: MDR 006-03/21) stating the following:

“Accord-UK Ltd have informed MHRA that important safety warnings for the excipient Propylene glycol are missing from the patient information leaflet (PIL) used in the above batches (including the batches waiting QP certification) which should be present in accordance with the current annex to the Excipient Guidelines. Additionally, the warnings for sorbitol need updating although similar warnings are already present. The product is not subject to recall due to supply and shortage considerations.

The following excipient warnings have now been added to the PIL for future batches:

- Diazepam oral solution contains 409mg Propylene glycol per 5ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

- Diazepam oral solution contains 1.91g to 2.58g of sorbitol per 5ml solution. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. Calorific value 2.6 kcal/g sorbitol.

Advice for healthcare professionals

Healthcare professionals are requested when prescribing this medicine to inform patients and notify them of the information above. There is no risk to product quality as a result of this issue, therefore the associated batches are not being recalled at this time, also taking into consideration potential supply disruptions.

Yours faithfully,



Judit FEMÉR
Senior Medicines Inspector