



Department of
Health

An Roinn Sláinte

Máinnistrie O Poustie

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For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC/07/2021
Date: 09 March 2021

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Dear Healthcare Professional

Accord-UK Ltd

Diazepam 2mg/5ml Oral Solution Sugar Free

PL 0142/0103

Batch Number	Expiry Date	Pack Size	Livery	First Distributed
I54655	31/07/2021	100ml	Accord-UK Ltd	11/12/2019
I54797	30/09/2021	100ml	Accord-UK Ltd	17/03/2020
I54798	30/09/2021	100ml	Accord-UK Ltd	17/03/2020
I55223	28/02/2022	100ml	Accord-UK Ltd	12/05/2020
I55399	30/04/2022	100ml	Accord-UK Ltd	27/07/2020
I55506	31/05/2022	100ml	Accord-UK Ltd	16/09/2020
I55623	31/07/2022	100ml	Accord-UK Ltd	23/11/2020
I55894	31/10/2022	100ml	Accord-UK Ltd	25/01/2021
I54468	30/04/2021	100ml	Almus	24/09/2019
I54799	30/09/2021	100ml	Almus	17/03/2020
I55408	30/04/2022	100ml	Almus	02/09/2020
I55624	31/07/2022	100ml	Almus	22/01/2021

The following batches have been packed and are waiting QP certification:

Diazepam 2mg/5ml Oral Solution Sugar Free

PL 0142/0103

Batch Number	Expiry Date	Pack Size	Description	First Distributed
I56131	31/01/2023	100ml	Accord-UK Ltd	-
I56055	31/12/2022	100ml	Accord-UK Ltd	-
I56132	31/01/2023	100ml	Accord-UK Ltd	-

Active Pharmaceutical Ingredients: diazepam

Brief description of the problem

Accord-UK Ltd have informed us 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 patient's 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. The product is not subject to recall due to supply and shortage considerations.

- Accord-UK have confirmed that they will be providing hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the updated PIL information.
- Additionally, for all batches which have not been certified and are due to be released as per the notification above, Accord-UK have confirmed that they will be providing hard copies of the updated PIL with each delivery.
- Healthcare Professionals can also contact Accord-UK Ltd via the Customer Services Team on 0800373573 and request a hard copy of the updated PIL to be sent to them by post.
- The updated PIL information is available via the eMC website should healthcare professionals need access before hard copies are available:
 - <https://www.medicines.org.uk/emc/product/5783/smpc#gref>

Further Information

For more information or medical information queries, please contact: Accord-UK Ltd Medical Information Department on 01271 385257

For stock control queries, please contact: Accord-UK Ltd Customer Services Team on 0800 373573

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

A handwritten signature in black ink, appearing to read "Cathy Harrison". The signature is fluid and cursive, with a long horizontal stroke at the end.

Mrs Cathy Harrison
Chief Pharmaceutical Officer