



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 23 August 2023

EL (23)A/30

Our Ref: MDR 105-08/23

Dear Healthcare Professional,

Accord Healthcare Limited, UK

Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion

PL 20075/0443

SNOMED Code: 2ml- 35849311000001101

Batch No	Expiry Date	Pack Size	First Distributed
M2212320	06/2025	2ML	21-04-2023
M2212979	08/2025	2ML	18-01-2023

Active Pharmaceutical Ingredient: Irinotecan Hydrochloride

Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion

PL 20075/0443

SNOMED Code: 5ml- 35849511000001107

Batch No	Expiry Date	Pack Size	First Distributed
M2212561	07/2025	5ML	28-11-2022
M2216090	10/2025	5ML	18-04-2023

Active Pharmaceutical Ingredient: Irinotecan Hydrochloride

Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion

PL 20075/0443

SNOMED Code: 15ml- 35849711000001102

Batch No	Expiry Date	Pack Size	First Distributed
G2300725	11/2025	15ML	08-06-2023

Active Pharmaceutical Ingredient: Irinotecan Hydrochloride

Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for Infusion

PL 20075/0443

SNOMED Code: 25ml- 20275211000001106

Batch No	Expiry Date	Pack Size	First Distributed
M2210458	02/2025	25ML	30-11-2022
M2211881	07/2025	25ML	06-01-2023
G2300727	09/2025	25ML	16-06-2023
M2301081	11/2025	25ML	02-06-2023



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Active Pharmaceutical Ingredient: Irinotecan Hydrochloride

**Irinotecan Hydrochloride 20 mg/ml Concentrate for Solution for
Infusion**

PL 20075/0443

SNOMED Code: 50ML-N/A

Batch No	Expiry Date	Pack Size	First Distributed
G2202180	05/2024	50ML	18-01-2023
G2300728	05/2024	50ML	10-07-2023
M2211019	07/2025	50ML	13-10-2022

Active Pharmaceutical Ingredient: Irinotecan Hydrochloride

Brief description of the problem

Accord Healthcare Ltd, UK has informed the MHRA about an error with the Patient Information Leaflets (PILs) that have been packaged in the above batches of these products. The PIL does not include the most up to date safety information regarding the contraindication for Gilbert's syndrome. The full information missing from the PILs is reproduced below.

Missing Information in PIL:

"Section 2. What you need to know before you are given Irinotecan Injection

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Irinotecan Hydrochloride if you have Gilbert's syndrome, an inherited condition that can cause elevated bilirubin levels and jaundice (yellow skin and eyes)."

Advice for healthcare professionals

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the product and where possible, provide an updated PIL. The updated PIL is available electronically and can be downloaded from the Accord website link below:

[PL 20075-0443 - Irinotecan HCL 20mg/ml Concentrate Solution for Infusion-PIL](#)

Healthcare professionals are advised to exercise caution when prescribing this product to UGT1A1 poor metabolisers, such as patients with Gilbert's syndrome, due to an increased risk of severe adverse reactions. Consult the Summary of Product Characteristics for further advice.

[PL 20075-0443 - Irinotecan HCL 20mg/ml Concentrate Solution for Infusion-SmPC](#)

Advice for patients

This issue is about missing information on the Patient Information Leaflets (PILs). The medicine itself is not affected and therefore patients do not need to take any action.



Medicines & Healthcare products Regulatory Agency

Talk to your doctor, pharmacist or nurse before using Irinotecan Hydrochloride if you have Gilbert's syndrome, an inherited condition that can cause elevated bilirubin levels and jaundice (yellow skin and eyes). Your cancer team can provide more information.

These products will have been prescribed and dispensed by the qualified healthcare professional(s) responsible for your care. If you have any concerns, please speak with your cancer team or your healthcare professional in the first instance.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please contact:

Accord Medical Information Department on 01271 385257, email- medinfo@accord-healthcare.com

For stock control enquiries please contact: Accord- Customer Services Team on 0800 373573

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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