**Інформація, отримана з іноземних систем повідомлення про продукцію, що становить серйозний ризик, за період 01.04.2022 – 30.06.2022**

**Великобританія**

[**https://www.gov.uk/drug-device-alerts?keywords=&alert\_type[]=devices&issued\_date[from]=&issued\_date[to]=**](https://www.gov.uk/drug-device-alerts?keywords=&alert_type%5b%5d=devices&issued_date%5bfrom%5d=&issued_date%5bto%5d=)

[**https://www.gov.uk/drug-device-alerts**](https://www.gov.uk/drug-device-alerts)

**https://www.gov.uk/drug-device-alerts?page=2**

* [Field Safety Notices: 27 June to 1 July 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-27-june-to-1-july-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 27 June to 1 July 2022

* + Alert type: Field safety notice
	+ Issued: 4 July 2022
* [Field Safety Notices: 20 to 24 June 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-20-to-24-june-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 20 to 24 June 2022

* + Alert type: Field safety notice
	+ Issued: 27 June 2022
* [Company led medicines recall: A.Vogel Ltd, Linoforce granules 12 years plus (THR 13668/0021), CLMR (22)A/05](https://www.gov.uk/drug-device-alerts/company-led-medicines-recall-avogel-ltd-linoforce-granules-12-years-plus-thr-13668-slash-0021-clmr-22-a-slash-05)

A.Vogel Ltd is recalling a specific batch of Pharmacy only medicine due to a small number of packs that were inadvertently supplied to non-pharmacy retail outlets.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 22 June 2022
* [Field Safety Notices: 13 to 17 June 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-13-to-17-june-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 13 to 17 June 2022

* + Alert type: Field safety notice
	+ Issued: 22 June 2022
* [Class 4 Medicines Defect Information: Altan Pharma Limited, Phenylephrine 0.08 mg/ml - solution for injection/infusion, EL(22)A/29](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-altan-pharma-limited-phenylephrine-0-dot-08-mg-slash-ml-solution-for-injection-slash-infusion-el-22-a-slash-29)

Altan Pharma Limited have identified an error relating to the product packaging. The incorrect concentration of phenylephrine base is provided on the overwrapping bag label.

* + Medical specialism: Anaesthetics and 7 others
	+ Issued: 16 June 2022
* [Company led medicines recall: PCCA Limited, Ketamine 50mg in 5ml Oral Solution and Ketamine 100mg in 5ml Oral Solution (unlicensed medicines), CLMR (22)A/04](https://www.gov.uk/drug-device-alerts/company-led-medicines-recall-pcca-limited-ketamine-50mg-in-5ml-oral-solution-and-ketamine-100mg-in-5ml-oral-solution-unlicensed-medicines-clmr-22-a-slash-04)

PCCA Limited have been made aware of an issue with the appearance of Ketamine 50mg in 5ml Oral Solution and Ketamine 100mg in 5ml Oral Solution.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 15 June 2022
* [Field Safety Notices: 6 to 10 June 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-6-to-10-june-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 6 to 10 June 2022

* + Alert type: Field safety notice
	+ Issued: 13 June 2022
* [Class 2 Medicines Recall: Bristol Laboratories Limited, Phenobarbital 60 mg Tablets, EL(22)A/28](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-bristol-laboratories-limited-phenobarbital-60-mg-tablets-el-22-a-slash-28)

Bristol Laboratories Limited are recalling a batch of this product as a precautionary measure due to low dissolution test results reported during ongoing stability studies.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 13 June 2022
* [Field Safety Notices: 30 May to 3 June 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-30-may-to-3-june-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 30 May to 3 June 2022.

* + Alert type: Field safety notice
	+ Issued: 7 June 2022
* [Class 4 Medicines Defect Information: OxyContin 20 mg prolonged release tablets, EL (22)A/27](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-oxycontin-20-mg-prolonged-release-tablets-el-22-a-slash-27)

Napp Pharmaceuticals Limited have identified an error relating to the Braille printed on the cartons. The Braille message on the Oxycontin 20mg prolonged release tablets incorrectly states strength as 15mg.

* + Medical specialism: Dispensing GP practices and 2 others
	+ Issued: 1 June 2022
* [Class 4 Medicines Defect Information: Esomeprazole 40mg Powder for Solution for Injection/Infusion, EL (22)A/26](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-esomeprazole-40mg-powder-for-solution-for-injection-slash-infusion-el-22-a-slash-26)

DEMO SA PHARMACEUTICAL INDUSTRY has informed us that the Product Code/GTIN (PC) number found on the above batch is incorrect. The GTIN number that should have been allocated for this batch is 5200040321010.

* + Medical specialism: Dispensing GP practices and 2 others
	+ Issued: 31 May 2022
* [Field Safety Notices: 23 to 27 May 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-23-to-27-may-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 23 to 27 May 2022.

* + Alert type: Field safety notice
	+ Issued: 30 May 2022
* [Company led medicines recall: Consilient Health UK Ltd, Invita D3 800 IU Soft Capsules, CLMR (22)A/03](https://www.gov.uk/drug-device-alerts/company-led-medicines-recall-consilient-health-uk-ltd-invita-d3-800-iu-soft-capsules-clmr-22-a-slash-03)

Consilient Health UK Ltd is recalling a specific batch due to limited units from the batch being distributed prior to batch release.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 30 May 2022
* [Class 4 Medicines Defect Information: Orifarm UK Ltd, Loprazolam 1mg Tablets, EL (22)A/25](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-orifarm-uk-ltd-loprazolam-1mg-tablets-el-22-a-slash-25)

Orifarm UK have informed us of an error with the Patient Information Leaflet (PIL) packaged within the packs of certain batches. The product name stated in the heading of the PIL has been spelt incorrectly as “lorazolam”, in…

* + Medical specialism: Dispensing GP practices and 2 others
	+ Issued: 26 May 2022
* [National Patient Safety Alert: NovoRapid PumpCart in the Roche Accu-Chek Insight insulin pump: risk of insulin leakage causing hyperglycaemia and diabetic ketoacidosis (NatPSA/2022/004/MHRA)](https://www.gov.uk/drug-device-alerts/national-patient-safety-alert-novorapid-pumpcart-in-the-roche-accu-chek-insight-insulin-pump-risk-of-insulin-leakage-causing-hyperglycaemia-and-diabetic-ketoacidosis-natpsa-slash-2022-slash-004-slash-mhra)

The MHRA continues to receive serious reports of harm associated with insulin leakage for the NovoRapid PumpCart prefilled insulin cartridge in the Accu-Chek Insight Insulin pump. In some patients, there were serious consequ…

* + Alert type: National patient safety alert
	+ Medical specialism: Dispensing GP practices and 3 others
	+ Issued: 26 May 2022
* [Class 2 Medicines Recall: hameln pharma ltd, Water for Injections BP – 100ml vial, EL (22)A/24](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-hameln-pharma-ltd-water-for-injections-bp-100ml-vial-el-22-a-slash-24)

hameln pharma ltd are recalling batches of product additional to the batch recalled on 15 February 2022 (reference EL(22)A/06).

* + Medical specialism: Pharmacy
	+ Issued: 25 May 2022
* [Field Safety Notices: 16 to 20 May 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-16-to-20-may-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 16 to 20 May 2022.

* + Alert type: Field safety notice
	+ Issued: 24 May 2022
* [Class 4 Medicines Defect Information: GlaxoSmithKline UK Ltd, Zovirax I.V. 500 mg, EL (22)A/22](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-glaxosmithkline-uk-ltd-zovirax-iv-500-mg-el-22-a-slash-22)

GlaxoSmithKline UK Ltd have informed the MHRA that an incorrect version of the Summary of Product Characteristics section 4.2 and the Patient Information Leaflet is inside the sealed pack, and contains unapproved text.

* + Medical specialism: Critical care and 8 others
	+ Issued: 9 May 2022
* [Class 2 Medicines Recall: Quadrant Pharmaceuticals Ltd, Mefenamic Acid 500mg film coated tablets, EL (22)A/23](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-quadrant-pharmaceuticals-ltd-mefenamic-acid-500mg-film-coated-tablets-el-22-a-slash-23)

Quadrant Pharmaceuticals Ltd are recalling a specific batch of Mefenamic Acid 500mg Film-Coated Tablets as a precautionary measure, due to observations of a defective layer of film coating in some tablets, resulting in the t…

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 17 May 2022
* [Field Safety Notices: 09 to 13 May 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-09-to-13-may-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 09 to 13 May 2022

* + Alert type: Field safety notice
	+ Issued: 16 May 2022
* [Field Safety Notices: 02 to 06 May 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-02-to-06-may-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 02 to 06 May 2022

* + Alert type: Field safety notice
	+ Issued: 9 May 2022
* [Class 2 Medicines Recall: Pfizer Limited, Accupro 5mg, 10mg, 20mg, 40mg film-coated tablets, EL(22)A/21](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-pfizer-limited-accupro-5mg-10mg-20mg-40mg-film-coated-tablets-el-22-a-slash-21)

Pfizer Limited are recalling all batches of Accupro 5mg, 10mg, 20mg, 40mg film-coated tablets as a precautionary measure

* + Medical specialism: Dispensing GP practices and 2 others
	+ Issued: 5 May 2022
* [Field Safety Notices: 25 to 29 April 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-25-to-29-april-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 25 to 29 April 2022

* + Alert type: Field safety notice
	+ Issued: 3 May 2022
* [Class 2 Medicines Recall: Fresenius Kabi Limited, Sodium bicarbonate 1.26% Solution for infusion, EL(22)A/20](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-fresenius-kabi-limited-sodium-bicarbonate-1-dot-26-percent-solution-for-infusion-el-22-a-slash-20)

Fresenius Kabi Limited are recalling a specific batch of product as a precautionary measure due to the identification of particles in the solution for injection, following routine batch analysis and subsequent batches manufa…

* + Medical specialism: Anaesthetics and 20 others
	+ Issued: 28 April 2022
* [Class 2 Medicines Recall: Crescent Pharma Limited, Paroxetine 40mg Film Coated Tablets, EL(22)A/19](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-crescent-pharma-limited-paroxetine-40mg-film-coated-tablets-el-22-a-slash-19)

Crescent Pharma Limited are recalling a specific batch of Paroxetine 40mg Film Coated Tablets as a precautionary measure.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 27 April 2022
* [Field Safety Notices: 18 to 22 April 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-18-to-22-april-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 18 to 22 April 2022

* + Alert type: Field safety notice
	+ Issued: 25 April 2022
* [Class 4 Medicines Defect Information: Pfizer Limited, Depo-Medrone with Lidocaine 40 mg/mL (1 mL and 2 mL vials – single vial preparations), EL (22)A/18](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-pfizer-limited-depo-medrone-with-lidocaine-40-mg-slash-ml-1-ml-and-2-ml-vials-single-vial-preparations-el-22-a-slash-18)

Pfizer Limited have informed the MHRA that an outdated version of the Patient Information Leaflet (PIL) has been included in the packaging of the specific batches mentioned in this notification.

* + Medical specialism: Dispensing GP practices and 2 others
	+ Issued: 21 April 2022
* [Field Safety Notices: 11 to 15 April 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-11-to-15-april-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 11 to 15 April 2022

* + Alert type: Field safety notice
	+ Issued: 19 April 2022
* [Field Safety Notices: 4 to 8 April 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-4-to-8-april-2022)

Summary List of field safety notices (FSNs) from medical device manufacturers from 4 to 8 April 2022

* + Alert type: Field safety notice
	+ Issued: 11 April 2022
* [Class 2 Medicines Recall: USV UK Limited, Olopatadine USV 1mg/ml Eye Drops, Solution, EL(22)A/17](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-usv-uk-limited-olopatadine-usv-1mg-slash-ml-eye-drops-solution-el-22-a-slash-17)

USV UK Limited are recalling specific batches of products as a precautionary measure due to out of specification results for impurities during routine stability testing.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 11 April 2022
* [Paclitaxel drug-coated balloons (DCBs) or drug-eluting stents (DESs): Updated position on use in patients with critical limb ischaemia and intermittent claudication DSI/2022/003](https://www.gov.uk/drug-device-alerts/paclitaxel-drug-coated-balloons-dcbs-or-drug-eluting-stents-dess-updated-position-on-use-in-patients-with-critical-limb-ischaemia-and-intermittent-claudication-dsi-slash-2022-slash-003)

The MHRA’s recommendations for using paclitaxel-coated devices in patients with intermittent claudication and critical limb ischaemia.

* + Alert type: Device safety information
	+ Medical specialism: Cardiology and 2 others
	+ Issued: 5 April 2022