**Інформація, отримана з іноземних систем повідомлення про продукцію, що становить серйозний ризик, за період 01.01.2022 – 31.03.2022**

**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**

* [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
* [Field Safety Notices: 28 March to 1 April 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-28-march-to-1-april-2022)

List of field safety notices (FSNs) from medical device manufacturers from 28 March to 1 April 2022.

* + Alert type: Field safety notice
	+ Issued: 4 April 2022
* [Field Safety Notices: 21 to 25 March 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-21-to-25-march-2022)

List of field safety notices (FSNs) from medical device manufacturers from 21 to 25 March 2022.

* + Alert type: Field safety notice
	+ Issued: 28 March 2022
* [Class 2 Medicines Recall: Pfizer Limited, Accuretic 10/12.5 mg film-coated tablets, EL (22)A/16](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-pfizer-limited-accuretic-10-slash-12-dot-5-mg-film-coated-tablets-el-22-a-slash-16)

Pfizer Ltd are recalling batch number DD4842 as a precautionary measure due to the identification of a nitrosamine above the acceptable limit.

* + Medical specialism: Dispensing GP practices and 2 others
	+ Issued: 28 March 2022
* [Field Safety Notices: 14 to 18 March 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-14-to-18-march-2022)

List of field safety notices (FSNs) from medical device manufacturers from 14 to 18 March 2022.

* + Alert type: Field safety notice
	+ Issued: 21 March 2022
* [Class 4 Medicines Defect Information: Benzylpenicillin benzathine 1.2 Million I.U. and 2.4 Million I.U. powder and solvent for suspension for injection, EL (22)A/15](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-benzylpenicillin-benzathine-1-dot-2-million-iu-and-2-dot-4-million-iu-powder-and-solvent-for-suspension-for-injection-el-22-a-slash-15)

Brancaster Pharma Limited have notified us of an issue relating to the label of the Water for Injections (solvent) packaged in each finished product pack.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 17 March 2022
* [Company led medicines recall: Advanced Accelerator Applications NETSPOT (Kit for the preparation of gallium Ga 68 dotatate injection) [unlicensed medicine], CLMR (22)A/02](https://www.gov.uk/drug-device-alerts/company-led-medicines-recall-advanced-accelerator-applications-netspot-kit-for-the-preparation-of-gallium-ga-68-dotatate-injection-unlicensed-medicine-clmr-22-a-slash-02)

Advanced Accelerator Applications is recalling specific batches of this product as a precautionary measure due to an out of specification result that was identified during stability testing.

* + Medical specialism: Pharmacy
	+ Issued: 16 March 2022
* [Field Safety Notices: 7 to 11 March 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-7-to-11-march-2022)

List of field safety notices (FSNs) from medical device manufacturers from 7 to 11 March 2022.

* + Alert type: Field safety notice
	+ Issued: 15 March 2022
* [Class 4 Medicines Defect Information, Ayrton Saunders Limited, Beclometasone dipropionate 50 micrograms/dose Nasal Spray (Various Liveries), EL (22)A/14](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-ayrton-saunders-limited-beclometasone-dipropionate-50-micrograms-slash-dose-nasal-spray-various-liveries-el-22-a-slash-14)

Ayrton Saunders Limited have identified an error relating to the Braille printed on the cartons.

* + Medical specialism: Pharmacy
	+ Issued: 15 March 2022
* [Class 4 Medicines Defect Information: CNX Therapeutics Ltd, Latuda film-coated tablets, EL (22)A/13](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-cnx-therapeutics-ltd-latuda-film-coated-tablets-el-22-a-slash-13)

CNX Therapeutics Ltd. have notified the MHRA that the batches of Latuda film-coated tablets listed in this notification will be released without EAN barcodes on the cartons.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 14 March 2022
* [Class 4 Medicines Defect Information: Boots Company Plc, Decongestant Tablets and Decongestant with Pain Relief Tablets, EL (22)A/12](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-boots-company-plc-decongestant-tablets-and-decongestant-with-pain-relief-tablets-el-22-a-slash-12)

Boots have identified an error with the printed patient information leaflet provided with batches of the Decongestant Tablets and Decongestant with Pain Relief Tablets.

* + Medical specialism: Pharmacy
	+ Issued: 10 March 2022
* [Field Safety Notices: 28 February to 4 March 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-28-february-to-4-march-2022)

List of field safety notices (FSNs) from medical device manufacturers from 28 February to 4 March 2022.

* + Alert type: Field safety notice
	+ Issued: 8 March 2022
* [Class 2 Medicines Recall: Wockhardt UK Ltd, Diazepam RecTubes 2.5mg Rectal Solution, EL (22)A/11](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-wockhardt-uk-ltd-diazepam-rectubes-2-dot-5mg-rectal-solution-el-22-a-slash-11)

Wockhardt UK Ltd are recalling a batch of Diazepam RecTubes 2.5mg Rectal Solution due to an out of specification result for assay during routine stability testing.

* + Medical specialism: Dispensing GP practices and 1 others
	+ Issued: 7 March 2022

 [Field Safety Notices: 21 to 25 February 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-21-to-25-february-2022)

List of field safety notices (FSNs) from medical device manufacturers from 21 to 25 February 2022.

* Alert type: Field safety notice
* Issued: 2 March 2022

 [Class 3 Medicines Recall: Kyowa Kirin Services Ltd. Isotard 60mg XL Tablets, EL (22)A/10](https://www.gov.uk/drug-device-alerts/class-3-medicines-recall-kyowa-kirin-services-ltd-isotard-60mg-xl-tablets-el-22-a-slash-10)

Kyowa Kirin Services Ltd. are recalling a batch of Isotard 60mg XL Tablets as a precautionary measure due to microfibres/crystals of the Active Pharmaceutical Ingredient (API) being present on the surface of the tablets…

* Medical specialism: Dispensing GP practices and 1 others
* Issued: 2 March 2022

 [UPDATE: Class 4 Medicines Defect Information: Atnahs Pharma UK Limited, Naprosyn Tablets (all strengths), Naprosyn EC 250mg Gastro-Resistant Tablets, Naprosyn EC 500mg Gastro-Resistant Tablets, EL (22)A/09](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-atnahs-pharma-uk-limited-naprosyn-tablets-all-strengths-naprosyn-ec-500mg-gastro-resistant-tablets-el-22-a-slash-09)

Atnahs Pharma UK Limited have identified additional missing information on the PIL of the certain product batches.

* Medical specialism: Dispensing GP practices and 1 others
* Issued: 23 February 2022

 [Field Safety Notices: 14 to 18 February 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-14-to-18-february-2022)

List of field safety notices (FSNs) from medical device manufacturers from 14 to 18 February 2022.

* Alert type: Field safety notice
* Issued: 21 February 2022

 [Class 2 Medicines Recall: medac GmbH (t/a medac Pharma LLP), Fluorouracil Injection, 50 mg/ml, solution for injection (2500mg/50ml vial), EL (22)A 08](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-medac-gmbh-t-slash-a-medac-pharma-llp-fluorouracil-injection-50-mg-slash-ml-solution-for-injection-2500mg-slash-50ml-vial-el-22-a-08)

medac GmbH (t/a medac Pharma LLP) are recalling certain product batches as a precautionary measure due to visual detection of glass lamellae particles during an ongoing stability study.

* Medical specialism: Dispensing GP practices and 1 others
* Issued: 17 February 2022

 [Surdial X Haemodialysis machine: potential for devices to remove excess fluid outside of machine specification. DSI/2022/002](https://www.gov.uk/drug-device-alerts/surdial-x-haemodialysis-machine-potential-for-devices-to-remove-excess-fluid-outside-of-machine-specification-dsi-slash-2022-slash-002)

The MHRA are aware of instances of Surdial X machines removing excess fluid via ultrafiltration outside of its specification. There is a risk to patients who are unable to tolerate excess fluid removal.

* Alert type: Device safety information
* Medical specialism: Renal medicine
* Issued: 17 February 2022

 [Stop using Vaginal Speculums with smoke tube and Gynaecological Hysteroscopy sheaths from Gemini Surgical UK: all lots and batches. DSI/2022/001](https://www.gov.uk/drug-device-alerts/stop-using-vaginal-speculums-with-smoke-tube-and-gynaecological-hysteroscopy-sheaths-from-gemini-surgical-uk-all-lots-and-batches-dsi-slash-2022-slash-001)

The MHRA has become aware that Vaginal Speculums with smoke tube and Gynaecological Hysteroscopy sheaths from Gemini Surgical UK are being sold with a falsely applied CE mark. This means that these devices have been sold wit…

* Alert type: Device safety information
* Medical specialism: General surgery and 1 others
* Issued: 17 February 2022

 [Class 2 Medicines Recall: Uni Health Distribution, Efudix 5% w/w cream, EL (22)A 07](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-uni-health-distribution-efudix-5-percent-w-slash-w-cream-el-22-a-07)

Uni Health Distribution is aware of a potential issue where the leaflet contained within Efudix 5% w/w cream (2 x 20g) pack, batch 80193439/B may be incorrect.

* Medical specialism: Pharmacy
* Issued: 17 February 2022

 [Field Safety Notices: 7 to 11 February 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-7-to-11-february-2022)

List of field safety notices (FSNs) from medical device manufacturers from 7 to 11 February 2022.

* Alert type: Field safety notice
* Issued: 15 February 2022

 [Class 2 Medicines Recall: hameln pharma ltd, Water for Injections BP – 100ml vial, EL (22)A 06](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-hameln-pharma-ltd-water-for-injections-bp-100ml-vial-el-22-a-06)

hameln pharma ltd is recalling a batch of a product as a precautionary measure as remaining vials may no longer be in line with the licensed product specification

* Medical specialism: Pharmacy
* Issued: 15 February 2022

 [Company led medicines recall: Bucain Hyperbar 5mg/ml Solution for Injection (unlicensed medicine), CLMR (22)A/01](https://www.gov.uk/drug-device-alerts/company-led-medicines-recall-bucain-hyperbar-5mg-slash-ml-solution-for-injection-unlicensed-medicine-clmr-22-a-slash-01)

Mawdsley-Brooks & Company Limited (UK importer) is recalling a specific batch of this product as a precautionary measure due out of specification result for pH that was identified during routine stability testing.

* Medical specialism: Pharmacy
* Issued: 14 February 2022

 [Field Safety Notices: 31 January to 4 February 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-31-january-to-4-february-2022)

List of field safety notices (FSNs) from medical device manufacturers from 31 January to 4 February 2022.

* Alert type: Field safety notice
* Issued: 8 February 2022

 [Class 4 Medicines Defect Information: Atnahs Pharma UK Limited, Naprosyn Tablets (all strengths), Naprosyn EC 250mg Gastro-Resistant Tablets, EL (22)A/05](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-atnahs-pharma-uk-limited-naprosyn-tablets-all-strengths-naprosyn-ec-250mg-gastro-resistant-tablets-el-22-a-slash-05)

Atnahs Pharma UK Limited have identified missing information on the PIL of the above batches.

* Medical specialism: Dispensing GP practices and 1 others
* Issued: 3 February 2022

 [Class 4 Medicines Defect Information: Flamingo Pharma UK Ltd, Ibuprofen 400mg Tablets, EL (22)A/04](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-flamingo-pharma-uk-ltd-ibuprofen-400mg-tablets-el-22-a-slash-04)

Flamingo Pharma UK Ltd have identified an error relating to the embossed batch number on some cartons of Ibuprofen 400mg tablets.

* Medical specialism: Pharmacy
* Issued: 1 February 2022

 [Field Safety Notices: 24 to 28 January 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-24-to-28-january-2022)

List of field safety notices (FSNs) from medical device manufacturers from 24 to 28 January 2022.

* Alert type: Field safety notice
* Issued: 31 January 2022

 [Class 4 Medicines Defect Information: Antibiotice SA, Piperacillin / Tazobactam 4g/0.5 g, powder for solution for infusion, EL (22)A/03](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-antibiotice-sa-piperacillin-slash-tazobactam-4g-slash-0-dot-5-g-powder-for-solution-for-infusion-el-22-a-slash-03)

Antibiotice SA have identified an error on PIL of the above batches regarding the sodium content.

* Medical specialism: Pharmacy
* Issued: 31 January 2022

 [Class 4 Medicines Defect Information: Fresenius Kabi Limited, Kabiven Emulsion for Infusion, EL (22)A/02](https://www.gov.uk/drug-device-alerts/class-4-medicines-defect-information-fresenius-kabi-limited-kabiven-emulsion-for-infusion-el-22-a-slash-02)

Fresenius Kabi Limited have identified an error on the infusion bag packaged in certain batches.

* Medical specialism: Pharmacy
* Issued: 25 January 2022

 [Field Safety Notices: 17 to 21 January 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-17-to-21-january-2022)

List of field safety notices (FSNs) from medical device manufacturers from 17 to 21 January 2022.

* Alert type: Field safety notice
* Issued: 25 January 2022

 [Class 2 Medicines Recall: SANTEN Oy (trading as Santen UK Limited) IKERVIS 1 mg/mL eye drops, emulsion , EL (22)A/01](https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-santen-oy-trading-as-santen-uk-limited-ikervis-1-mg-slash-ml-eye-drops-emulsion-el-22-a-slash-01)

SANTEN Oy (trading as Santen UK Limited) are recalling the above batches of products as a precautionary measure due to detection of particles/crystals of the active pharmaceutical ingredient ciclosporin.

* Medical specialism: Dispensing GP practices and 1 others
* Issued: 19 January 2022

 [Field Safety Notices: 10 to 14 January 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-10-to-14-january-2022)

List of field safety notices (FSNs) from medical device manufacturers from 10 to 14 January 2022.

* Alert type: Field safety notice
* Issued: 17 January 2022

 [Field Safety Notices: 3 to 7 January 2022](https://www.gov.uk/drug-device-alerts/field-safety-notices-3-to-7-january-2022)

List of field safety notices (FSNs) from medical device manufacturers from 3 to 7 January 2022

* Alert type: Field safety notice
* Issued: 10 January 2022