

SPS Medication Safety Update May 2024

Recent critical patient safety alerts, reports, and publications

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Patient Safety Alerts



[Shortage of Erelzi \(etanercept\) 50mg solution for injection in pre-filled pen](#)

3rd May 2024

Erelzi® (etanercept) 50mg solution for injection in pre-filled pen will be out of stock from early May until mid-July 2024.

All affected providers **MUST**:

1. Not start any new patients on Erelzi® (etanercept) products.
2. Work with the appropriate Regional Pharmacy Procurement Specialist (RPPS) to understand individual patient needs, particularly their dexterity, to inform which patients will switch to the following alternatives:
 - a. Benepali® (etanercept) 50mg solution for injection in pre-filled pens;
 - b. Enbrel® (etanercept) 50mg solution for injection in pre-filled pens;
 - c. Erelzi® 50mg pre-filled syringes (PFS)
3. Secondary care pharmacy homecare teams to link in with prescribers and relevant homecare providers to clarify, implement and expedite any processes required to minimise the effects on patient care as much as possible

Patient Safety Alerts



Shortage of Orenzia ClickJect (abatacept) 125mg/1ml solution for injection pre-filled pens

23rd May 2024

Orenzia® Clickject™ (abatacept) 125mg/1ml solution for injection pre-filled pens will be out of stock from mid-June 2024

All affected providers **MUST**:

- Not start new patients on any Orenzia® (abatacept) products.
- Work with their homecare provider(s) to identify which patients will switch to Orenzia® 125mg/1ml PFS, prioritising paediatric patients and those being treated for severe treatment-resistant morphea.
- Remaining patients should be reviewed and prescribed Orenzia® 250mg powder for concentrate for solution for infusion, if appropriate. Trusts should then:
 - a. Work with their homecare provider(s) to understand their capacity for support, and
 - b. Organise appointments for patients to receive the infusion in a hospital setting where necessary.
- Where the above options are not considered appropriate, review patients on a case-by-case basis to consider other treatment options.

Recent regulator and statutory body activity



Medicines & Healthcare products
Regulatory Agency

[Drug Safety Update: Montelukast: reminder of the risk of neuropsychiatric reactions](#)

Healthcare professionals prescribing montelukast should be alert to the risk of neuropsychiatric reactions in all patients including children and adolescents. Reported neuropsychiatric reactions include sleep disorders, hallucinations, anxiety and depression, as well as changes in behaviour and mood. Healthcare professionals should advise patients and their caregivers to be alert to these risks and seek medical advice as soon as possible if neuropsychiatric reactions occur.

[Drug Safety Update: Finasteride: reminder of the risk psychiatric side effects and of sexual side effects \(which may persist after discontinuation of treatment\)](#)

A patient alert card is being introduced for men taking finasteride to help raise awareness of the risk of psychiatric side effects and sexual dysfunction, including the potential for sexual dysfunction to persist after treatment has stopped. Healthcare professionals are reminded to monitor patients for both psychiatric and sexual side effects.

Recent regulator and statutory body activity



Medicines & Healthcare products
Regulatory Agency

Class 3 Medicines Recall Information

[Neon Healthcare Ltd, Suprefact \(Buserelin\) 1 mg/ml solution for injection \(Cheplapharm – Canadian Livery\), EL\(24\)A/14](#)

Neon Healthcare Ltd is recalling the specific batch mentioned in this notification as a precautionary measure. Distributed in packaging for the Canadian market and not UK.

Class 4 Medicines Recall Information

[Doncaster Pharma Limited, Keppra 500mg film-coated tablets, EL\(24\)A/15](#)

Doncaster Pharma Limited have identified an error relating to the Braille printed on the cartons on various parallel imported packs which have been repackaged by BModesto B.V.

[Cygnum Pharma Ltd, Trazodone Hydrochloride 50mg/5ml Oral Solution, EL \(24\)A/16](#)

Cygnum Pharma Ltd. Have informed MHRA that the European Article Number (EAN) barcode printed on various packs of Trazodone Hydrochloride 50mg/5ml Oral Solution, is defective and returns the incorrect information.

[Fresenius Kabi Limited, Sodium Chloride 0.9% Intravenous Infusion BP \(Freeflex and Freeflex Plus\), EL \(24\)A/17](#)

Fresenius Kabi Limited have informed the MHRA of a packaging error with specific batches of Sodium Chloride Intravenous Infusion 0.9% Freeflex and Freeflex PLUS.

Pharmacovigilance Risk Assessment Committee (PRAC)



[CHMP recommends new contra-indications for Reytaz \(atazanvir sulfate\)](#)

Co-administration with encorafenib, ivosidenib, carbamazepine, phenobarbital, and phenytoin as new contraindications

[Hydroxyprogesterone caproate medicines to be suspended from the EU market](#)

This follows a safety review by the PRAC, which concluded there is a possible risk of cancer in people exposed to 17-OPHC in the womb. These medicines are authorised in some EU countries (not the UK) to prevent pregnancy loss of premature birth, and for other gynaecological disorders.

Prevention of Future Death Reports (Regulation 28)



Courts and Tribunals Judiciary

[Ref 2024-0252 – Mixed overdose of oramorph, oxycodone and quetiapine \(8th May 2024\)](#)

- Patient with depression and schizophrenia. Died due to a mixed overdose of oramorph, oxycodone and quetiapine.
- Patient had not received annual medication reviews, also recently started on HRT but received no follow up as per NICE guidance.

[Ref 2024-0205 – Toxic effects of tramadol, cocaine, alcohol and buprenorphine \(29th April 2024\)](#)

- Death of rugby player following mixed accidental overdose of tramadol, cocaine, alcohol and buprenorphine.

Drug shortages and discontinuations

- Recent medicine shortages and discontinuations are available via: the [SPS Medicines Supply Tool](#) (registration required to access)

[Shortage of Pabrinex \(Vitamins B and C\) Intravenous High Potency Solution for injection ampoules](#)

Updated information previously released on 3rd April. Unlicensed thiamine injections should be considered. SPS has produced pages to support.

[Shortage of Tegretol \(carbamazepine\) 100mg/5ml liquid](#)

Generic carbamazepine 100mg/5ml oral suspension sugar free remains available but is unable to support an increase in demand. Consider prescribing unlicensed carbamazepine 100mg/5ml oral suspension.

[Shortage of Pancreatic enzyme replacement therapy \(PERT\)](#)

Creon® 10,000 and 25,000 capsules are in limited supply until 2026. Nutrizym® 22 capsules are out of stock until mid-August 2024. Pancrex V® capsules & powder are available but unable to support increase in demand. Professional bodies have issued clinical advice.

[Shortage of Humalog \(insulin lispro\) 100units/ml solution for injection 10ml vials](#)

These are out of stock with an estimated resupply date of late May 2024. Humalog® cartridges and Humalog KwikPen® and Junior KwikPen® remain available and can support increased demand. NovoRapid® and Trurapi® (insulin aspart) 100units/ml 10ml vials remain available.

[Shortage of Humulin S \(insulin soluble human\) 100units/ml solution for injection 10ml vials](#)

These are out of stock with an estimated resupply date of 14th June 2024. Actrapid® vials remain available and can be used when Humulin S® supply has been exhausted.

This is not a comprehensive list. Only critical safety medication shortages have been highlighted.

Specialist Pharmacy Service



[New: Prescribing thiamine in patients at risk of refeeding syndrome](#)

Pabrinex was previously used for refeeding syndrome. However, IM Pabrinex has been discontinued, and IV Pabrinex is affected by a long-term supply issue. This resource discusses use of oral thiamine and vitamin B, and IV thiamine in high-risk patients

[New: Choosing a medicine to delay periods](#)

Norethisterone is the licensed choice for delaying periods, but it is not always the most appropriate choice. This page discusses factors to consider when choosing a medicine to delay a period and the relevant counselling points such as licencing and efficacy.

[New: Assessing liver function and interpreting liver blood tests](#)

How to assess liver function including the purpose of liver blood tests, how to interpret them and what to do if they are abnormal. Part of a series on pages, also including, [‘Questions to ask when giving medicines advice in liver impairment’](#), [‘Information resources for managing medicines in liver impairment’](#) and [‘Calculating and using the Child-Pugh score’](#)

[New: Understanding enzyme or transporter-based drug interactions](#)

Many interactions are due to inhibition or induction of metabolising enzymes or drug transporters. Enzyme, transporter, and drug half-lives dictate duration.

[Update: Switching between mesalazine oral tablet preparations](#)

Updated article gives an overview of differences between mesalazine tablet preparations to facilitate decision making about switching. This update includes an amendment in the products listed and updates the drug release characteristics for some of the listed products.

Specialist Pharmacy Service



Updated versions of the following PGDs:

[Benzympenicillin injection for suspected meningitis](#)

[Emtricitabine/tenofovir and raltegravir tablets for HIV PEP](#)

[Trimethoprim for Urinary Tract Infection \(UTI\)](#)

[Nitrofurantoin for Urinary Tract Infection \(UTI\)](#)

[Fluconazole 150mg capsules for candidiasis](#)

[Copper Intrauterine Device \(Cu-IUD\)](#)

[Etonogestrel \(e.g. Nexplanon®\) implant for contraception](#)

[Progestogen-Only Intra-Uterine Device \(LNG-IUD\) for contraception](#)

[Progestogen only pill \(POP\) for contraception](#)

PGD explainer videos:

[Must reads PGD explainer videos](#)

[Supply and administration PGD explainer videos](#)

[Planning for PGDs explainer videos](#)

SPC changes

[Semaglutide containing products \(Wegovy, Ozempic, Rybelsus\) ▼](#)

Intestinal obstruction has been added as an adverse event (frequency not known). Information on interaction with warfarin has been updated to discuss other coumarin derivatives and advise frequent INR monitoring if semaglutide is started in those on such treatment.

[Rifinah 150mg/100mg Tablets \(isoniazid, rifampicin\) and Rifadin \(rifampicin\) 150mg, 300mg capsules and oral suspension](#)

SPC updated to note use in combination with lurasidone is contra-indicated, as it markedly decreases the exposure of lurasidone compared to the use of lurasidone alone. Cerebellar syndrome has also been added as an adverse effect that has been mainly reported in those with CKD.

[Revised SPC: Lioresal \(baclofen\) Tablets 10mg](#)

SPC updated to include hypertonia as symptom of withdrawal/abrupt discontinuation, to include 'other drugs known to lower blood pressure' in the interactions section, & to add the adverse effects face swelling, peripheral oedema, alopecia, hypersensitivity & sexual dysfunction.

[Aldurazyme \(laronidase\) 100 U/ml concentrate for solution for infusion](#)

SPCs now includes use for home infusion in patients who are tolerating their infusions well and have no history of moderate or severe infusion-associated reactions for a few months.

[Kynmobi \(apomorphine hydrochloride\) 10mg sublingual film - all strengths](#)

SPC now advises that concomitant use with ondansetron is contraindicated due to reports of profound hypotension and loss of consciousness when subcutaneous apomorphine was administered with a 5HT3 antagonist.

[Cotellic \(cobimetinib hemifumarate\) 20 mg Film-coated Tablets](#)

SPC updated to include stomatitis as adverse drug reaction (frequency 'very common').

SPC changes

Clarithromycin products

Concomitant treatment with ivabradine is now contra-indicated, owing to CYP3A4 inhibition by clarithromycin which can cause elevated levels of ivabradine. Also, caution is now advised with co-administration with edoxaban, particularly in those with a high risk of bleeding.

Selexid (pivmecillinam) tablets

SPC now warns that severe cutaneous adverse reactions (SCAR) have been reported in relation to beta-lactam treatment, including pivmecillinam (unknown frequency). When suspected, treatment should be discontinued immediately and appropriate therapy and/or measures should be taken.

Rapamune (sirolimus) – all formulations

SPC updated regarding the risk of interaction with cannabidiol, with a possible increase in systemic exposure and toxicity, due to inhibition of intestinal P-glycoprotein efflux

Lumykras (sotorasib) 120mg film-coated tablets

Decreased sotorasib exposure when co-administered with omeprazole. SPC now recommends taking acid-reducing agents (e.g. PPI/H2 receptor antagonists) with an acidic beverage (e.g. cola) or taking sotorasib 4 hours before or 10 hours after the antacid.

Ibrance (Palbociclib) – all strengths

Erythema multiforme has been added as an uncommon adverse drug reaction with palbociclib treatment.

Inderal (propranolol hydrochloride) 40mg film-coated tablets

SPC now includes depression as an adverse effect with unknown frequency.

Genotropin (somatropin) products

Headache has been added to SPC as an adverse reaction of unknown frequency

Direct HCP communication

In March 2024, the following letters were sent or provided to relevant healthcare professionals:

[Fiasp® FlexTouch® \(fast-acting insulin aspart\) 100 units/ml solution for injection 3ml pre-filled pen: Supply Shortage in the UK](#)

[Oestrogel \(estradiol\) Pump-Pack 750 micrograms/actuation Gel Recall VERORAB, powder and solvent for suspension for injection - PLGB 46602/0029](#)

[Diazepam Desitin 10mg Rectal Solution BSV](#)

[GAVRETO®▼ \(pralsetinib\): Planned transition of Market Authorisation Holder for GAVRETO®▼ \(pralsetinib\) from Roche Products Ltd to BluePrint Medicines resulting in discontinuation of supply from Roche Products Ltd](#)

[Tresiba® FlexTouch® 100 U/mL solution for injection \(insulin degludec\): Supply Shortage in the UK and Tresiba® FlexTouch® 200 U/mL solution for injection \(insulin degludec\): Medication error](#)

[Norditropin NordiFlex® \(somatropin\): Product Discontinuation Norditropin® FlexPro® 5mg/1.5ml \(somatropin\): Drug Shortage and Pause in production](#)

Manufacturer Educational RMM

RMM - Caprelsa (vandetanib)

The healthcare professional guide contains information about risks of QTc prolongation, Torsades de pointes, sudden death, posterior reversible encephalopathy syndrome, teeth & bone abnormalities in children, and also a dosing and monitoring guide for paediatric patients.

RMM – Lutathera (lutetium oxodotreotide)

This guide includes information on how the treatment works, considerations before treatment, how it is given, the precautions to take after treatment, and possible side effects.

RMM – Finasteride

Alert card for patients to carry with them, highlighting adverse effects of depression, suicidal thoughts, decreased libido and erectile dysfunction.

National guidance, publications and resources

[Royal Pharmaceutical Society: Responding to Patient Safety Incidents: The Standards](#)

These standards replace the 2016 version of the RPS 'Professional standards for the reporting, learning, sharing, taking action and review of incidents'.

[NHS England: Influenza season 2023/24: ending the prescribing and supply of antiviral medicines in primary care](#)

The most recent surveillance data from UK Health Security Agency (UKHSA) indicates that circulation of influenza in the community has returned to baseline levels.

Primary research- Medication Safety

[The Safety of Outpatient Health Care: Review of Electronic Health Records](#)

Study (n=3103) found adverse drug reactions were the most frequent adverse events in the outpatient setting (170/266; 63.8%), followed by health-care associated infections (14.8%), with rates higher among older adults. Authors call for urgent interventions to limit harm.

Source: Annals of Internal Medicine

[Limit packaging size for opioids prescribed at post-surgical discharge](#)

Article from authors perspective notes oversupply of opioids at hospital discharge provides opportunity to improve opioid prescribing and patient safety. The author claims hospital pharmacies have insufficient time or resources to dispense smaller quantities, putting patients at risk. Decreasing the default number of opioid tablets on all electronic prescriptions at post-surgical discharge has been shown to reduce the number prescribed without changing refill rates.

Source: Lancet