Medicines & Healthcare products Regulatory Agency

# MHRA SAFETY ROUND-UP

## April 2025

### Summary of the latest safety advice for medicines and medical device users

## Contents





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## Fezolinetant▼(Veoza): risk of liver injury; new recommendations to minimise risk

Access the full article

***Specialisms:*** *Dispensing GP practices, General practice and Obstetrics, gynaecology and fertility*

## Summary

Fezolinetant treatment is associated with a risk of drug induced liver injury. New recommendations have been introduced to minimise this risk. Liver function should be monitored before and during treatment in all patients taking fezolinetant. Fezolinetant should be avoided in patients with known liver disease or at a higher risk of liver disease.

Fezolinetant is currently only available through a private prescription.

**Key Advice for Healthcare Professionals:**

- cases of serious liver injury with elevated transaminases, bilirubin and signs and symptoms of hepatic dysfunction have been reported during treatment with fezolinetant. These were generally reversible on discontinuation of therapy
- avoid fezolinetant in patients with known liver disease or patients at higher risk for liver disease
- treatment with fezolinetant must not be initiated if serum alanine aminotransferase (ALT) or serum aspartate aminotransferase (AST) levels are ≥2x the upper limit of normal or if total bilirubin levels are ≥2x the upper limit of normal



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**Key Advice for Healthcare Professionals *continued*:**

- treatment with fezolinetant must be discontinued if:
    - transaminase elevations are ≥3x the upper limit of normal with: total bilirubin >2x the upper limit of normal OR if patients develop symptoms of liver injury
    - transaminase elevations >5x the upper limit of normal
- perform liver function tests, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), serum alkaline phosphatase (ALP) and serum bilirubin (total and direct), prior to treatment initiation, monthly during the first 3 months of treatment and periodically thereafter based on clinical judgment
- liver function tests must also be performed when signs or symptoms suggestive of liver injury occur
- monitoring should be maintained until liver function tests have normalised
- patients should be advised to seek immediate medical attention if they develop any sign or symptoms of liver injury, including fatigue, pruritus, jaundice, dark urine, pale faeces, nausea, vomiting, decreased appetite and/or abdominal pain
- a Direct Healthcare Professional Communication (DHPC) has been disseminated alongside this Drug Safety Update
- report suspected adverse drug reactions associated with fezolinetant via the Yellow Card scheme

**Key Advice for Healthcare Professionals to Provide to Patients:**

- fezolinetant is used for the treatment of moderate to severe vasomotor symptoms, including hot flushes and night sweats, associated with the menopause
- there have been cases of liver problems in people taking fezolinetant, which were generally reversible following discontinuation of treatment
- all patients will now have their liver function tested before and during treatment
- you will have a blood test to check your liver function before you start taking fezolinetant. This will be repeated monthly during the first 3 months of treatment and then afterwards depending on when your doctor deems appropriate
- seek medical attention immediately if you develop symptoms suggesting a problem with your liver. These include tiredness, itching, yellowing of the skin and eyes, dark urine, light-coloured stools, feeling or being sick, loss of appetite or stomach pain
- always read the leaflet that is provided alongside your medicine, which contains information about taking fezolinetant and a full list of known possible side effects
- report suspected adverse drug reactions to the Yellow Card scheme

# Short-acting beta 2 agonists (SABA) (salbutamol and terbutaline): reminder of the risks from overuse in asthma and to be aware of changes in the SABA prescribing guidelines

Access the full article

***Specialisms:*** *General practice, Pharmacy, Respiratory disease and allergy*

## Summary

Healthcare professionals and patients are reminded of the risk of severe asthma attacks and increased mortality associated with overuse of SABA with or without anti-inflammatory maintenance therapy in patients with asthma. Healthcare professionals should be aware of the change in guidance that no longer recommends prescribing SABA without an inhaled corticosteroid.

**Key Advice for Healthcare Professionals:**

- excessive use of SABA to relieve acute asthma symptoms may mask progression of the underlying disease and contribute to an increased risk of severe and potentially life-threatening asthma exacerbations
- do not prescribe SABA to people of any age with asthma without a concomitant prescription of an inhaled corticosteroid[1] (see Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN) NICE guideline [NG245], 2024)
- ensure all patients with asthma receive optimal anti-inflammatory maintenance therapy even when their asthma is well controlled and that treatment is individualised to the patient
- review and adjust asthma treatment in patients who take more than twice weekly “as needed” SABA
- urgently review patients where there has either been an increase in the number of prescriptions requested for SABA reliever inhalers or a failure to collect prescribed anti-inflammatory maintenance treatment
- anti-inflammatory reliever (AIR) therapy and maintenance and reliever therapy (MART) are recommended alternatives for people over 12 years of age with poorly controlled asthma[1]
- report suspected adverse drug reactions to the Yellow Card scheme

**Key Advice for Healthcare Professionals to Provide to Patients:**

- seek urgent medical assistance if worsening asthma symptoms (for example, chest tightness, wheezing, coughing, or difficulty breathing) are not relieved by using the asthma reliever medicines prescribed by a healthcare professional to be used during an asthma attack
- if a blue inhaler is prescribed as the asthma reliever medication to be used during an asthma attack, a separate asthma preventer therapy will always be prescribed for regular daily use as well
- use the asthma anti-inflammatory maintenance medication as prescribed by a healthcare professional even when asthma is well-controlled and the blue inhaler is rarely or never needed
- if the blue inhaler does not have a dose counter, manually track the doses used and ensure you always have access to a spare inhaler before your current inhaler runs out or expires.
- follow your agreed asthma plan if you have one or ask your healthcare professional for an asthma review if the prescribed asthma blue reliever inhaler is needed more than twice a week.
- your healthcare professional can provide advice on recommended alternative treatments (to the blue inhaler) for people over 12 years of age with poorly controlled asthma.
- report suspected adverse drug reactions to the Yellow Card scheme

## Letters, medicines recalls and device notifications sent to healthcare professionals in March and April 2025

### Direct Healthcare Professional Communications

In March and April 2025, the following Direct Healthcare Professional Communications were sent or provided to relevant healthcare professionals:

- Zentiva Bosutinib 100mg film coated tablets PL 17780/1298 – supply with Spanish blister foils
- Epilim Chrono 500 Controlled Release Tablets (sodium valproate) - pack size 30 tablets: partial product name error on the blister foil - sent to a limited number of affected pharmacies in December 2024



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## Medicine Recalls and Notifications

In March and April 2025, recalls and notifications for medicines were issued on:

**Class 2 Medicines Recall: Lercanidipine HCl 20mg Tablets, Recordati Industria, EL(25)A/17.** Issued 17 April 2025.

Recordati Pharmaceuticals Limited informed the MHRA of an error in the strength of the product printed on some of the faces (sides) of the product carton. The error is limited to one batch of Lercanidipine HCl 20mg Tablets. The packs are incorrectly labelled as 10mg on some sides of the product carton when they are 20mg tablets.

**Class 2 Medicines Recall: Synalar GEL 30g, Synalar GEL 60g, (fluocinolone acetonide 0.025%) Reig Jofre UK,EL(25)A/16.** Issued 8 April 2025.

It has been identified that the batches of Synalar Gel 30g and 60g listed in this notification contain a residual solvent (benzene) at a level exceeding the ICH limit of 2ppm. Reig Jofre UK are recalling the batches as a precautionary measure. This recall is at the pharmacy and wholesaler level.

**Class 2 Medicines Recall: Utrogestan Vaginal 200 mg Capsules (progesterone), EL(25)A/13.** Issued 1 April 2025.

Uni Health Distribution Ltd has informed the MHRA of a typographical error on the approved carton overlabel for certain batches of Utrogestan Vaginal 200 mg Capsules. The carton label references ‘micrograms’ where it should actually state ‘milligrams’.

**Class 3 Medicines Recall: Urospir 50mg/5ml Oral Solution, EL(25)A/14.** Issued 2 April 2025.

Rosemont Pharmaceuticals Limited is recalling a single batch of Urospir 50mg/5ml Oral Solution (spironolactone) as a precautionary measure. The recall is due to errors in some of the dose calculation in millilitres being stated incorrectly in the SmPC and PIL.

**Class 4 Medicines Defect Notification: Renacet 475 mg and 950 mg Tablets (calcium acetate), RenaCare NephroMed GmbH, EL(25)A15.** Issued 7 April 2025

RenaCare NephroMed GmbH has informed the MHRA of the presence of an undeclared excipient in the coating of the tablets. This excipient is Macrogol 6000, which has always been included in Renacet Tablets but has been omitted from the list of excipients in error.



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**Class 4 Medicines Defect Notification: Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension, EL(25)A/12.** Issued 31 March 2025

Cross Healthcare Limited have informed the MHRA that there is a printing defect on the outer labels for the Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension, batch 77518.

**Class 4 Medicines Defect Notification: Brilique 90mg Tablets, EL(25)A/18.** Issued 24 April 2025

G Pharma Ltd have informed the MHRA that there is an error in the spelling of the active ingredient included on the imported carton. The spelling should be 'Ticagrelor' but has been printed as 'Tricagelor' under the brand name and in the content statement.

**Class 4 Medicines Defect Notification: Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg Capsules, Jubilant Pharmaceuticals NV, EL(25)A/19.** Issued 29 April.

Jubilant Pharmaceuticals BV has informed the MHRA that the outer carton (box) of the product batches mentioned in this notification are missing the medicines legal classification for a Prescription Only Medicine 'POM'. There is no risk to product quality or safety of the medicines.

## Medical Device Field Safety Notices

Find recently published Field Safety Notices

## Report suspected drug reactions and device incidents on a Yellow Card

Please continue to report suspected adverse drug reactions and device incidents. Your report will help us safeguard public health.

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates and particularly if a side effect continued or started after treatment was stopped



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**Report a medicine**

Healthcare professionals should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

**Reporting for medical devices**

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website or via the Yellow Card app
- in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
- in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

**Reporting for Patients**

**Report a medicine or medical device**

Patients should report via a Yellow Card to:

- the Yellow Card website
- the Yellow Card app; download from the Apple App Store or Google Play Store

## News Round Up

### BCR-ABL tyrosine kinase inhibitors and interstitial lung disease

Healthcare professionals are reminded that BCR-ABL tyrosine kinase inhibitors (e.g. imatinib, dasatinib, nilotinib, and bosutinib) can cause interstitial lung disease (ILD). When assessing patients with acute or unexplained worsening respiratory symptoms, consider ILD as a possible cause. Signs and symptoms include cough, difficulty breathing, and painful breathing.

Healthcare professionals should inform patients of this potential risk and advise them to read the Patient Information Leaflet that accompanies their medicine.

For more information, the Summary of Product Characteristics and Patient Information Leaflets can be found on the MHRA website.

### Risk Minimisation Measures for Medicines Guidance

We have published new guidance for healthcare professionals on risk minimisation measures available for medicines. Risk minimisation measures are put in place to facilitate the safe and effective use of medicines by healthcare professionals, patients and their carers or guardians. They can include: patient guidance, healthcare professional



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guidance, patient cards, access and distribution programmes and Pregnancy Prevention Programmes.

## Update to UK Clinical Trials signed into law

New regulations for running clinical trials in the UK have now been signed into law. A 12-month roll-out began on 11 April to deliver the most significant update to UK clinical trials regulation in two decades – with the aim of strengthening patient safety, accelerating approvals, enabling innovation and helping more people benefit from taking part in vital research. Additionally, new analysis of the current clinical trial landscape in the UK shows clear opportunities to shape the future of medical research and patient care.

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