Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(25)A/14

Action within 5 days

Issued 02 April 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Rosemont Pharmaceuticals Ltd

MEDICINE DETAILS

Urospir 50mg/5ml Oral Solution

PL: 00427/0251

Active Ingredient: Spironolactone

SNOMED code: 43189611000001104

GTIN: 05016119000539

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
1014870	30/09/2025	150ml	29/11/2024

Background

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 section 4.2 of the SmPC (Summary of Medicinal Product Characteristics) and section 3 of the PIL (Patient Information Leaflet or package insert). The product correctly contains 50mg/5ml and the pack (carton) is labelled correctly. This recall is at pharmacy and wholesaler level.

Approximately 1200 packs have been distributed within the UK market.

Advice for Healthcare Professionals:

Stop supplying the above batch immediately. Quarantine all stock from this batch and return it to your supplier using your supplier's approved process.

For products that have already been dispensed to patients and where prescribers have used the Rosemont SmPC for dose considerations by volume; these prescriptions should be reviewed.

- This should only impact prescriptions where the volume (ml) has been written on the prescription, which could have led to an error in dose. e.g. incorrectly written as 100mg daily (20ml), whereas it should state 100mg daily (10ml).
- Prescribers (GPs, Independent Prescribers Nurse Prescribers and all other relevant prescribers) should ensure that the correct dose had been requested.
- This impacts patients that have been prescribed spironolactone oral solution from 29/11/2024 to 31/03/2025.
- Should there be concern that a patient has been given a higher than required dose, the physician should review the case and contact the patient where appropriate.

Pharmacists who receive queries from patients should consider checking with the prescriber, where appropriate, to ensure that correct dose has been prescribed.

Details of the errors in the SmPC have been outlined in Appendix 1 (incorrect doses marked in strikethrough, correct doses highlighted in yellow, bold and underlined).

Advice for Patients:

Patients who are taking Urospir 50mg/5ml Oral Solution (spironolactone) should continue to take the medication. Patients concerned about their dose, or are experiencing any of the side effects in Appendix 2 should contact their GP or pharmacist, who can check the correct dose and can provide advice on side effects.

Any suspected adverse reactions should also be reported online via the Yellow Card scheme or via the Yellow card app available from the Apple App Store or Google Play Store.

Additional information:

For all medical information enquiries and information on this product, please contact pharmacovigilance@rosemontpharma.com, or telephone 0113 244 1400.

For stock control enquiries please contact customerservices@rosemontpharma.com, or telephone 0113 244 1999.

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

Defective Medicines Report Centre
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Canary Wharf
London
E14 4PU

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DMRC@mhra.gov.uk

Appendix 1

Section 4.2 Posology and Method of Administration

Severe heart failure (New York Heart Association Class III-IV)
Based on the Randomized Aldactone Evaluation Study (RALES: see also section 5.1), treatment in conjunction with standard therapy should be initiated at a dose of spironolactone 25 mg (2.5 ml) once daily if serum potassium is ≤ 5.0 mEq/L and serum creatinine is ≤ 2.5 mg/dL. Patients who tolerate 25 mg once daily may have their dose increased to 50 mg ~~(10 ml)~~ **(5ml)** once daily as clinically indicated. Patients who do not tolerate 25 mg once daily may have their dose reduced to 25 mg every other day.

Malignant ascites
Initial dose usually 100 mg (20 ml)/day to 200 mg/day ~~(20 ml twice a day)~~ **(10 ml twice daily).** In severe cases the dosage may be gradually increased up to 400 mg/day (use a suitable spironolactone formulation; see NOTE above). When oedema is controlled, maintenance dosage should be individually determined.

Nephrotic syndrome
Usual dose 100 mg (10 ml)/day to 200 mg/day ~~(20 ml twice a day)~~ **(10 ml twice daily).** Spironolactone has not been shown to be anti-inflammatory, nor to affect the basic pathological process. Its use is only advised if glucocorticoids by themselves are insufficiently effective.

Paediatric population
Initial daily dosage should provide 1-3 mg of spironolactone per kilogram (kg) body weight (~~0.2 ml/kg-0.6 ml/kg~~) **(0.1 ml/kg – 0.3 ml/kg)** given in divided doses. Dosage should be adjusted on the basis of response and tolerance (see sections 4.3 and 4.4). Due to the level

of medium chain triglycerides in Spironolactone Oral Solution, it is recommended that doses of 3mg/kg be administered using the 50 mg/5ml Oral Solution.

Details of the errors in the PIL are as follows (incorrect doses marked in strikethrough, correct doses highlighted in yellow, bold and underlined):

Section 3 How to take Urospir

Adults

The adult dose varies from 25 mg ~~(5 ml)~~ **(2.5 ml)** to 400 mg spironolactone a day, depending on the condition being treated. If you are not sure how much to take, ask your doctor or pharmacist.

Urospir can only be used for a single dose of up to 100 mg ~~(20 ml)~~ **(10 ml).** If you need to take more than 100 mg of spironolactone ~~(more than 20 ml)~~ **(more than 10ml)** a day, this should be taken in two equally divided doses.

Urospir is only suitable for doses up to 200 mg a day ~~(20 ml twice a day)~~ **(10ml twice a day)**. If you need to take a dose higher than 200 mg a day your doctor will prescribe a different product.

Appendix 2

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. **Tell your doctor immediately** if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- itchiness and blistering of the skin around the lips and the rest of the body, red or purple rash spreading and forming blisters (Stevens-Johnson syndrome)
- detachment of the top layer of skin from the lower layers of skin, all over the body (toxic epidermal necrolysis -TEN)
- skin rash, fever and swelling (which could be symptoms of something more serious, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- yellow skin and eyes (jaundice)
- spironolactone can cause impairment of liver function
- irregular heartbeat which can be fatal, tingling sensation, paralysis (loss of muscle function) or difficulty in breathing; which may be symptoms of raised potassium levels in your blood. Your doctor will conduct regular blood tests to monitor potassium and other electrolyte levels. They may stop your treatment if necessary.

List of other side effects of spironolactone by frequency:

Very common: may affect more than 1 in 10 people

- raised potassium in the blood.

Common: may affect up to 1 in 10 people

- Confusion
- Dizziness
- vomiting or feeling sick
- itching of the skin

- rash
- muscle or leg cramps
- kidney failure or abnormal function
- breast enlargement in men
- breast pain (in men)
- feeling generally unwell.

Uncommon: may affect up to 1 in 100 people

- changes in the breast such as breast lumps
- disturbances in body electrolytes such as high blood calcium
- abnormal functioning of the liver
- skin allergy with development of itchiness and hives, nettle like rash
- menstrual problems in women
- breast pain (in women).

Not known: frequency cannot be estimated from the available data

- lowered white blood cell count in blood
- reduced number of cells that fight infection – white blood cells which make infections more likely
- reduced number of cells that help with blood clotting which increases risk of bleeding or bruising
- change in sex drive for both men and women
- digestion problems, stomach upset
- skin condition presenting with fluid-filled blisters (pemphigoid)
- hair loss
- excessive hair growth.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.