

## Nitrofurantion: reminder of the risks of pulmonary and hepatic adverse drug reactions

**1 Introduction:** In April 2023 the MHRA issued a [drug safety update](#) advising that healthcare professionals prescribing nitrofurantoin should be alert to the risk of pulmonary and hepatic adverse drug reactions and advise patients to be vigilant for signs and symptoms in need of further investigation. The MHRA received a Coroner's report following the death of a patient who experienced acute pulmonary damage and respiratory failure following a 10day course of nitrofurantoin for a UTI. A similar incident in Manchester resulted in a patient suffering pulmonary damage following long-term nitrofurantoin usage.

**2 Nitrofurantoin:** Broad spectrum antibacterial agent for adults, children and infants over 3 months old for treatment and prophylaxis of acute or recurrent uncomplicated UTI or pyelitis. Indicated to last between 3 and 7 days in line with [GMMMG guidance](#). Some patients may be suitable for a daily dose as prophylaxis for recurrent UTIs.

**3 Potential risks:** The potential for acute pulmonary damage is well documented in the [product information for nitrofurantoin](#). Subacute and chronic pulmonary adverse reactions have been observed in patients treated with nitrofurantoin. Symptoms of acute pulmonary reactions usually include fever, chills, cough, chest pain, dyspnoea, pulmonary infiltration with consolidation or pleural effusion on chest X-ray, and eosinophilia. Nitrofurantoin can rarely cause hepatic reactions including cholestatic jaundice, chronic active hepatitis, autoimmune hepatitis, and hepatic necrosis.

**4 Pulmonary damage:** Can occur with long or short-term use. Patients receiving long term therapy for example with recurrent UTIs, should be closely monitored for new or worsening respiratory symptoms, especially if elderly. Advise patients to be vigilant for new or worsening respiratory symptoms and promptly investigate any symptoms that may indicate a pulmonary adverse reaction. If symptoms of pulmonary damage occur, nitrofurantoin should be discontinued immediately.

**5 Hepatic reactions:** Healthcare professionals should be vigilant for signs and symptoms of liver dysfunction in patients taking nitrofurantoin for any duration but particularly for long term use. Patients should be monitored for changes in biochemical tests that would indicate hepatitis or liver injury. Consider any pre-existing conditions that might mask the symptoms of a hepatic reaction and the patient's ability to recognise symptoms and seek advice in the event of a hepatic reaction. Nitrofurantoin should be discontinued immediately if hepatitis occurs.

**6 Advice:** Use caution when prescribing nitrofurantoin in patients with pulmonary disease or hepatic dysfunction, which may mask the signs and symptoms of adverse reactions. Advise patients to carefully read the advice in the Patient Information Leaflet about symptoms of possible pulmonary and hepatic reactions and to seek medical advice if they experience these symptoms. Report suspected adverse drug reactions (ADRs) to the [Yellow Card scheme](#).

**7 Summary of advice to give to patients and caregivers:** Seek medical advice if you experience trouble breathing, shortness of breath, a lingering cough, coughing up blood or mucus, or pain or discomfort when breathing. These may be symptoms of a side effect affecting the lungs. Seek medical advice if you develop yellowing of the skin or eyes, upper right abdominal pain, dark urine and pale or grey-coloured stools, itching or joint pain and swelling. These may be symptoms of a side effect affecting the liver.

## References

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2. GMMMG (2024). Greater Manchester Antimicrobial Guidelines, Greater Manchester Medicines Management Group Clinical Guidance and Pathways. Available at <https://gmmmg.nhs.uk/wp-content/uploads/2024/02/GM-Antimicrobial-guidelines-January-2024-v15.pdf>. Accessed 3 April 2024.
3. Summary of Product Characteristics and Patient Information Leaflets. (2024). Nitrofurantoin. Available at <https://www.medicines.org.uk/emc/search?q=Nitrofurantoin+> . Accessed 3 April 2024.
4. Yellow Card Scheme (2024). Yellow Card reporting site, Medicines and Healthcare Products Regulatory Agency. Available at <https://yellowcard.mhra.gov.uk/>. Accessed 3 April 2024.

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