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NHS Lancashire and South Cumbria Integrated Care Board

MLCSU Clinical

Prescribing Tip For Information

Reminder of the risk of pulmonary and hepatic adverse drug reactions with Nitrofurantoin

The MHRA has released a Safety Alert advising healthcare professionals prescribing Nitrofurantoin to be aware of the risks of pulmonary and hepatic adverse drug reactions and advise patients to be vigilant of the signs and symptoms in need of further investigation. The MHRA has received a Coroner's Report following the death of a patient who experienced acute pulmonary damage and respiratory failure after being treated with a 10-day course of Nitrofurantoin for a Urinary Tract Infection.

The Summary of Product Characteristics states acute, 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.

- **If symptoms of pulmonary damage occur, Nitrofurantoin should be discontinued immediately.** The Patient Information Leaflet (PIL) advises patients that lung adverse reactions may occur, and that patient should consult a doctor immediately if they notice symptoms of a lung reaction. **Close monitoring of pulmonary conditions is advised for patients receiving long-term therapy (especially elderly people.)**

The alert also reminds healthcare professionals of the risk of hepatic drug reactions. Nitrofurantoin rarely causes hepatic reactions, including cholestatic jaundice, chronic active hepatitis, autoimmune hepatitis, and hepatic necrosis.

- **Nitrofurantoin should be discontinued immediately if hepatitis occurs**. It is important to monitor patients periodically for changes in biochemical tests which could indicate hepatic dysfunction and for clinical signs or symptoms of liver abnormality, **especially in patients taking long-term Nitrofurantoin**.

Advice for Healthcare Professionals

- Advise patients and carers to be vigilant for new or worsening respiratory symptoms and investigate any symptoms that may indicate a pulmonary adverse reaction.
- Pulmonary reactions may occur with short or long-term use of Nitrofurantoin, and increased vigilance for acute pulmonary reactions is required in the first week of treatment.
- Patients receiving long-term therapy should be closely monitored for new or worsening respiratory symptoms, especially if elderly.
- Immediately discontinue Nitrofurantoin if new or worsening symptoms of pulmonary damage occur.
- Be vigilant for symptoms and signs of liver dysfunction in patients taking Nitrofurantoin of any duration, but particularly with long-term use, and monitor patients periodically for signs of hepatitis and for changes in biochemical tests that would indicate hepatitis or liver injury.
- 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 PIL regarding symptoms of possible pulmonary and hepatic reactions and to seek medical advice if they experience these symptoms.
- Review prophylactic antibiotics for UTIs regularly as per the pathway on LSCMMG to see if the patient can be considered for a trial without antibiotic prophylaxis.
- Refer to the national antimicrobial guidelines for managing common infections which advises on treatment choices, course lengths and dosages.
- Report suspected adverse drug reactions (ADRs) to the Yellow Card scheme

To contact the Medicines Optimisation Team please phone 01772 214302
If you have any suggestions for future topics to cover in our prescribing tips please contact Nicola.schaffel@nhs.net
All content accurate and correct on the date of issue of this tip.