East Lancashire Health Economy Medicines Management Board
www.elmmb.nhs.uk NHS

MHRA Drug Safety Update

April 2023

MHRA Regulating Medicines and Medical Devices

Nitrofurantoin: reminder of the risks of pulmonary and hepatic adverse drug reactions

Healthcare professionals prescribing nitrofurantoin should be alert to the risks of pulmonary and hepatic adverse drug reactions and advise patients to be vigilant for the signs and symptoms in need of further investigation.

Risk of pulmonary damage:
The potential for acute pulmonary damage with nitrofurantoin is well-documented. The Summary of Product Characteristics (SmPC) states that 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. For subacute pulmonary reactions, fever and eosinophilia occur less often than in the acute form.

Risk of hepatic reactions:
Nitrofurantoin can rarely cause hepatic reactions, including cholestatic jaundice, chronic active hepatitis, autoimmune hepatitis, and hepatic necrosis.

The onset of hepatitis may be gradual and may not have obvious symptoms at first.

Advice for healthcare professionals:

- ✓ Advise patients and caregivers to be vigilant for new or worsening respiratory symptoms while taking nitrofurantoin and promptly investigate any symptoms that may indicate a pulmonary adverse reaction.
- ✓ Pulmonary reactions may occur with short-term 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, for example for recurrent urinary tract infections, 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 for 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. Nitrofurantoin should be discontinued immediately if hepatitis occurs.
- ✓ Use caution when prescribing nitrofurantoin in patients with pulmonary disease or hepatic dysfunction, which may mask the signs and symptoms of adverse reactions.
- ✓ Report suspected adverse drug reactions (ADRs) to the Yellow Card scheme.

Advice for healthcare professionals to give to patients and caregivers:

- ✓ Advise patients to read carefully 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.
- ✓ Nitrofurantoin is an effective antibiotic used to prevent and treat infections of the bladder, kidney, and other parts of the urinary tract, but it has been linked to side effects affecting the lungs and liver.
- ✓ If you are taking nitrofurantoin, 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.
- ✓ Talk to your doctor or another healthcare professional promptly 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.

The full MHRA alert can be accessed via the following link.

For further information, please call 01254 282862 or email lscicb-el.adminmmt@nhs.net