NHS Forth Valley

Prescriberfile

From the Primary Care Prescribing Group

Treating Nausea & Vomiting During Pregnancy – Treatment Options

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Please Circulate to All Staff

The Scottish Medicines Consortium (SMC) have recently issued advice for the drug Xonvea® (doxylamine succinate 10mg + pyridoxine (vitamin B6) 10mg). **Xonvea® is not recommended for use in NHS Scotland for the treatment of nausea and vomiting of pregnancy** (NVP) in women who do not respond to conservative management.

Xonvea® has demonstrated a small but clinically significant difference in symptoms and well-being compared to placebo. There is no high quality evidence comparing the efficacy and safety of Xonvea® versus other commonly used antiemetics (anithistamines or phenothiazines).

There are no other licensed options for the treatment of NVP.

The MHRA has advised that use of antihistamines or phenothiazines for NVP is not off-label because they are not explicitly contraindicated in pregnancy[1]. Although antihistamines and phenothiazines are not specifically licensed for treating nausea and vomiting of pregnancy, their use is established in clinical practice and most have been used in pregnancy without any known adverse effects on the developing baby.

The United Kingdom Medicines Information Group (UKMi) have recently issued the following advice[2].

- Most cases of NVP resolve within 16-20 weeks with no harm to the pregnancy.
- Non-pharmacological options should be considered first - changes in diet, use of ginger or wrist (P6) acupressure.
- Prescribing treatment in the first trimester is usually not indicated unless the symptoms are debilitating.
- The Royal College of Obstetricians and Gynaecologists (RCOG) currently recommend an antihistamine as the 1st line treatment option e.g. promethazine or cyclizine, both of which can cause sedation. It is suggested that prochlorperazine be used with caution due to the risk of dystonic reactions in young pregnant women.
- Second line treatments recommended by RCOG are domperidone and metoclopramide due to concerns about maternal side effects.
- Doses of antiemetic drugs used for NVP correspond with doses used for their licensed indications.
- Treatment of severe NVP, or hyperemesis gravidarum should be managed in hospital by specialists.

Key Messages

- Recommend non-pharmacological options 1st line
- Consider promethazine or cyclizine as 1st line pharmacological treatment options
- Xonvea® should not be prescribed as it is not recommended for use by the SMC and is non-Formulary in FV

References

1. NICE Evidence Summary [ES20]. Doxylamine/pyridoxine (Xonvea) for treating nausea and vomiting of pregnancy. June 2019.

2.. UKMi Medicines Q&As – How can nausea and vomiting be treated during pregnancy?: Aug 19

Inside this issue:

Key Points of interest:

- Xonvea® is **not** SMC recommended.
- Various Drug Safety Updates
- **Freestyle Libre:**

◊ refer patients with skin reactions to Diabetes Service for review.

◊ Individual requirements for blood glucose testing strips will continue but will be reduced from previous.

- Sodium Aurothiomalate ('GOLD injection') - discontinued by manufacturer. Review patients.

MHRA Drug Safety Updates

Selected highlights from recent Drug Safety Update Bulletins from the MHRA (https://www.gov.uk/drug-safety-update)

Prescribers are encouraged to subscribe directly to the Drug Safety Updates Bulletin which is only available by email.

www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/email-signup

Rivaroxaban 15mg and 20mg tablets should be taken with or after food – A small number of reports have been received by the MHRA suggesting an increased risk of thromboembolic events in patients taking the tablets on an empty stomach. Clinical trials of rivaroxaban showed that absorption of the higher strength tablets was optimal when taken with a high-fat , high-calorie meal. **Patients taking rivaroxaban 15mg or 20mg** tablets should be advised to take **with or after food**. Lower strengths of **rivaroxaban (2.5mg, 10mg) can be taken with or without food**. For further information see the July Update.

Direct-acting oral anticoagulants (DOACs) – Increased risk of recurrent thrombotic events in patients with antiphospholipid syndrome - Recent study has shown an increased risk of recurrent thrombotic events with rivaroxaban versus warfarin in patients with triple-negative antiphospholipid syndrome and a history of thrombosis. All DOACs (edoxaban, apixaban, dabigatran, rivaroxaban) are **not** recommended in patients with antiphospholipid syndrome. **Current patients should be reviewed to determine if continued treatment with a DOAC is appropriate or if patient should be switched to warfarin instead**. For further information see the June Update.

Risk of diabetic ketoacidosis (DKA) in patients co-prescribed GLP-1 receptor agonists (GLP1-RA) and insulin who have doses of insulin rapidly reduced or discontinued – Patients should be advised to monitor their blood glucose regularly when a GLP-1RA is initiated or if the dose of insulin is reduced. Dose reduction of insulin should be undertaken in a step-wise manner.
Patients should be advised of the signs and symptoms of DKA and advised on what action to take if they occur. For further information see the June Update.

Febuxostat – Increased risk of cardiovascular death in patients with a history of major cardiovascular disease – Findings from a Phase IV study (the CARES study) which was looking at patients with gout and a previous history of major CVD (myocardial infarction, stroke or unstable angina) have shown a higher risk for cardiovascular-related death and for all-cause mortality in patients assigned to febuxostat than those assigned to allopurinol. The MHRA have recommended that febuxostat should be avoided in patients with pre-existing major cardiovascular disease unless there are no other appropriate options. Clinicians are reminded that febuxostat is recommended for 2nd line use in patients where allopurinol is ineffective at maximum tolerated doses, contra-indicated or not tolerated and is for initiation by Specialists. For further information see July Update.

Further Advice on Patients Using Freestyle Libre

Following on from the June 2019 article, the Diabetes Team have requested that any patients experiencing skin reactions to Freestyle Libre are referred to the Service for review. The patients can continue to use the sensors pending the review, but as advised previously should be advised not to apply any creams or sprays under the sensor.

People with Type 1 diabetes using the Libre flash glucose monitoring will still require to do capillary blood glucose monitoring with strips, for example if symptoms are not consistent with the Libre readings or to confirm a hypoglycaemic episode. The number of strips and lancets will vary, although this will be significantly reduced compared to previous requirements - patients will request prescriptions for these when a further supply is required.

Sodium Aurothiomalate ('GOLD injection') (Myocrisin®) has been permanently discontinued by the manufacturer, Sanofi, as of June 2019 due to a shortage of the active pharmaceutical ingredient. No new patients should be commenced on sodium aurothiomalate injection. Patients currently prescribed sodium aurothiomalate should be identified and arrangements put in place to transfer patients to a suitable therapeutic alternative.

Contact Information:
General Primary Care Prescribing Advice:
Contact your Primary Care Pharmacist; or alternatively
Primary Care Prescribing Support Team on 01324 566722

For Advice Related to Management of Controlled Drugs:
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