

Prescriberfile

From the Primary Care Prescribing Group

Updated pregabalin safety information and contraception requirements when prescribing teratogenic medicines

Prescribers will be aware that there have been a number of updates from the MHRA Drug Safety Bulletin over the last year highlighting the safety and risks of anti-epileptics during pregnancy (see Prescriberfile from [April](#) and [Oct/Nov 2021](#)).

The [April 2022 Drug Safety Update](#) has updated the [advice on pregabalin](#) following a new Norwegian study which has shown that **use in the first trimester is associated with a slightly increased risk of major congenital malformations compared with exposure to no antiepileptic drugs or to lamotrigine or duloxetine**. The study looked at the use of pregabalin in all licensed indications (being most commonly used in neuropathic pain or anxiety disorder).

- Patients on pregabalin should **use effective contraception** during treatment and **avoid use in pregnancy unless clearly necessary**.
- Patients on pregabalin should be made aware of the risks to an unborn baby (a [patient safety leaflet](#) is available) and the need for effective contraception during treatment.
- Patients planning a pregnancy or who become pregnant during treatment should make an appointment with their GP to discuss their condition and medicines.
- In cases where the benefits outweigh the risks and it is clearly necessary to use pregabalin during a pregnancy, the lowest effective dose should be used.

General reminder for prescribers of ANY anti-epileptic drug:

- At initiation and annual review, discuss the risks associated with antiepileptic drugs, untreated epilepsy during pregnancy and review treatment according to clinical condition and circumstances with reference to the [MHRA safety review](#).
- Patients planning a pregnancy or who become pregnant should be referred for specialist advice on antiepileptic treatment from the specialist managing their epilepsy treatment. The Consultant Obstetrician managing the patient during their pregnancy should also be informed by the GP Practice.
- Folic acid (5mg daily) should be offered to those planning a pregnancy.

- Prescribers should take steps to ensure that patients of childbearing potential are reviewed to ensure treatment in line with the updated advice on pregabalin.
- It is likely that further information will be issued on other antiepileptic as the evidence develops.

The FSRH updated its advice document on [interactions with hormonal contraception](#) in May 2022, more clearly including specific reminders and statements on contraception requirements during use of teratogenic medicines in patients of childbearing potential, in line with its associated document on [teratogenic medicines](#). This updated FSRH document provides the following advice on contraception requirements with teratogenic medicines which is in line with the previous [Prescriberfile](#) in Oct/Nov 2021:

- **During use of a teratogen that is NOT an enzyme inducer (and no other enzyme-inducing drug being taken)** use of the copper IUD, the etonogestrel implant (Nexplanon[®]) or a levonorgestrel-releasing IUS (eg Levosert[®]) is recommended. If combined hormonal contraception, a progestogen-only pill or depot medroxyprogesterone acetate is used, condoms should be used reliably in addition[§]. (**Pregabalin is not an enzyme inducer**)
- **During use of a teratogen that is an enzyme inducer or a potential enzyme inducer (or if an enzyme-inducing drug is also being taken)** use of the copper IUD or a levonorgestrel-releasing IUS (eg Levosert[®]) is recommended, or depot medroxyprogesterone acetate PLUS condoms. Use of combined hormonal contraception, progestogen-only pills and the etonogestrel implant is **not recommended**[§].

[§]FSRH do not consider depot medroxyprogesterone acetate used alone to be a highly-effective method of contraception (it has a failure rate of 6%). The failure rate of oral contraceptives is 9% when used alone.

Volume 31 No. 3

June 2022

Please Circulate to All Staff

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Supply issues

For the latest Supply Issues affecting Primary Care and local associated guidance see [here](#)

Key Points of interest:

- Pregabalin—effective contraception required.
- Advice on contraception requirements for teratogens.
- New Iron Deficiency Guidelines—new oral treatment recommendations
- Formulary Updates—Vagirux[®] replacing Vagifem[®]
- Fear of Flying—patient resources

New Guideline—Treatment of Iron Deficiency in Adults

A new guideline on the [Diagnosis and Treatment of Iron Deficiency Anaemia \(IDA\) in Adults](#) has been approved by the Area Drugs & Therapeutics Committee and is available via the FV Guidelines intranet site.

Key Changes to note:

- A recommendation that **oral iron is prescribed once daily** (rather than twice daily or three times daily) as this is likely to lead to better iron absorption and patient adherence. In some individuals, if recommended by a specialist, alternate day dosing may also be prescribed.
- Advice on monitoring is provided — including advice following any change in dosing regimen.

See the [guideline](#) for full details.

Updates to the NHS Forth Valley Formulary

The following changes to the [Forth Valley Formulary](#) have been agreed by the New Drugs & Formulary Group. Additions and deletions of medicines are based on formulary submissions, new drug assessment requests or formulary section reviews. ADTC decisions relating to SMC assessments can be accessed [here](#). Relevant messages will be added to *ScriptSwitch*[®] to support prescribers in primary care.

Contraception, Vaginal and Vulval Conditions ([BNF Ch 7](#))

Key changes to the contraception section:

- Preferred brands of **copper IUDs and levonorgestrel intra-uterine devices updated**
- **Vaginal and vulval infections**
 - Metronidazole vaginal gel (Zidoval[®]) and dequalinium vaginal tablets (Fluomizin[®]) added.

Vaginal Atrophy - Vagirux[®] replaces Vagifem[®] as the cost-effective preferred brand of estradiol vaginal tablets.

- Any new prescriptions should be prescribed as Vagirux[®] and patients currently prescribed Vagifem[®] should be considered for switching to Vagirux[®] at their next prescription request (potential for up to £40K saving based on current usage).
- Note that Vagirux[®] contains only one **multi-use** applicator per pack (used up to 24 times). This differs from Vagifem[®] which has individual single-use applicators.
- A message has been added to Scriptswitch.

Other changes

- **Ear Infections - ciprofloxacin +dexamethasone ear drops** for the treatment of acute otitis media in patients with tympanostomy tubes – added to the Formulary for specialist initiation/recommendation ([BNF Chapter 12](#))
- **Addition of naloxone nasal spray (Nyxoid[®])** ([BNF Ch4](#)) – for the reversal of opioid toxicity/overdose. 2nd line in patients where IM naloxone (Prenoxad[®]) is considered unsuitable – **prescription by Substance Misuse Services only.**

Fear of Flying—Considerations

As things slowly return to normal and the holiday season begins, we are aware that some prescribers may have received request from patients to prescribe benzodiazepines for fear/phobia of flying.

The use of benzodiazepines for phobias/fear of flying is not a licensed indication and is not recommended by aviation medicine specialists. Benzodiazepines, may delay responses in the event of flight emergencies and have been implicated in passenger incidents, with potential implications for the prescriber.

- A number of resources and support for patients with a phobia of flying are available:
- [Fit for Travel](#) – information for patients
- A number of airlines provide courses aimed at alleviating fear of flying (see box on right)

Example Fear of Flying Courses:

British Airways: [Health and wellbeing tips | Flying health](#) (general passenger advice)
Virgin Atlantic: [flyingwithoutfear](#)
EasyJet: [Fearless Flyer](#)

Many GP Practices in the UK have made leaflets available on the [internet](#) for patients, explaining their Practice policy on prescribing for fear of flying.

Contact Information:

General Primary Care Prescribing Advice:
 Contact your Primary Care Pharmacist; or alternatively
 Primary Care Prescribing Support Team on 01324 567937
 Email: FV.prescribingsupport@nhs.scot

For Advice Related to Management of Controlled Drugs:
 Kirsty Peacock, Inspection Officer for Controlled Drugs,
 NHS Forth Valley, Forth Valley Royal Hospital Tel: 01324-566743
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