NHS Telford and Wrekin Clinical Commissioning Group

NHS Shropshire Clinical Commissioning Group

Prescribing information for high-dose fexofenadine in the management of urticaria in adults

This prescribing information document outlines the prescribing responsibilities between the specialist and GP. GPs are invited to participate. If the GP feels that such prescribing is outside their area of expertise or have clinical concerns about the safe management of the drug in primary care, then he or she is under no obligation to do so. In such an event, clinical responsibility for the patient's health remains with the specialist. If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable.

Consultant details	GP details	Patient details
Name:	Name:	Name:
Address:	Address:	NHS Number:
Email:	Email:	Date of birth:
Contact number:	Contact number:	Contact:

Introduction

Fexofenadine is a second generation non-sedating H_1-antihistamine used in the treatment of allergic disorders. Fexofenadine is a pharmacologically active metabolite of terfenadine.

Licensed indication:
In adults and children 12 years and older, the licensed dose is 180mg daily for the relief of symptoms associated with chronic idiopathic urticaria.

Unlicensed indication (the focus of this document):
As advised by European[i] and British Association of Dermatologists[ii] guidelines, doses of antihistamines up to four times the recommended daily dose may be used in the treatment of urticaria.

Adult dosage and administration

The licensed maximum recommended daily dose is 180mg once daily taken before a meal.
Doses of up to four times the daily recommended dose have been used in the treatment of severe urticaria (unlicensed indication)[i]
Available as: 30mg, 120mg and 180mg tablets

Specialist responsibilities

- Provide patient/carer with relevant written information on the unlicensed use of high-dose fexofenadine and possible side-effects.
- Request whether the GP is willing to participate in continued prescribing.
- Monitor the patient and condition progression at agreed specified intervals and evaluate the need to continue therapy, sending a written summary to the GP whenever the patient is reviewed.
- Provide any other advice or information for the GP including dose adjustments.
- Have a mechanism in place to receive prompt referral back from the GP in cases of clinical need.
- Report any adverse drug reactions to the MHRA via the Yellow Card scheme.

Primary Care responsibilities

- Respond to the specialist's request for primary care prescribing.
- Prescribe fexofenadine according to dose advised by specialist.
- Report any adverse drug reactions to specialist and the usual bodies (MHRA).
- Ensure no drug interactions with any other medicines.

Adverse effects, Precautions and Contra-indications[iii]

Contraindications

- Hypersensitivity to fexofenadine.

Precautions

- There are limited data on the use of this drug in older people and renally or hepatically impaired patients. Fexofenadine should be administered with care in these special groups.
- Patients with a history of, or ongoing cardiovascular disease should be warned that antihistamines as a medicine class are associated with tachycardia and palpitations.
- Current evidence indicates that fexofenadine doses of 800mg as a single dose, up to 690mg twice daily for 1 month or 240mg once daily for a year show no clinically significant adverse reactions compared to placebo.
- Given a lack of clinical data, fexofenadine should be avoided in pregnancy and breastfeeding mothers as after administration of terfenadine (the pro-drug for fexofenadine), fexofenadine was found to cross into human breast milk.

Adverse effects

- **Common side effects:** headache, drowsiness, dizziness, nausea
- **Uncommon side effects:** fatigue
- **Other side effects reported:** hypersensitivity reactions (angioedema, chest tightness, dyspnoea, flushing, systemic anaphylaxis); insomnia, nervousness, tachycardia, palpitations, diarrhoea, rash, urticaria, pruritis.

Common Drug Interactions

- Fexofenadine does not undergo hepatic biotransformation and so does not interact with other medicinal products through hepatic mechanisms.
- Co-administration of fexofenadine with **erythromycin** or **ketoconazole** has been found to result in 2-3 times increase in the plasma concentrations of fexofenadine, though this was not accompanied by any effects on the QT interval or any increase in adverse events compared to monotherapy.
- Administration of antacid containing **aluminium** or **magnesium hydroxide gels** 15 minutes prior to fexofenadine caused a reduction in bioavailability, most likely due to binding in the gastro-intestinal tract. It is advisable to leave 2 hours between administration of fexofenadine hydrochloride and aluminium and magnesium hydroxide containing antacids.

Communication

For any queries relating to this patient's treatment with fexofenadine, please contact the consultant named at the top of this document.

This information is not inclusive of all prescribing information, potential adverse effects and drug interactions. Please refer to full prescribing data in the Summary of Product Characteristics (www.medicines.org.uk) or the British National Formulary (www.bnf.org).

[i] EAACI/GA2LEN/EDF/WAO guideline: management of urticaria. *Allergy* 2009; 64; 1427-1443
[ii] Guidelines for evaluation and management of urticarial in adults and children. British Association of Dermatologists, *British Journal of Dermatology* 2007; 157; 1116-1123
[iii] Telfast 180mg film-coated tablets – Summary of Product Characteristics. Available at www.medicines.org.uk/emc/medicine/21369