

PATIENT / CARER QUESTIONNAIRE

Name of organisation (only applicable if you are submitting information on behalf of a patient organisation or support group):

Crohn`s and Colitis UK

Medicine and indication under consideration:

Ferric maltol (Feraccru®) for the treatment of iron deficiency anaemia in adults with inflammatory bowel disease

Date by which questionnaire should be received:

23rd September 2016

We would like to understand the patient / carer experience and any information you are able to provide, either positive or negative, would be very helpful. We contact clinical experts to give the clinical facts and views.

Please complete this questionnaire and email it to the All Wales Therapeutics and Toxicology Centre (AWTTC) at the email address below. Alternatively, you may complete the questionnaire by hand and return it to the postal address below. Should you have any queries or if, for whatever reason, you find it difficult to complete this questionnaire then please contact AWTTC (see contact details below) and we will endeavour to help. It is not possible for questionnaires to be presented in person at the appraisal meetings – the patient advocate (i.e. the lay member) will undertake this role. The information contained in this questionnaire will not be posted on the www.awmsg.org, but will be circulated to members with other documents prior to the appraisal meetings.

Section 1: General information and medicine-specific details:

- To be completed by patients, carers and family members, or patient organisations on their behalves.
- Experience of the condition and associated treatments (information may be equally relevant to any future submissions that you might make).
- Information *specific* to the medicine under consideration.

Section 2: Patient organisation details:

- Only to be completed if you are submitting information on behalf of a patient organisation or support group.
- These details may not change and can be used for any other questionnaires that the patient organisation wishes to complete (in relation to other medicines/appraisals).

Section 1: General information & medicine-specific details

Section 1 should be completed by patients, carers and family members, or patient organisations on their behalves.

Experience of the condition and associated treatments

Q1 Please state whether you are an individual patient, a patient carer or a family member, or a patient organisation

Patient Organisation

Q2 From a patient or patient carer perspective, please state how this condition affects your day to day life

Crohn`s Disease & Ulcerative Colitis are the 2 main forms of Inflammatory Bowel Disease (IBD) with an estimated 15,000 patients in Wales and 300,000 UK wide; the symptoms being frequent and bloody diarrhoea, pain, fatigue, weight loss and anaemia.

Other symptoms associated with these conditions include inflammation of the joints (elbows, wrists, knees and ankles - affecting about 1 in 10 patients), skin (including mouth ulcers, more rarely pyoderma gangrenosum and erythema nodosum which affects about one in 10 people), liver or eyes (such as episleritis, scleritis and unestis).

The conditions follow an unpredictable, relapsing and remitting course, with variation in the pattern and complexity of symptoms. There is no known cure.

The frequent and urgent need for the toilet, together with loss of sleep and the invisible symptoms of pain and continual or profound fatigue, can severely affect self-esteem and social functioning.

Patients with active and quiescent Inflammatory Bowel Disease (IBD) often report symptoms of fatigue.

`` The fatigue is horrendous, I am a professionally qualified person, I have a life I need to get on with. And fatigue is an absolute killer. There are days when you just can't move, and no, you can't have a day off as life isn't like that. ``

Emotionally, people with IBD can experience difficulties in coping with their lives and feelings of anger, embarrassment, frustration, sadness and fear of needing surgery or developing cancer.

For many individuals the fear of incontinence or 'an accident' in public is a constant worry. The result is a devastating impact on their ability to engage in activities away from the home such as going to work, shopping and socialising. Various coping strategies are often used by people with IBD to avoid having an "accident". Some people avoid eating or drinking prior to leaving their home. Others avoid placing themselves in a situation where they may be without immediate access to the toilet, confining themselves to their homes instead and leaving many feeling isolated.

Q3 What experience have you had of any treatments for the condition in question? Include any advantages or disadvantages

Through it's Social Media and other networks Crohn`s and Colitis UK sought comments and views from people with 1st hand experience of iron deficiency anaemia related to their IBD. The following is a selection of their responses.

`` Being iron deficient has stopped me from being active e.g. going to the gym, sleeping throughout the day, feeling like I really need to manage my energy carefully. Missed get togethers with friends and family. I have had iron tablets, capsules and iron IV infusions. The tablets and capsules made me feel nauseous and I also had diarrhea ``

`` In my case I am unable to take iron tablets as they cause constipation and I struggle with keeping my bowels moving. Despite my high daily bowel output I need to keep everything flowing. So I have iron infusions when needed. This has its pluses and minuses, the downside to this is my haemoglobin had to drop very low before I can have an infusion. This causes my bowel contractions to be very weak and my having tummy pains daily and struggling to keep moving, i could have spicy food and have a good movement and two hours later my stomach is hurting again. This is daily until I have my infusion. ``

`` Iron deficiency anaemia has a big impact on life. It is hard enough living with the day to day symptoms of ulcerative colitis without anaemia too. The main symptom for me was fatigue, as an ibd patient I already live with quite severe fatigue but iron deficiency anaemia makes this worse. My ferritin was also dangerously low too so I had quite severe side effects like tachycardia and experienced daily headaches. I am unable to tolerate iron tablets and was given an iron infusion this worked well for me but came with side effects of its own. I also had to travel to a hospital not local to me for this as the waiting list where I live is very long. I do think new treatments need to be made available. ``

`` Also where my haemoglobin drops so low I am extremely fatigued, I have dizzy spells and feelings of faintness with my pulse racing when I walk up stairs or hills or any excursion like this. Also the tiredness can make daily life like going to work very difficult, when I'm at work the day is a struggle and I've had difficulties with previous managers because of this with they're lack of understanding and compassion which unfortunately is all too common. This effects my hobbies as I enjoy fitness training and martial arts, while I'm anaemic training is very difficult and sometimes can't be done. ``

`` On average from having bloods taken to having my infusion is a wait of between two and three months. Which is a very long time when your getting more exhausted by the week. ``

`` I have been lucky that in the last few years I have been treated with Iron infusions. My colitis means I cannot tolerate iron tablets or iron liquid, the infusions are a life saver. I have to have more than one, but once I have it I feel better for a long period of time. ``

``However, I had to ask for the infusions, as I felt so awful. It was not offered to me. Please remember those of us that suffer. ``

``I can't take any form of iron supplement without aggravating my UC ``

``My daughter has chrohns and she takes ferrous gluconate 300mg 3x a day it makes her life so much better as her levels dont stay up without them.. These were better on her tummy then sulphate they flared everything up ``

``I needed iron tablets last year, bloody awful things to take long term. They abused my body more than the crohns did so ended up leaving them in the cupboard never to be seen again. Hope they find a better way of administration ``

Q4 Which aspects of living with this condition are NOT MET by the treatments currently available? What do patients need the most help with?

For the purposes of this consultation Crohn`s and Colitis only sought comments about iron deficiency treatments and medications, other medicines aim to control symptoms, reduce flare ups and prevent relapses.

Patients may need to take medications on an ongoing basis sometimes for many years; these are most commonly Anti Inflammatory medications, Corticosteroids and Immuno Suppresives. For some people Biological Therapies will be required.

Around 7/10 people with Crohn`s Disease and 2/10 with Ulcerative Colitis may require surgery.

Quality of life for many people is affected by repeated flare ups and the fear of incontinence and, as patients have told us, fatigue related to both their IBD and iron deficiency causes disruption to their work, education and social activities therefore any medication that can help alleviate this disruption to daily life would be warmly welcomed by patients.

The new medicine

Q5 What do you consider are the advantages / benefits (or disadvantages / risks) of this new medicine for patients/carers? What impact might this new medicine have on your life?

Summarising the responses given by patients, oral iron medicines often cause side effects and are not easily tolerated by this group of patients. While iron infusions would appear to be a better option this is sometimes not offered, can have long waits between infusions and require time away from work or education.

This new medicine is taken orally and may minimise the possibility of side effects thus improving the distressing symptoms described by patients and allowing them more control over their daily lives.

`` I have Crohn's disease and was diagnosed in 2013 when I was 13. Since I was small I have always had digestion problems and borderline anaemia. So it seems odd that the standard treatment is to give somebody iron tablets that interfere with digestion further and are not digested properly. I understand it is about value for money and this is a cheaper option, but it is ineffective. I have spent all of my life feeling tired as I was not iron deficient enough to have an iron transfusion and the tablets created more pain for me. It was only after surgery when I had a resection that I am now allowed regular iron transfusions. This takes time out of work, but luckily my employers are understanding for appointments, just not my symptoms. They see I become more tired, but it's the wait I between each transfusion which can be annoying. I work in the public sector and my argument is that I am more productive when I am alert and healthier, so in the long term a better treatment could save money for the government, in my case. I realise that not everybody is in this position however. ``

Section 2: Patient organisation details

Section 2 should ONLY be completed if you are submitting information on behalf of a patient organisation or support group.

All patient information should be anonymous and organisations are reminded of the [Data Protection Act](#), the [Freedom of Information Act 2000](#) and [Human Rights Act](#). AWTTTC will treat all submitted information in confidence but it will be normal practice for AWTTTC in its advice to AWMSG to make reference to having taken into consideration any submission received from a patient/patient carer or support group. If, for whatever reason, you would prefer your organisation not to be named, please tick the box in question 6.

Information about your organisation

Q1 Please provide an overview of your organisation

It would be helpful to include its aims and an outline of membership

Crohn's and Colitis UK is the major UK charity offering information and support to anyone in the UK affected by these conditions, which come under the umbrella description Inflammatory Bowel Disease or IBD. Established in 1979, the charity's services include information and support services, a wide range of accredited information sheets and booklets, and a nationwide network of locally-based groups. The charity, which currently has 29,000 members UK-wide, also raises awareness, campaigns for improved health and public service provision for patients and funds vital research.

Q2 Please list any pharmaceutical companies that are corporate members of your organisation

Abbvie/ Allergan/ Janssen/ Merck(MSD)/ Napp Pharmaceuticals/ Shire Pharmaceuticals/ Takeda/ Tillots/ TopiVert/ Vifor Pharma

Q3 Please provide full details of any funding received from the pharmaceutical companies received within the last TWO years

Pharmaceutical company	Amount of funding received	Purpose of funding
Abbvie	£95,619	Partnership Funding/ Supported Self Management Materials
Actavis	£43,753	Partnership Funding/ Meeting costs
Janssen	£11,000	Partnership Funding/ patient forum costs
MSD	£33,470	Partnership Funding/ Staff attendance at conferences
NAPP	£10,918	Partnership Funding

Shire £10,000 Takeda £46,130 TopiVert £2,400 Vifor Pharma £350.00		Partnership Funding Printing of patient information leaflets Partnership Funding Staff attendance at conference

Q4 Please provide details of any individual(s) who played a significant role in informing your submission

The description should include the following:

- Is the individual a shareholders or director of the pharmaceutical company who manufacture this medicine?
- Has the individual, or the organisation of which they are part, received support in cash or kind from the company, but not related to this specific medicine?
- Has the individual, or the organisation of which they are part, received support in cash or kind in respect of this specific medicine?
- Has the individual participated in clinical trial work for this specific medicine?

We gather information to inform our submission from patients, our Helplines, Local Groups and one to one discussions.

None of the people we have been informed by are shareholders or directors of the pharma company or have received support in cash or kind from the company either related or unrelated to this medicine.

No patient referred specifically to this medicine allowing the assumption that no one has participated in a clinical trial.

Q5 Would you prefer your organisation NOT to be named in the final report presented to AWMSG? If so, please put 'X' in the box