

Patient Group Submission Form

The Scottish Medicines Consortium (SMC) is committed to working in partnership with patient groups to capture patient and carer experiences, and use them to inform decision-making.

Before you make a submission

Following a consultation with patient groups, we have changed the way you submit to SMC. You are now asked to complete a Patient Group Partner Registration Form before you make a submission. The registration form requests general information about your organisation. It only needs to be completed once and should save you time with any further submissions to SMC. If you have not already completed a registration form, please do this before you make your submission.

You can find the form here: www.scottishmedicines.org.uk/Public_Involvement

You will find it helpful to read our guide for Patient Group Partners, which gives details about the type of information you need to capture in the submission form. **Please read this before you make your submission and use it to help you complete each question.**

You can read the guide here: www.scottishmedicines.org.uk/Public_Involvement

Contact us

If you have any more questions after reading the guide, the SMC Public Involvement Team can support you throughout the submission process. You can email us at: hcis.SMCPublicInvolvement@nhs.net or phone: **0141 414 2403**. Please do not hesitate to get in touch, as we are here to help you.

Name of medicine:

Ferric Maltol Feraccru

Indication (what the medicine is used for):

For the treatment of iron deficiency anaemia (IDA) in adult patients with inflammatory bowel disease (IBD)

Submission date:

September 30th 2016

Name of organisation making submission:

Crohn`s and Colitis UK

Who is the main contact for submissions to SMC?

Name:	Elaine Steven
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- 1. Please provide details of any individuals who have had a significant role in preparing your submission and who have an interest to declare. (Please write no more than 300 words)**

None

- 2. Please tell us how you gathered information about the experiences of patients and carers to help inform your submission. (Please write no more than 300 words)**

We gathered information from a specific ask via our Social Media channels and website to inform our submission

3. How does this condition affect the day-to-day lives of people living with it? (Please write no more than 400 words)

Crohn`s Disease & Ulcerative Colitis are the 2 main forms of Inflammatory Bowel Disease (IBD) with an estimated 26,000 patients in Scotland 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.

4. How well are patients managing their condition with medicines which are currently available in NHSScotland? (Please write no more than 400 words)

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.

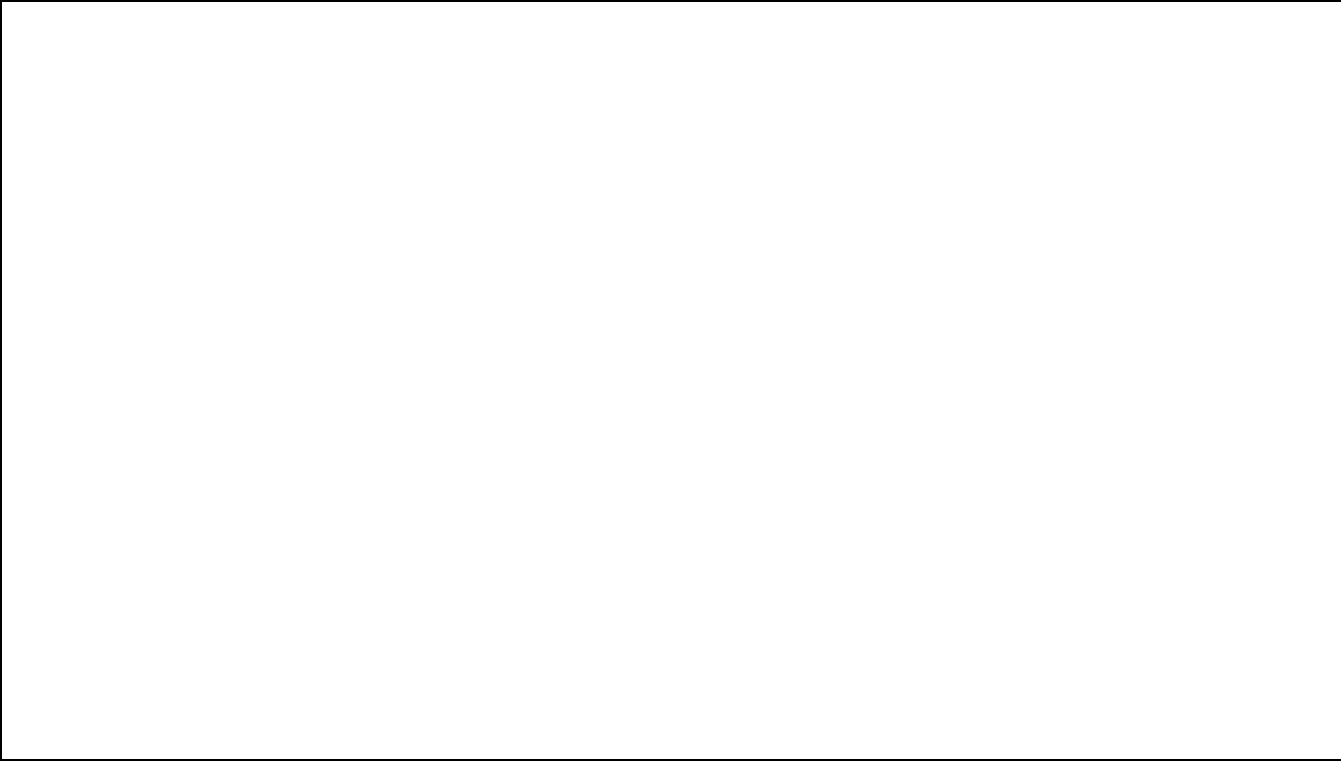
Being iron deficient has stopped me from being active e.g. going to the gym, sleeping throughout the day, feeling like I really need to manage my energy carefully. Missed get togethers with friends and family.

I have had iron tablets, capsules and iron IV infusions.

The tablets and capsules made me feel nauseous and I also had diarrhea``

``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.``



5. Would this medicine be expected to improve the patient's quality of life and experience of care, and if so, how? (Please write no more than 400 words)

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 Suppressives. 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.

`` I've suffered with iron deficiency Aneamia for the best part of ten years. I constantly feel drained and tired and every day is a struggle. I have had ulcerative colitis since age 19 and many surgeries and now I'm awaiting surgery to have a permanent ileostomy. I'm still worried that even though my damaged bowel will be removed I will still suffer from aneamia. I can't absorb anything from my food and being so aneamic constantly, I'm now b12 deficient and have osteopenia. I feel like the best years of my life have been robbed because I'm constantly tired and breathless and everything is such an effort, even things like going up stairs and shopping and holding down a job. I get regular blood tests to check my ferritin levels and receive regular infusions of Ferrinject. I think you're not meant to have loads but I have one atleast every three month. I don't feel it makes a difference and on days I feel ok it never lasts long. It makes me feel sad that I used to be so energetic and full of life and now I am so pale and tired. Sometimes when it's really bad I can feel my heart beat in my ears and I may have only walked a few steps. Being aneamic and having ulcerative colitis has been a challenge but I have IBD and IBD does NOT have me. If there was a better way of helping people like me feel a little more normal I would take it. ``

6. How would treating a patient with this medicine impact the patient's family or carers? (Please write no more than 400 words)

IBD can have an affect on personal relationships and family life - both in terms of creating new relationships and maintaining existing ones.

Fatigue related to IBD can significantly affect an individual's quality of life and ability to carry out everyday tasks and can also affect their ability to undertake physical activities, memory and concentration, social activities, emotional and mental wellbeing, work and education. Consequently some people living with IBD may require significant support from their carers and families.

Any medication that can alleviate these, often difficult and distressing symptoms will, therefore, also have a beneficial effect on a patient`s family and carers who have, not only to assist on occasion, but watch a loved one suffering through this condition.

7. Are there any disadvantages of the new medicine compared to current standard treatments? (Please write no more than 400 words)

Given the responses from patients with 1st hand experience of using current medications for their IDA there would appear to be no disadvantages to this new medicine as it would meet the unmet need of those IBD patients who wish to take an oral product to treat their IDA and who are unable to tolerate currently available treatments.

``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.``

8. Please summarise the key points of your submission in no more than 200 words:

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.

(This is the information that will be used in the published Detailed Advice Document (DAD) summary of Patient Group Submissions. It will also be used during the presentation at the SMC committee meeting. It is very important that you concisely capture the key messages of your submission here.)

9. Do you consent for a summary of your submission to be included in the Detailed Advice Document for this medicine?

Yes

No

Thank you for completing this form.

Please email it to: hcis.SMCPublicInvolvement@nhs.net

If you are unable to email this form to us, please send by post to the address below:

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