Together we *do more.*
Together we *know more.*

MICROSCOPIC COLITIS

Looking for it is finding it

MC is one of many conditions that cause chronic diarrhoea[1,2]

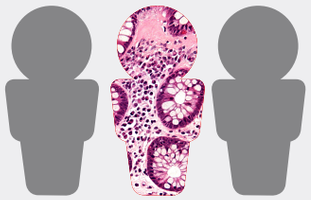
It therefore cannot be differentiated through symptoms alone[1,2]

Patient characteristics	MC	IBS	IBD	Bile acid malabsorption	Coeliac disease	Colorectal cancer	Ischaemic colitis
Mean age	>50	<40	<40	Any	Any	More common >55	Older
Gender	F>M	F>M	Equal	F>M	Equal	M>F	Equal
Stool consistency	Watery	Watery/loose	Loose	Watery	Loose	Variable*	Variable*
Nocturnal	Yes	No	Possible	Possible	No	Unlikely	No
Incontinence	Yes	Possible	Yes	Possible	No	Possible	No
Pain	Unusual	Yes	Possible	No	No	Unlikely	Yes
Blood	No	No	Possible	No	No	Possible	No
Bloating	No	Yes	Possible	No	Possible	Possible	No
Weight loss	Possible	No	Yes	No	Possible	Possible	Yes
Faecal calprotectin	150 µg/g	150 µg/g	150 µg/g	150 µg/g	–	–	–
Diagnostic tests	Serial colonic biopsies including right side	Clinical history	Colonoscopy, biopsies, imaging	SeHCAT	IgA TTGAB	Colonoscopy	CT, MRI, angiography

In particular, there is considerable overlap between the symptoms of MC and the diagnostic criteria for IBS[3]

As UK primary physicians regularly diagnose IBS without specialist referral, MC can be missed[4]

One in three MC patients were initially diagnosed with IBS[3]



CT: computed tomography
IBD: inflammatory bowel disease
IBS: irritable bowel syndrome
IgA: immunoglobulin A
MC: microscopic colitis
MRI: magnetic resonance imaging
SeHCAT: radioactive ^{75}Selenium test
TTGAB: tissue transglutaminase antibody

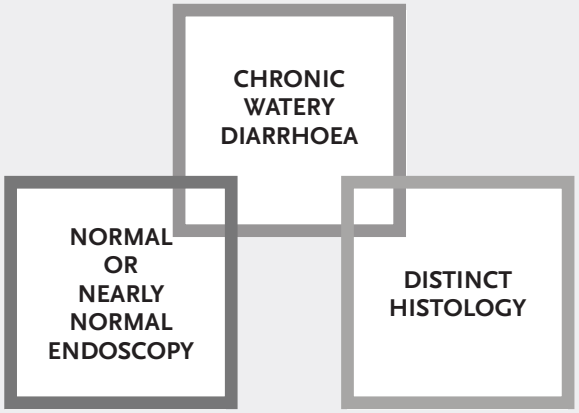
*diarrhoea may occur

1. Output from a meeting between the Primary Care Society for Gastroenterology and secondary care physicians, October 2016.
2. Arasaradnam RP *et al*. Gut 2018; 67(8): 1380-99.
3. Limsui D *et al*. Inflamm Bowel Dis 2007; 13(2): 175-81.
4. Münch A *et al*. Frontline Gastroenterol 2019; doi:10.1136/gastro-2019-101227 [Epub ahead of print]

MC is effectively 'invisible' in primary care[1]

Because it requires a histological diagnosis, MC cannot be found with the objective methods applied in primary care[1]

MC is diagnosed as a triad:[2]



MC may be more common than previously thought. With an estimated incidence of up to 17,800 new cases per year in the UK, MC occurs at a rate comparable to ulcerative colitis and Crohn's disease[3-5]

However, its true frequency may still be underestimated[3]

Without a diagnosis, patients may endure an invisible struggle with their condition[1]

One watery stool per day
=
Decreased QoL

Even one watery stool a day can mean patients suffer[8]

1. Pihl Lesnovska K *et al.* J Clin Nurs 2019; 28(19-20): 3408-15.
2. Engel PJH *et al.* Ann Transl Med 2018; 6(3): 69.
3. Tong J *et al.* Am J Gastroenterol 2015; 110(2): 265-76.
4. Office for National Statistics. Statistical Bulletin: 26 June 2019.
5. National Institute for Health and Care Excellence, 2019. Ulcerative colitis: management [NG130].
6. Hjortswang H *et al.* Inflamm Bowel Dis 2009; 15(12): 1875-81.

MC: microscopic colitis
QoL: quality of life

Some patients may be especially susceptible to MC[1]

The cause of MC is still unclear, but some groups are at a higher risk:[1,2]

- smokers
- women
- people over 50
- PPI, NSAID and SSRI users

These questions may help identify patients with characteristic features of MC[1]

How long have you had diarrhoea?
4+ weeks

What is the most common form of your stool?
Typically watery – Bristol stool chart 6 or 7

Have you had problems with bowel urgency or incontinence?
Typical of MC

Have you taken new medication prior to the chronic diarrhoea?
PPIs, NSAIDs and SSRIs have all been linked with MC

Do you wake up at night to use the toilet?
Nocturnal incontinence occurs in 40% of cases

Do you have blood in your stools?
Blood is not typically present

Have you been diagnosed with any long-term condition?
Autoimmune disease is present in up to 50% of cases

MC: microscopic colitis
NSAID: non-steroidal anti-inflammatory drug
PPI: protein pump inhibitor
SSRI: selective serotonin reuptake inhibitor

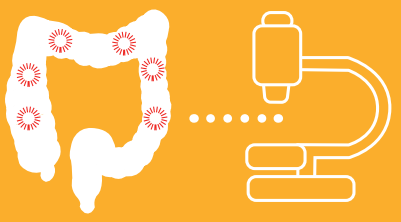
1. Output from a meeting between the Primary Care Society for Gastroenterology and secondary care physicians, October 2016.
2. Miehlke S *et al.* Lancet Gastroenterol Hepatol 2019; 4(4): 305-14.

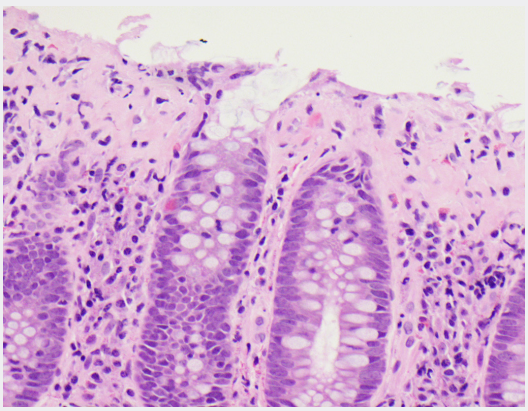
Making an accurate diagnosis relies on histology[1]

The colon is macroscopically normal in most patients, so it's not until biopsies are examined that MC becomes apparent[1]

The gold standard

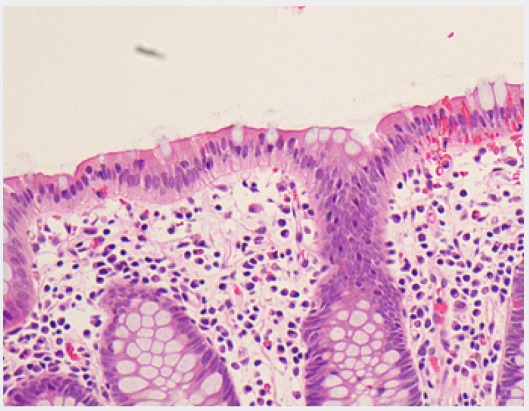
of diagnosis is colonoscopy with at least two biopsies each from the right, left and transverse colon[2,3]





Collagenous colitis

Thickened collagen band more than 10 µm in thickness[4]



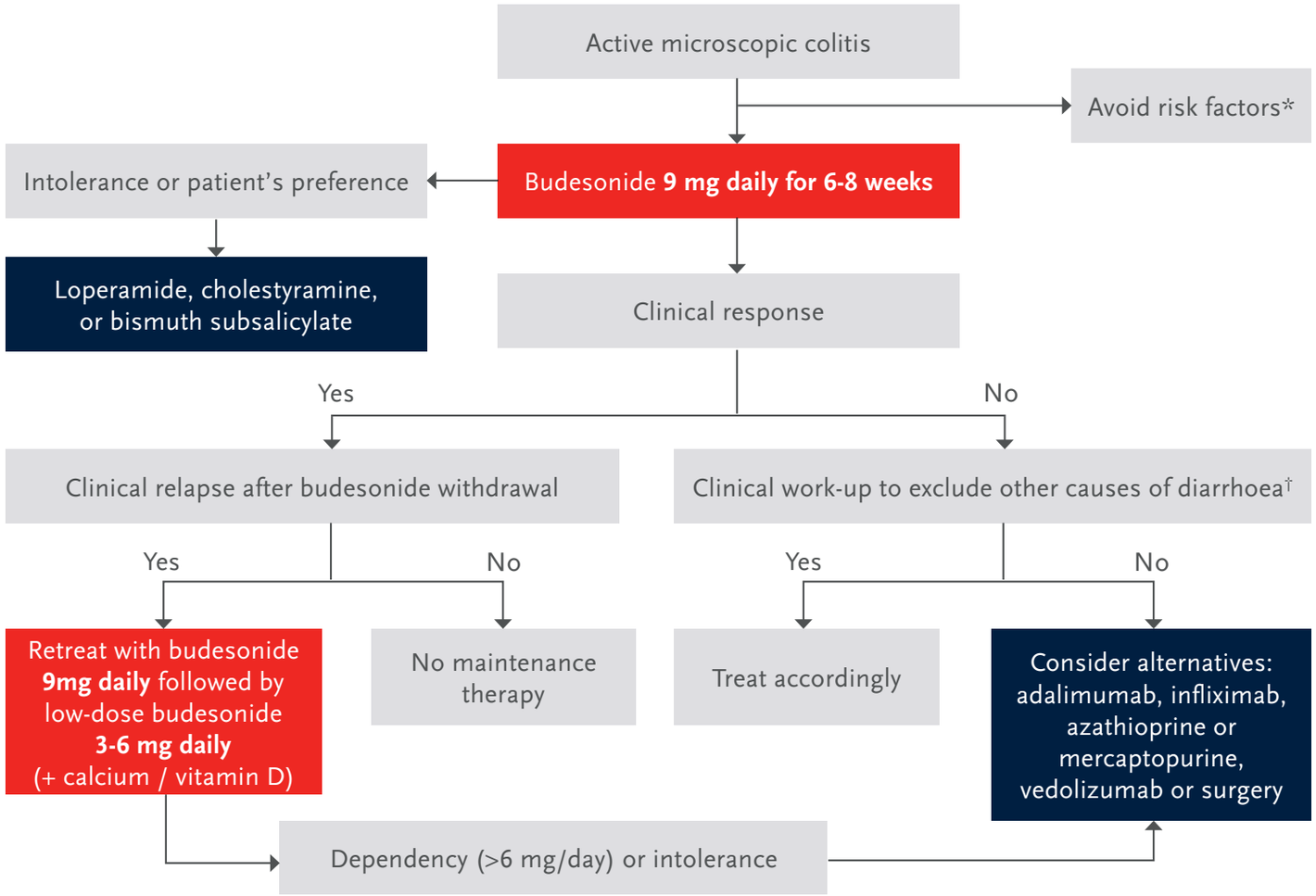
Lymphocytic colitis

More than 20 intraepithelial lymphocytes per 100 epithelial cells[4]

MC: microscopic colitis

1. Münch A *et al*. Frontline Gastroenterol 2019;0:1-7
2. Rees CJ *et al*. Gut 2016; 65(12): 1923-9.
3. Langner C *et al*. Histopathology 2015; 66(5): 613-26.
4. Münch A *et al*. J Crohns Colitis 2012; 6(9): 932-45.

Therapeutic recommendations for patients with MC[1]



Budesonide is recommended by expert guidelines as first-line therapy for MC based on randomised placebo-controlled trials and meta-analyses[2,3]

European Microscopic Colitis Group & United European Gastroenterology[2]

American Gastroenterological Association[3]

Budenofalk 3 mg capsules are licensed for the induction and maintenance of remission of MC[4]

Prescribing information is available on the reverse

*Smoking, non-steroidal anti-inflammatory drugs, proton-pump inhibitors, SSRI, and postmenopausal hormone therapy.

†Bile acid malabsorption, coeliac disease, lactose intolerance, pancreas insufficiency, small intestine bacterial overgrowth.

Adapted from Miehlke 2019[1]

MC: microscopic colitis
SSRI: selective serotonin reuptake inhibitor

1. Miehlke S *et al*. Lancet Gastroenterol Hepatol 2019; 4(4): 305-14.
2. Mielhke S *et al*. United European Gastroenterol J 2020; doi. org/10.1177/2050640620951905.
3. Nguyen GC *et al*. Gastroenterol 2016; 150(1): 242-6.
4. Budenofalk Summary of Product Characteristics.

Once you find it, you can treat it

MORNING COFFEE

Budenofalk capsules are licensed for the induction and maintenance of remission of MC[1]

Find it

It is estimated that MC occurs around as frequently as UC and Crohn's in the UK[4]

Treat it

You can prescribe Budenofalk to induce remission rapidly and maintain it effectively[3]

Worth it

Making a diagnosis isn't always straightforward, but making a difference with treatment can be[5]

MC: microscopic colitis
UC: ulcerative colitis

1. Budenofalk Summary of Product Characteristics.
2. Gentile *et al*. Gut and Liver, Vol. 12, No. 3, May 2018, pp. 227- 235.
3. Miehlke S *et al*. Gastroenterol 2014; 146(5): 1222-30.
4. Miehlke S *et al*. Gastroenterol 2018; 155(6): 1795-1804.e3.
5. Münch A *et al*. Gut 2016; 65(1): 47-56.
6. Stewart *et al*. Clinical Gastroenerology and Hepatology 2011; 9:881-890.
7. Mielhke S *et al*. United European Gastroenterol J 2020; doi.org/10.1177/2050640620951905.
8. Pihl Lesnovska K *et al*. J Clin Nurs 2019; 28(19-20): 3408-15.

Budenofalk® 3mg
budesonide Capsules

Together we *do more.*
Together we *know more.*

Collaboration **Formulation** **Value**

At Dr Falk, we do things differently. Our focus is on people. So for every treatment we develop, from gastroenterology to liver disease, we do it our way.

It's a simple formula.
We call it the Dr Falk way.

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To download your copy of the Budenofalk Microscopic Colitis Educational booklet please scan here:

Prescribing Information (Refer to full SPC before prescribing)
Presentation: Budenofalk® gastro-resistant capsules, each containing 3mg budesonide, 240mg sucrose and 12mg lactose monohydrate. Budenofalk® gastro-resistant granules, each sachet contains 9mg budesonide, 828mg sucrose, 36mg lactose monohydrate and 900mg sorbitol. **Indications: Capsules:** Induction of remission of mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon. Microscopic colitis. Autoimmune hepatitis. **Granules:** Induction of remission of mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon. Induction of remission in patients with active microscopic colitis in adults aged ≥ 18 years. **Dosage:** All - take with a glass of water half an hour before meals. Take once-daily doses in the morning. *Adults:* **Capsules: Crohn's disease:** 9mg once daily or 3mg three times a day. **Microscopic colitis:** Induction of remission: 9mg once daily. Maintenance: lowest effective dose - 6mg once daily or 6mg once daily alternating with 3mg once daily. **Autoimmune hepatitis:** induction of remission: 3mg three times a day. Maintenance: 3mg twice a day. Increase back to 9mg daily if ALAT &/or ASAT increase. Granules: **Crohn's disease and induction of remission in microscopic colitis:** 9mg once daily in the morning. **Duration of treatment:** Induction: Crohn's disease, microscopic colitis: 8 weeks. Autoimmune hepatitis - until remission is achieved then maintenance for at least 24 months. Do not stop any treatment abruptly but taper gradually. **Contra-indications:** hypersensitivity to any constituent. Hepatic cirrhosis. **Warnings/Precautions:** Change from other steroids may result in symptoms due to reduced systemic steroids. Use with caution in patients with tuberculosis, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataracts or family history of glaucoma or diabetes or any condition in which glucocorticosteroids may have undesirable effects. Not appropriate for upper GI Crohn's or extraintestinal symptoms. Prolonged, high dose use may result in glucocorticosteroid systemic effects. Infection: suppression of the inflammatory response and immune function increases susceptibility to infections and their severity. Clinical presentation of infections may be atypical and presentation of serious infections may be masked. Chickenpox and herpes zoster are of particular concern. Passive immunisation needed within 10 days in exposed non-immune patients taking systemic glucocorticosteroids. Urgent specialist care required on confirmed chickenpox. Give normal immunoglobulin immediately after measles exposure. Do not give live vaccines to those with chronic glucocorticosteroid use. Antibody response to other vaccines may be diminished. With severe liver function disorders: increased systemic bioavailability expected. Central serous chorioretinopathy or other causes may result in blurred vision/visual disturbances. Consider referral to ophthalmologist. Suppression of the HPA axis and reduced stress response: supplementary systemic glucocorticoid treatment may be needed. Avoid concomitant treatment with CYP3A4 inhibitors. Do not use in patients with galactose or fructose intolerance, glucose – galactose malabsorption, sucrase – isomaltase insufficiency or total lactase deficiency or congenital lactase deficiency. In autoimmune hepatitis evaluate transaminase levels every 2 weeks for the first month and then every 3 months.

Interactions: Co- treatment with CYP3A inhibitors including cobicistat containing products may increase side effects and should be avoided where possible. Beware concomitant administration of cardiac glycosides and saluretics. CYP3A4 inducers: may reduce systemic and local exposure, necessitating dose adjustment of budesonide. CYP3A4 substrates: may compete with budesonide increasing plasma concentrations depending on relative affinities. S mall, non-significant effect of cimetidine on budesonide kinetic effects. Oestrogens/ oral contraceptives (not oral low dose combination contraceptives) may elevate plasma concentrations and enhance corticosteroid effects. Steroid-binding compounds and antacids may reduce budesonide efficacy; administer at least 2 hours apart. Because adrenal function may be supressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values). **Use in pregnancy and lactation:** Avoid use in pregnancy unless essential. Do not breastfeed during Budenofalk treatment. **Undesirable effects:** Cushing's syndrome, growth retardation in children, glaucoma, cataracts, blurred vision, dyspepsia, abdominal pain, constipation, gastric or duodenal ulcers, pancreatitis, increase in risk of infections, muscle and joint pain and weakness and twitching, osteoporosis, osteonecrosis, headache, pseudotumor cerebri (including papilloedema) in adolescents, depression, irritability and euphoria, psychomotor hyperactivity, anxiety, aggression, allergic exanthema, petechiae, ecchymosis, contact dermatitis, delayed wound healing, increased risk of thrombosis, vasculitis (after withdrawal from long-term treatment), fatigue, malaise. Side effects characteristic of systemic glucocorticosteroid therapy may occur. Exacerbation or reappearance of extraintestinal manifestations when switching from systemically acting glucocorticosteroids may occur. Frequency is likely to be lower than with equivalent dosage of prednisolone. **Legal category:** POM. **Costs: UK NHS:** 60 sachets £135; 100 capsules £75.05. **Ireland** (PtW): 60 sachets: €145.84; 100 capsules: €77.95. **Licence holder:** Dr Falk Pharma GmbH, Leinenweberstr.5, D-79108 Freiburg, Germany. **Licence numbers:** (granules) PL08637/0020 (UK) PA573/2/3 (IE) (capsules) PL08637/0002 (UK) PA573/2/1 (IE). **Prepared:** February 2024

Further information available on request.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play Apple App Store (UK residents) or at email: medsafety@hpra.ie or at http://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form (residents in Ireland). Adverse events should also be reported to Dr Falk Pharma UK Ltd at PV@drfalkpharma.co.uk

Date of preparation: February 2024

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