Salofalk® Granules
mesalazine

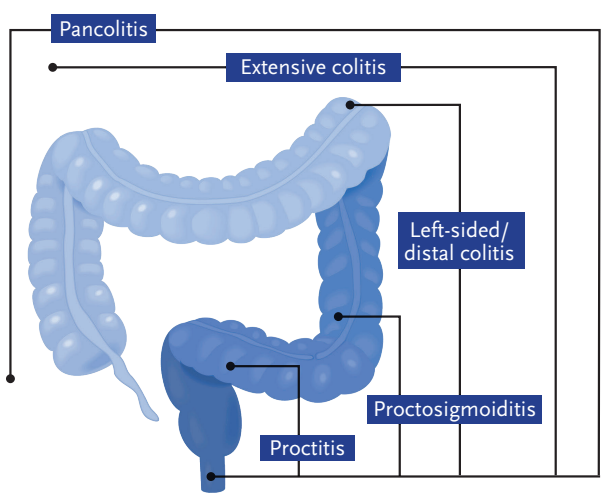
AN ORAL TREATMENT FOR ULCERATIVE COLITIS*

GOING PLACES

*mild-to-moderate

When UC gets in the way of life, where mesalazine gets to matters

Classification of UC by disease extent



Approximately 80% of patients with UC present with disease limited to the distal or left side of the colon[1]

Mesalazine is the mainstay first-line therapy for UC[2]

When it comes to the distal colon, however, the effectiveness of some oral mesalazine formulations can be disappointing because of their release characteristics[3,4]

To treat distal disease, mesalazine needs to reach the distal colon at a high enough concentration[5,6]

With this in mind, the pH at which pH-dependent formulations start to work may be an important factor to consider[7,8]

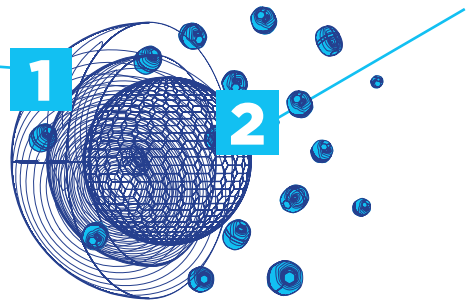
Compared with healthy controls, the colon may be more acidic in patients with UC and some may not reach a pH of 7[5]

Targeting release to pH 6 may help ensure all the active drug is released, even when the pH of the colon is affected by UC[8]

Salofalk Granules are specifically designed to treat UC[3,9]

pH-DEPENDENT DELIVERY

Their pH-sensitive coating ensures mesalazine release starts at the terminal ileum where the pH is ≥6



EXTENDED COLONIC RELEASE

The insoluble polymer matrix at the granule core provides sustained delivery of mesalazine throughout the colon to the rectum

Scan the QR code for an animation on how Salofalk Granules are released in the colon

At their effective doses, Salofalk Granules have a surface area 8 times greater than Salofalk tablets[10]

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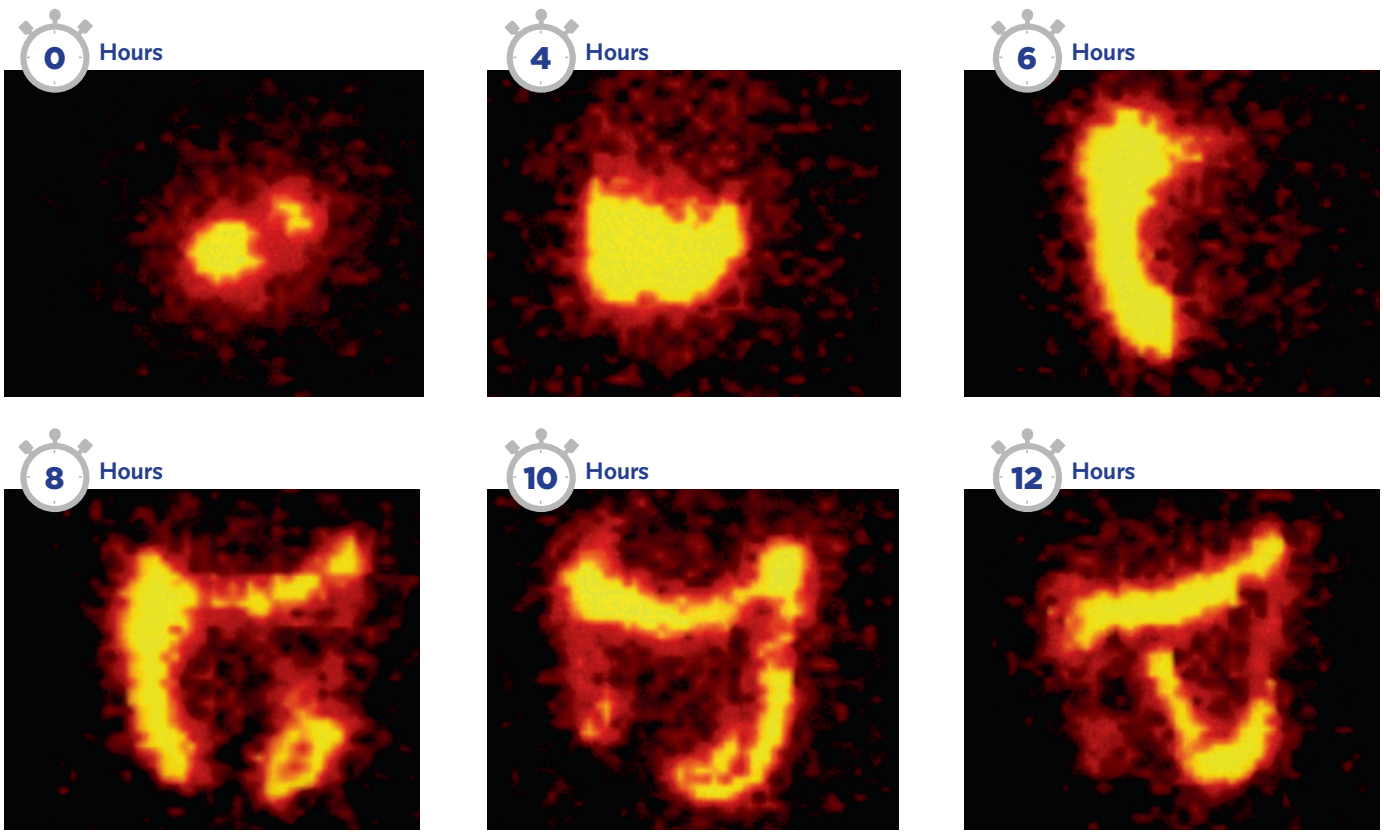
Together we *do more.*

Dr. Falk

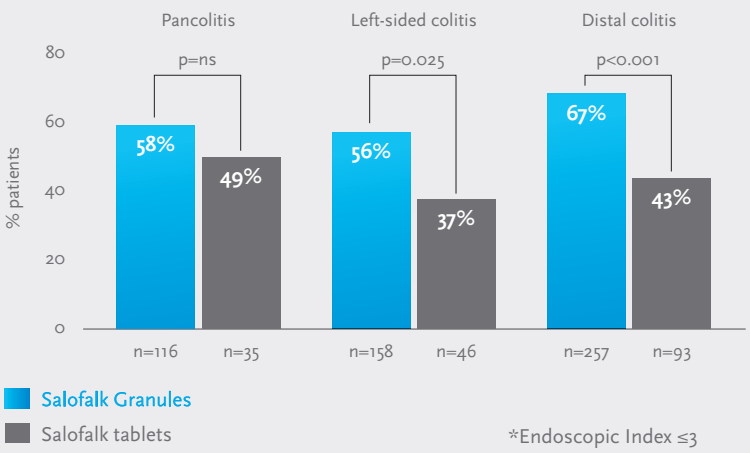
Salofalk Granules reach all parts of the colon[10]

Spread and prolonged release of Salofalk Granules to the distal colon shown using gamma-scintigraphy[10]



Salofalk Granules deliver efficacy to the distal colon[3]

Patients in endoscopic remission at week 8[3]*



*Endoscopic Index ≤3

In left-sided and distal colitis, significantly more patients achieved endoscopic remission with Salofalk Granules than with Salofalk tablets[3]

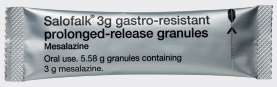
Salofalk Granules are also superior to Salofalk tablets for the induction of clinical remission in distal colitis[3]

12 DAYS

Once-daily Salofalk Granules bring rapid relief; median time to symptom resolution was only 12 days (≤3 stools/day, all without blood)[6]

Salofalk® Granules
mesalazine

Salofalk Granules are designed to encourage adherence[6]



- **Once-daily dosing**
- **Easy to swallow**
- **Vanilla flavoured**

Salofalk Granules are suitable for both induction and maintenance of remission in mild-to-moderate UC[11]

The majority of patients prefer once-daily dosing; with the 3g size, even the maximum daily dose can be taken as a single, once-daily sachet[6,11]

Flexibility of multiple sachet sizes

	Inducing remission	Maintaining remission
Adults	1.5-3.0g/day	1.5-3.0g/day
Children (aged 6+)	30-50mg/kg/day up to a maximum of 75mg/kg/day	15-30mg/kg/day

Optimising maintenance therapy with Salofalk Granules may benefit patients and healthcare providers[12]

Real-world data show changing patients inadequately maintained on other mesalazine formulations to Salofalk Granules resulted in:[12]

87% fewer hospital visits

69% fewer days off work

44% fewer GP visits

50% fewer steroid courses

In this study, changing patients to Salofalk Granules also supported a cost-effective approach to UC management[12]

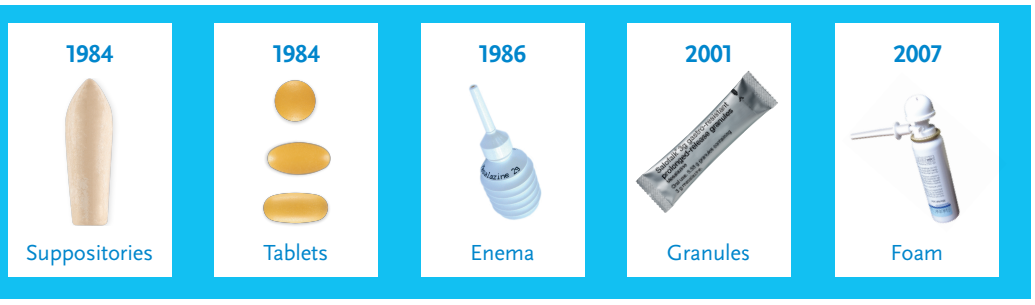
Scan the QR codes to see the NHS prices for different mesalazine brands

IRE:

UK:

Salofalk – the complete range of mesalazine formulations

1984 Dr Falk launch the world's first mesalazine preparation – Salofalk suppositories[13]



TODAY Salofalk has the widest range of mesalazine formulations in the UK, offering choice for patients with different preferences

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Together we *do more.*

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Salofalk® Granules
mesalazine

All things Dr Falk: Together in one place

Falk+ Plus

The community app for healthcare professionals in digestive and metabolic diseases from Dr Falk Pharma UK

Download the app on https://install.events/falkplus

available on your desktop and mobile devices

The you•••track app helps patients track their progress

Patients can search for 'you•••track' in their app store or download it at:

www.drfalk.co.uk/patients/patient-support/you-track-smartphone-app/

you-track

Prescribing Information (Please refer to full SmPC before prescribing):
Presentation: Salofalk® prolonged-release granules containing 500mg, 1g, 1.5g or 3g mesalazine per sachet. **Salofalk gastro-resistant tablets** containing 250mg, 500mg (UK only) or 1g (UK only) of mesalazine. **Salofalk 1g/actuation rectal foam** containing 1g mesalazine per actuation. **Salofalk enema 2g** (UK only) enema containing 2g mesalazine in 59ml of suspension. **Salofalk 4g enema** (IE only) enema containing 4g mesalazine in 60ml of suspension. Salofalk Suppositories containing 250mg (IE only), 500mg (UK only) or 1g mesalazine. **Indications: granules:** treatment of acute episodes and maintenance of remission of mild to moderate ulcerative colitis. **Tablets: 250mg (UK):** treatment of mild to moderate acute exacerbations and maintenance of remission of ulcerative colitis. **250mg (IE):** management of ulcerative colitis and in the treatment of Crohn's disease. **500mg:** treatment of acute episodes and maintenance of remission of ulcerative colitis 1g: treatment of acute episodes of mild to moderate ulcerative colitis. **Enema 2g:** treatment and prophylaxis of acute attacks of mild ulcerative colitis, especially in the rectum/sigmoid colon/descending colon. **Enema 4g:** management of ulcerative colitis, alone or, particularly in the acute phase, with corticosteroids. **1g rectal foam:** treatment of active, mild ulcerative colitis of the sigmoid colon and rectum. **250mg suppositories (IE):** management of ulcerative colitis, alone or, particularly in the acute phase, with corticosteroids. **500mg (UK only) and 1g suppositories:** treatment of mild and moderate attacks of ulcerative colitis in the rectum. **Dosage: granules:** adults: acute episodes: once daily 1 sachet of 3g granules, 1 or 2 sachets of 1.5g granules, 3 sachets of 1g granules or 3 sachets of 500mg granules (equivalent to 1.5 – 3g mesalazine daily), preferably taken in the morning. Alternatively, take in three divided doses. Maintenance: 1 sachet of 500mg granules 3 times a day (1.5g mesalazine daily). Where needed, 3g per day in a single morning dose. **250mg tablets:** adults and elderly: acute treatment 6 -12 tablets daily in 3 divided doses. Maintenance: 6 tablets daily in 3 divided doses. **500mg tablets:** 1 or 2 tablets 3 times daily. Maintenance: 1 tablet 3 times daily. **1g tablets:** 1 tablet three times a day. **Children (all formulations):** there is only limited documentation for an effect in children (age 6-18 years). Dosage in children 6 years and older - oral formulations: active disease – on individual basis starting with 30-50mg/kg/day either once daily (granules) or in divided doses (tablets and granules). Maximum 75mg/kg/day. Total dose should not exceed recommended adult dose. Maintenance - on individual basis starting with 15-30mg/kg/day in divided doses. Total dose should not exceed recommended adult dose. Generally recommended that half the adult dose may be given to children up to a body weight of 40kg and the normal adult dose to those above 40kg. **2g, 4g enema:** adults and elderly: 1 enema a day at bedtime. **1g Rectal Foam:** adults: 2 administrations once a day at bedtime. Divided dose is also possible (1 administration night and morning). **Suppositories 250mg:** 2 suppositories 3 times a day; maintenance - 1 suppository 3 times a day. **500mg suppositories:** adults and elderly: 1–2 suppositories, 2–3 times daily. **1g suppositories:** adults and elderly: 1 suppository once daily. **Method of administration: Oral: granules:** taken on the tongue and swallowed, without chewing, with plenty of liquid. **Tablets:** taken whole without chewing, one hour before meals with liquid. Duration of treatment is usually 8 weeks; to be determined by physician. **Rectal:** read the SmPC and/or patient information leaflet for administration details. Duration of treatment - to be determined by physician. **Contra-indications:** hypersensitivity to salicylates or any of the excipients. Severe impairment of renal or hepatic function. **Warnings/Precautions:** blood tests and urinary status should be determined before and during treatment. Caution is recommended in patients with impaired hepatic function. Not to be used in patients with impaired renal function. Mesalazine-induced renal toxicity should be considered if renal function deteriorates during treatment - stop treatment immediately in such case. Cases of nephrolithiasis reported; ensure good hydration. Serious blood dyscrasias have been reported very rarely with mesalazine. Hematological investigations should be performed if patients suffer from unexplained haemorrhages, bruises, purpura, anaemia, fever or pharyngolaryngeal pain. Salofalk should be discontinued in case of suspected or confirmed blood dyscrasia. Cardiac hypersensitivity reactions (myocarditis, and pericarditis) induced by mesalazine have been rarely reported. Salofalk should then be discontinued immediately. Patients with pulmonary disease, in particular asthma, should be very carefully monitored. Patients with a history of reaction to preparations containing sulphasalazine should be kept under close medical surveillance. Discontinue immediately if there are acute intolerance reactions e.g., abdominal cramps, acute abdominal pain, fever, severe headache and rash. Severe cutaneous adverse reactions (SCARs), including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported. Discontinue treatment at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity. Tablets may (rarely) be excreted undissolved in patients with the ileocecal valve removed. Urine may be discoloured red-brown after contact with sodium hypochlorite bleach used in toilets. **Salofalk granules:** contain aspartame as a source of phenylalanine. May be harmful to patients with phenylketonuria. Also contain sucrose: 0.04mg (500mg granules), 0.08mg (1000mg granules), 0.12mg (1.5g granules) 0.24mg (3g granules). **Salofalk tablets:** for patients on a sodium-controlled diet: the 250mg/500mg tablets contain 48mg/49mg of sodium - 2.4%/2.5% of maximum daily sodium intake. **Salofalk enema 2g/4g:** sodium benzoate may cause local irritation. Potassium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm. **Salofalk foam:** propylene glycol may cause skin irritation, sodium metabisulphite may rarely cause severe hypersensitivity reactions and bronchospasm, cetostearyl alcohol may cause local skin reactions (e.g., contact dermatitis). **Salofalk 500mg suppositories:** cetyl alcohol may cause local skin reactions. **Interactions:** specific interaction studies have not been performed. With concomitant treatment with azathioprine, 6-mercaptopurine or thioguanine consider a possible increase in their myelosuppressive effects. There is weak evidence that mesalazine might decrease the anticoagulant effect of warfarin. **Salofalk granules (additionally):** lactulose, or similar preparations which lower stool pH: possible reduction of mesalazine release from granules due to decreased pH caused by bacterial metabolism of lactulose. **Use in pregnancy and lactation:** do not use Salofalk during pregnancy unless the potential benefit outweighs the possible risks. Limited experience in the lactation period. Salofalk should only be used during breast-feeding if the potential benefit outweighs the possible risks; if the breast-fed infant develops diarrhoea, breast-feeding should be discontinued. **Undesirable effects:** altered blood counts (aplastic anaemia, agranulocytosis, pancytopenia, neutropenia, leukopenia, thrombocytopenia), hypersensitivity reactions such as allergic exanthema, drug fever, lupus erythematosus syndrome, pancolitis, headache, dizziness, peripheral neuropathy, peri- and myo-carditis, allergic and fibrotic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis), abdominal pain, diarrhoea, dyspepsia, flatulence, nausea, vomiting, acute pancreatitis, cholestatic hepatitis, hepatitis, rash, pruritus, photosensitivity, especially with pre-existing skin conditions, alopecia, severe cutaneous adverse reactions (SCARs) including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), arthralgia, myalgia, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, nephrolithiasis, asthenia, fatigue, oligospermia (reversible), changes in hepatic function parameters, changes in pancreatic enzymes, eosinophil count increased. **Salofalk rectal foam** may also cause abdominal distension, anal discomfort, application site irritation and painful rectal tenesmus. **Salofalk enema and suppositories** may also cause constipation. **Legal category:** POM. **Cost** - UK - basic NHS price; IE - Pt W: **granules:** 500mg (100 sachets) £28.74; €27.93. 1g (50 sachets) £28.74; €32.87. 1.5g (60 sachets) £48.85; €49.66. 3g (60 sachets) £97.70; €99.73. **Tablets** 250mg (100s) £16.19; €13.48. 500mg (100s) £32.38. 1g £58.50 (90s). **Enema:** (7) £29.92; €30.36. **1g/actuation rectal foam:** 14 administrations per canister, £30.17; €31.55. **Suppositories:** 250mg (30) €10.70. 500mg (30) £14.81. 1g (30) £29.62; €36.49. **Product licence number: granules:** 500mg: PL08637/0007; PA573/3/1. 1g: PL08637/0008; PA573/3/2. 1.5g: PL08637/0016; PA573/3/7. 3g: PL08637/0025; PA573/3/6. **Tablets:** 250mg: PL10341/0004; PA573/4/3; 500mg: PL08637/0019; 1g: PL08637/0027. **Enema 2g:** PL10341/0008. **Enema 4g:** PA573/4/1. **1g/actuation rectal foam:** PL08637/0003; PA573/4/5. **Suppositories:** 250mg: PA573/4/2. 500mg: PL10341/0009; 1g: PL08637/0018; PA573/4/4. **Product licence holder: 250mg tablets (UK), 2g enema, 500mg suppositories:** Dr Falk Pharma UK Ltd, Bourne End Business Park, Cores End Road, Bourne End, SL8 5AS. **250mg tablets** (IE), **500mg and 1g tablets, all granules, 1g foam, 250mg, 1g suppositories, 4g enema:** Dr Falk Pharma GmbH, Leinenweberstr.5, D-79108 Freiburg, Germany.
Date of preparation: February 2024

Further information is available on request.

Adverse events should be reported. In the UK: reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. **In Ireland,** reporting forms and information can be found at https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form.
Adverse events should also be reported to Dr Falk Pharma UK Ltd at PV@drfalkpharma.co.uk

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Abbreviations:
UC: ulcerative colitis
ns: not significant

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Together we *do more.*

Dr Falk