

Aminosalicylates and IBD agents

Mesalamine (5-aminosalicylic acid, 5-ASA) is a topical mucosal anti-inflammatory that never needs to leave the gut to work, and its various oral formulations exist almost entirely to solve one engineering problem: getting the drug released in the colon rather than absorbed in the stomach, a problem sulfasalazine solved decades earlier by chaining 5-ASA to a carrier molecule that bacteria only cleave once it reaches the colon.

Online guide: <https://www.medguideglobal.com/pharmacology/gastrointestinal/aminosalicylates-and-ibd-agents>

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Quick revision

One Liner: Mesalamine (5-ASA) is a topical gut-mucosal anti-inflammatory whose entire pharmaceutical story is delivery engineering - pH-dependent coatings, sustained-release granules and rectal formulations all exist to get the drug to the inflamed colonic or rectal mucosa intact, and sulfasalazine achieves the same colonic release by a completely different, older trick: a bacterially-cleaved prodrug bond.

1. Mesalamine is 5-aminosalicylic acid (5-ASA), the same active moiety that sulfasalazine delivers to the colon as a metabolite, but given directly rather than as part of a larger prodrug molecule. [7]
2. Its anti-inflammatory action is topical, exerted directly on the gut mucosa it contacts, rather than depending on substantial systemic absorption - which is why so much of its pharmaceutical formulation work is about controlling exactly where in the gut the drug is released. [7]
3. Lialda uses a pH-dependent (Eudragit-type) coating combined with a multi-matrix core designed to release mesalamine progressively through the colon; Asacol uses a similar pH-dependent coating releasing mainly in the terminal ileum and beyond. [1][2]
4. Canasa delivers mesalamine as a rectal suppository directly to the rectal mucosa, used specifically for ulcerative proctitis rather than disease extending higher in the colon. [3]
5. Sulfasalazine is itself a 5-ASA prodrug: colonic bacteria cleave its azo bond to release mesalamine (the active anti-inflammatory moiety) and sulfapyridine (a sulfonamide carrier largely responsible for sulfasalazine's distinct additional side-effect profile, covered on this site's sulfonamides page). [4]
6. Renal impairment, including minimal change disease and interstitial nephritis, has been reported with mesalamine, which is why renal function is checked before starting and periodically during treatment. [1]
7. For patients who do not respond adequately to a 5-ASA agent, step-up IBD therapy moves to immunomodulators (azathioprine) or biologic agents (infliximab), which act by different mechanisms covered in full on their own immunomodulator-hub pages rather than duplicated here. [5][6]

Overview

1. Mesalamine (mesalazine outside the US), or 5-aminosalicylic acid (5-ASA), is the active anti-inflammatory compound at the centre of this class, and the defining fact about how it works is that its action is topical rather than systemic: it acts directly on the gut mucosa it physically contacts, reducing inflammation through inhibition of the cyclo-oxygenase and lipoxygenase pathways, scavenging of free radicals, and reduced recruitment of inflammatory cells such as neutrophils and macrophages to the site of disease. Because the drug does not need to be absorbed into the bloodstream to work, and because too much of it dissolving in the stomach or small intestine would mean less reaching the actual site of colonic or rectal inflammation, an unusual amount of the pharmaceutical engineering behind mesalamine products has gone into controlling exactly where along the gut the drug is released. [7]
2. That engineering problem has been solved several different ways, and the differences between mesalamine brand formulations are essentially differences in delivery system rather than in the underlying drug. Lialda combines a

pH-dependent (Eudragit-type) outer coating, which dissolves only at pH 7 or above, with a multi-matrix core (MMX) designed to slow the drug's release as it passes through the colon, aiming for a more even distribution of mesalamine across the entire colon rather than a single release point. Asacol uses a comparable pH-dependent coating that dissolves at pH 7 or greater, releasing mesalamine mainly from the terminal ileum onward; because the coating, not the tablet's total dose, is what determines the release pattern, the label specifically notes that two Asacol 400 mg tablets have not been shown to be bioequivalent to a single Asacol HD 800 mg tablet with a different formulation. Pentasa, by contrast, uses ethylcellulose-coated microgranules for a more sustained, less pH-dependent release beginning in the small intestine, giving broader upper-gut and small-bowel coverage relevant to Crohn's disease. [1][2]

3. Rectal formulations solve the delivery problem in the simplest possible way: by placing the drug directly at the site of distal disease. Canasa suppositories deliver 1000 mg of mesalamine directly to the rectal mucosa and are indicated specifically for mildly to moderately active ulcerative proctitis, disease confined to the rectum, where a suppository can reach essentially all of the inflamed tissue without needing to survive transit through the upper gut at all. Mesalamine is also available as a rectal enema for disease extending somewhat higher into the distal colon than a suppository alone can reach. [3]

4. Sulfasalazine predates mesalamine as a treatment for ulcerative colitis and solves the same colonic-delivery problem by an entirely different chemical trick: it links 5-ASA to sulfapyridine by an azo bond that survives digestion in the stomach and small intestine intact, and is cleaved only by bacterial azoreductases once the drug reaches the colon, releasing mesalamine at the site where it is needed and sulfapyridine as a byproduct. Sulfapyridine itself has no established anti-inflammatory role in ulcerative colitis and is instead the carrier largely responsible for sulfasalazine's own distinct additional adverse-effect burden - including hypersensitivity reactions, hemolysis in glucose-6-phosphate dehydrogenase deficiency, and severe cutaneous reactions - which is why sulfasalazine's full safety and dosing profile is covered on this site's sulfonamides class page rather than duplicated here; this page treats it specifically as a 5-ASA prodrug. [4]

5. For patients whose ulcerative colitis or Crohn's disease does not respond adequately to a 5-ASA agent, or whose disease is more severe at diagnosis, IBD therapy steps up to drugs from entirely different pharmacological classes: immunomodulators such as azathioprine, which suppress broader immune activity rather than acting topically on the mucosa, and biologic agents such as infliximab, a TNF-alpha inhibitor given by infusion. Both belong to the immunomodulators hub on this site and are noted here only to place mesalamine correctly within the overall IBD treatment ladder - as typically the first-line agent for mild to moderate ulcerative colitis, with immunomodulators and biologics reserved for more severe, refractory, or steroid-dependent disease. [5][6]

Classification and drug examples

Intro: This class is organised around a single active moiety, mesalamine (5-ASA), grouped by how each formulation gets that moiety to the site of gut inflammation, plus sulfasalazine as an older prodrug route to the same active compound.

1. Name: pH-dependent (delayed) release oral mesalamine

1. Note: Coating dissolves only above a threshold pH reached in the distal small bowel/colon, targeting release to that region.

1. Name: Mesalamine (MMX multi-matrix formulation)

Lialda

1. Route: Oral

1. Note: Combines a pH-dependent coating with a multi-matrix core intended to release mesalamine progressively across the colon. [1]

2. Name: Mesalamine (delayed-release tablet)

Asacol

2. Route: Oral

2. Note: Coating dissolves at pH 7 or greater, releasing mainly from the terminal ileum onward; not bioequivalent

tablet-for-tablet across different Asacol strengths. [2] [1][2]

2. Name: Sustained (controlled) release oral mesalamine

2. Note: Ethylcellulose-coated microgranules release more gradually and less strictly by pH, giving broader small-bowel coverage.

Name: Mesalamine (controlled-release capsule)

Pentasa

Route: Oral

Note: Sustained-release microgranule formulation with release beginning earlier in the small intestine than the pH-dependent products. [7] [7]

3. Name: Rectal mesalamine

3. Note: Delivers the drug directly to distal disease without needing to survive upper-gut transit.

Name: Mesalamine suppository

Canasa

Route: Rectal

Note: Indicated specifically for mildly to moderately active ulcerative proctitis. [3] [3]

4. Name: Sulfonamide-linked 5-ASA prodrug

4. Note: 5-ASA bound to a sulfonamide carrier by an azo bond cleaved by colonic bacteria; full safety profile is covered on the sulfonamides class page, referenced here as a 5-ASA delivery mechanism.

Name: Sulfasalazine

1. Azulfidine

2. Azulfidine EN-tabs

Route: Oral

Note: An azo-bonded prodrug of mesalamine and sulfapyridine; sulfapyridine carries no established anti-inflammatory role and is the source of most of sulfasalazine's distinct additional adverse effects. [4] [4]

Mechanism of action

Summary: Mesalamine (5-ASA) acts topically on the gut mucosa it contacts, inhibiting cyclo-oxygenase and lipoxygenase pathways, scavenging free radicals, and reducing recruitment of inflammatory cells to reduce mucosal inflammation in ulcerative colitis and, to a lesser labelled extent, Crohn's disease. Because the effect is local rather than dependent on systemic absorption, every formulation in this class is an engineering solution to the same problem: releasing the drug where the inflamed mucosa actually is, whether that is achieved with a pH-sensitive coating, a sustained-release microgranule matrix, a rectal suppository, or - in sulfasalazine's case - a bacterially cleaved azo prodrug bond.

Target: Colonic and rectal mucosa (topical anti-inflammatory action); cyclo-oxygenase and lipoxygenase pathways, and inflammatory cell recruitment, within that mucosa

Cidal Static: Not applicable - this is a topical mucosal anti-inflammatory action, not an antimicrobial effect

Kill Kinetics: Not applicable in the cidal/static sense; clinical response in active ulcerative colitis is typically assessed over 2 to 8 weeks of continued dosing

1. Step: 1

1. Title: 5-ASA must reach the inflamed mucosa intact

1. Detail: Because mesalamine's action is topical, an oral formulation that dissolved and was absorbed entirely in the stomach or upper small intestine would deliver little active drug to the actual site of colonic or rectal disease - the starting design problem for every formulation in this class. [7]

2. Step: 2

2. Title: Delivery-system engineering solves that problem in different ways

2. Detail: pH-dependent coatings (Lialda, Asacol) dissolve only once the tablet reaches a region of the gut with pH 7 or higher; sustained-release microgranules (Pentasa) release more gradually and less strictly by pH; rectal suppositories

(Canasa) simply place the drug at the site of distal disease; sulfasalazine instead relies on colonic bacterial azoreductases to cleave its prodrug bond. [1][2][3][4]

3. Step: 3

3. Title: Released mesalamine acts locally on the mucosa

3. Detail: Once released at the target site, mesalamine inhibits cyclo-oxygenase and lipoxygenase activity, reducing production of pro-inflammatory prostaglandins and leukotrienes, and scavenges reactive oxygen species. [7]

4. Step: 4

4. Title: Reduced inflammatory cell recruitment follows

4. Detail: The combined effect reduces recruitment of neutrophils and macrophages to the mucosa and reduces local production of inflammatory cytokines including interleukin-1 and TNF-alpha, lowering mucosal inflammation. [7]

Major clinical uses

1. Drug: Mesalamine (MMX, delayed-release oral)

1. Organism: Not applicable

1. Indication: Induction and maintenance of remission in mildly to moderately active ulcerative colitis in adults, and treatment of mildly to moderately active ulcerative colitis in pediatric patients weighing at least 24 kg (Lialda)

1. Line: first-line for mild to moderate ulcerative colitis

1. Note: Administered with food and adequate fluids; tablets are not split or crushed. [1]

2. Drug: Mesalamine (delayed-release, terminal-ileum-targeted)

2. Organism: Not applicable

2. Indication: Treatment of mildly to moderately active ulcerative colitis; maintenance of remission of ulcerative colitis (Asacol)

2. Line: first-line for mild to moderate ulcerative colitis

2. Note: Two 400 mg tablets are not bioequivalent to one 800 mg Asacol HD tablet. [2]

3. Drug: Mesalamine (rectal suppository)

3. Organism: Not applicable

3. Indication: Mildly to moderately active ulcerative proctitis (Canasa)

3. Line: first-line for disease confined to the rectum

3. Note: Retained for one to three hours or longer where possible for maximal mucosal contact. [3]

4. Drug: Sulfasalazine

4. Organism: Not applicable

4. Indication: Mild to moderate ulcerative colitis, as adjunctive therapy and for prolonging remission; also used in rheumatoid arthritis (a distinct, non-IBD indication)

4. Line: an alternative first-line 5-ASA route where its distinct adverse-effect profile is acceptable

4. Note: Full sulfonamide-related safety profile is covered on this site's sulfonamides class page; only its role as a 5-ASA prodrug is discussed here. [4]

5. Drug: Azathioprine (step-up immunomodulator, context only)

5. Organism: Not applicable

5. Indication: Maintenance of remission in ulcerative colitis or Crohn's disease inadequately controlled by, or intolerant of, a 5-ASA agent

5. Line: second-line, step-up therapy

5. Note: Belongs to the immunomodulators hub; full profile not duplicated on this page. [5]

6. Drug: Infliximab (biologic step-up therapy, context only)

6. Organism: Not applicable

6. Indication: Moderately to severely active ulcerative colitis or Crohn's disease inadequately controlled by conventional therapy

6. Line: third-line/biologic step-up therapy

6. Note: A TNF-alpha inhibitor belonging to the immunomodulators/biologic hub; full profile not duplicated on this page. [6]

Pharmacokinetics

1. Drug: Mesalamine (MMX)

1. Route: Oral

1. Absorption: Formulated to minimise proximal absorption and maximise colonic release via combined pH-dependent coating and multi-matrix core

1. Csf Penetration: Not applicable

1. Metabolism: Acetylated in the gut mucosa and liver to N-acetyl-5-ASA

1. Elimination: Renal (as metabolite) and faecal

1. Dose Adjust: Renal function assessed before and periodically during treatment [1]

2. Drug: Mesalamine (delayed-release, Asacol-type)

2. Route: Oral

2. Absorption: Coating dissolves at pH 7 or greater, releasing mainly from the terminal ileum onward

2. Csf Penetration: Not applicable

2. Metabolism: Acetylated in the gut mucosa and liver

2. Elimination: Renal (as metabolite) and faecal

2. Dose Adjust: Not bioequivalent across differently formulated strengths of the same brand; renal function monitored [2]

3. Drug: Mesalamine (rectal suppository)

3. Route: Rectal

3. Absorption: Acts locally on rectal mucosa with limited systemic absorption relative to oral formulations

3. Csf Penetration: Not applicable

3. Metabolism: Local mucosal and hepatic acetylation of any absorbed fraction

3. Elimination: Renal (as metabolite) and faecal

3. Dose Adjust: Not established beyond 6 weeks of continuous use [3]

4. Drug: Sulfasalazine

4. Route: Oral

4. Absorption: The intact azo-bonded molecule is poorly absorbed until cleaved by colonic bacteria

4. Csf Penetration: Not applicable

4. Metabolism: Colonic bacterial azoreductase cleavage into mesalamine and sulfapyridine; sulfapyridine is further acetylated hepatically

4. Elimination: Renal (sulfapyridine metabolites) and faecal (mesalamine)

4. Dose Adjust: Adequate fluid intake maintained to reduce crystalluria risk; caution in G6PD deficiency because of sulfapyridine-related hemolysis risk [4]

1. This page gives no dose regimens by design. Dose selection depends on disease extent, severity, formulation and renal function, and belongs in a current prescribing reference used by the treating clinician.

2. Because mesalamine's action is topical, matching the delivery system (pH-dependent oral, sustained-release oral, or rectal) to the anatomical extent of disease is a bigger determinant of efficacy than choosing between brands with the same active moiety. [3][1]

Adverse effects

1. Effect: Headache, nausea and abdominal pain

1. Detail: Reported with oral mesalamine formulations, generally mild and self-limited. [1]

2. Effect: Flatulence and abdominal cramping

2. Detail: Reported with oral mesalamine, overlapping with symptoms of the underlying disease being treated, which

can complicate attributing new symptoms to the drug versus a flare. [2]

3. Effect: Rectal discomfort or urgency

3. Detail: Reported with mesalamine suppositories, generally mild. [3]

1. Effect: Renal impairment, including minimal change disease and interstitial nephritis

1. Detail: Renal impairment, including minimal change disease, acute and chronic interstitial nephritis, and rarely renal failure, has been reported in patients given mesalamine.

1. Action: Renal function is evaluated before starting mesalamine and periodically during therapy. [1]

2. Effect: Mesalamine-induced acute intolerance syndrome

2. Detail: A minority of patients develop an acute worsening of colitis symptoms, including cramping, bloody diarrhoea and sometimes fever, attributable to the drug itself rather than the underlying disease.

2. Action: Mesalamine is discontinued if this reaction is suspected, and it is generally avoided on rechallenge. [7]

3. Effect: Severe cutaneous adverse reactions and hematologic toxicity with sulfasalazine

3. Detail: Severe cutaneous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, and hemolytic anaemia in G6PD deficiency, have been reported with sulfasalazine - effects attributable to its sulfapyridine component rather than to the mesalamine it releases.

3. Action: These risks, and the associated monitoring, are covered in full on this site's sulfonamides class page rather than duplicated here. [4]

1. Drug: Lialda / Asacol

1. Effect: Renal monitoring before and during treatment is the main serious safety issue distinguishing oral mesalamine from rectal mesalamine, which has more limited systemic exposure. [1]

2. Drug: Canasa

2. Effect: Safety and effectiveness beyond 6 weeks of continuous use have not been established for the suppository formulation specifically. [3]

3. Drug: Sulfasalazine

3. Effect: Carries a distinct, additional adverse-effect burden compared with mesalamine-only formulations, attributable to its sulfapyridine carrier - detailed on this site's sulfonamides page. [4]

Contraindications, precautions and interactions

1. Known hypersensitivity to salicylates or to any component of the specific mesalamine formulation. [1]

2. Sulfasalazine: hypersensitivity to sulfonamides or salicylates; intestinal or urinary obstruction. [4]

1. Pre-existing renal disease is a reason for closer monitoring with any oral or rectal mesalamine formulation, given the reported association with renal impairment. [1]

2. New or worsening bloody diarrhoea, cramping or fever after starting mesalamine is evaluated for possible drug-induced acute intolerance rather than assumed to be disease progression. [7]

3. G6PD deficiency is a specific caution with sulfasalazine because of hemolysis risk from its sulfapyridine component. [4]

4. Adequate fluid intake is maintained during sulfasalazine therapy to reduce the risk of crystalluria and stone formation. [4]

1. With: Nephrotoxic agents, including NSAIDs

1. Effect: Increased risk of nephrotoxicity when combined with mesalamine; renal function and mesalamine-related adverse reactions are monitored more closely. [1]

2. With: Azathioprine or other immunomodulators

2. Effect: When 5-ASA agents are combined with azathioprine at the step-up stage of IBD therapy, additive hematologic effects are monitored for, since this combination sits across two different pharmacological classes. [5]

Comparison tables

Title: One active moiety, four delivery engineering solutions

Caption: Mesalamine's mechanism is identical across formulations; what differs is where in the gut each formulation is designed to release the drug, and sulfasalazine reaches the same active moiety by a bacterial-cleavage route instead of formulation chemistry.

1. Key: formulation

1. Label: Formulation

2. Key: release_mechanism

2. Label: Release mechanism

3. Key: target_region

3. Label: Primary target region

4. Key: typical_use

4. Label: Typical use

1. Formulation: Lialda (MMX)

1. Release Mechanism: pH-dependent coating plus multi-matrix core

1. Target Region: Colon, distributed progressively

1. Typical Use: Mild to moderate ulcerative colitis, induction and maintenance [1]

2. Formulation: Asacol

2. Release Mechanism: pH-dependent coating (dissolves at pH 7+)

2. Target Region: Terminal ileum and beyond

2. Typical Use: Mild to moderate ulcerative colitis [2]

3. Formulation: Canasa (suppository)

3. Release Mechanism: Direct rectal placement, no gut transit required

3. Target Region: Rectum

3. Typical Use: Ulcerative proctitis [3]

4. Formulation: Sulfasalazine

4. Release Mechanism: Colonic bacterial azoreductase cleavage of a prodrug bond

4. Target Region: Colon

4. Typical Use: Mild to moderate ulcerative colitis; also used in rheumatoid arthritis [4]

High-yield exam pearls

1. Pearl: Mesalamine's action is topical, not systemic - the drug does not need to be absorbed to work.

1. Why: This single fact explains why so many different formulations of the same active moiety exist: each is solving a delivery-location problem, not a potency problem. [7]

2. Pearl: Sulfasalazine is a mesalamine prodrug, not a separate drug with a separate mechanism.

2. Why: Its azo bond is cleaved by colonic bacteria specifically to release the same active 5-ASA that Lialda, Asacol and Canasa deliver directly; sulfapyridine, the carrier, is why sulfasalazine's side-effect profile differs. [4]

3. Pearl: Two Asacol 400 mg tablets are not bioequivalent to one Asacol HD 800 mg tablet.

3. Why: A classic labelled exception showing that with a pH-dependent coated formulation, the coating and tablet engineering - not simply the total mesalamine dose - determines the release profile. [2]

4. Pearl: Rectal mesalamine is chosen by disease location (proctitis), not by disease severity alone.

4. Why: Canasa's indication is specifically ulcerative proctitis - disease confined to the rectum - which a suppository can reach completely, unlike more proximal colonic disease. [3]

5. Pearl: Mesalamine can itself trigger an acute colitis-like intolerance reaction.

5. Why: New bloody diarrhoea or cramping after starting mesalamine is not automatically a disease flare - it can be the drug itself, a distinction with direct treatment implications. [7]

Common exam traps

1. Trap: Treating sulfasalazine and mesalamine as two unrelated drug classes.

1. Correction: Sulfasalazine is a prodrug of mesalamine; the two share the same active anti-inflammatory moiety, and sulfasalazine's distinct extra risks come from its sulfapyridine carrier, not from a different anti-inflammatory mechanism. [4]
2. Trap: Assuming all oral mesalamine formulations are interchangeable at the same total daily dose.
2. Correction: Different pH-dependent and sustained-release formulations target different regions of the gut and are not necessarily bioequivalent tablet-for-tablet even within the same brand family. [2]
3. Trap: Assuming infliximab or azathioprine are 5-ASA agents because they are used for the same diseases.
3. Correction: They belong to entirely different pharmacological classes (a TNF-alpha biologic and a thiopurine immunomodulator respectively) and are step-up therapies used when 5-ASA agents are insufficient, not alternative aminosalicylates. [6][5]
4. Trap: Overlooking that mesalamine itself can cause renal impairment.
4. Correction: Minimal change disease, interstitial nephritis and rarely renal failure are reported with mesalamine, which is why renal function is checked before and during treatment despite the drug's mainly topical mechanism. [1]

Self-test questions

1. Question: What is the relationship between sulfasalazine and mesalamine?
 1. They are unrelated drugs used for different diseases
 2. Sulfasalazine is a prodrug that colonic bacteria cleave to release mesalamine and sulfapyridine
 3. Mesalamine is a metabolite of sulfapyridine
 4. Sulfasalazine is a newer, more potent version of mesalamine
1. Explanation: Sulfasalazine's azo bond is cleaved by colonic bacterial azoreductases into mesalamine, the active anti-inflammatory moiety, and sulfapyridine, a carrier responsible for most of sulfasalazine's distinct additional side effects. [4]
2. Question: Why does mesalamine come in so many different oral and rectal formulations?
 1. Because each formulation is a chemically different drug
 2. Because mesalamine's action is topical on the gut mucosa, so formulation engineering controls where in the gut the drug is released
 3. Because different formulations have different active ingredients entirely
 4. Purely for marketing purposes with no pharmacological rationale
2. Explanation: Because mesalamine works topically rather than through systemic absorption, delivering it to the right part of the gut - via pH-dependent coatings, sustained-release granules, or rectal placement - is the central pharmaceutical problem this class solves. [7]
3. Question: Why is Canasa (mesalamine suppository) specifically indicated for ulcerative proctitis rather than more extensive colitis?
 1. Because it is more potent than oral mesalamine
 2. Because a rectal suppository can directly reach and treat disease confined to the rectum without needing to survive upper-gut transit
 3. Because oral mesalamine cannot treat ulcerative colitis at all
 4. Because proctitis requires a lower total dose of mesalamine
3. Explanation: A suppository delivers mesalamine directly to the rectal mucosa; this only adequately treats disease confined to that region, which is why the indication is specifically ulcerative proctitis rather than more proximal colonic disease. [3]
4. Question: What serious renal finding has been reported with mesalamine, requiring monitoring?
 1. Renal artery stenosis
 2. Minimal change disease and interstitial nephritis, rarely progressing to renal failure
 3. Polycystic kidney disease
 4. Renal cell carcinoma

4. Explanation: Mesalamine labelling reports minimal change disease, acute and chronic interstitial nephritis, and rarely renal failure, which is why renal function is assessed before starting and periodically during treatment. [1]
5. Question: When is step-up therapy with azathioprine or infliximab typically considered in ulcerative colitis?
 1. As first-line therapy for all patients regardless of severity
 2. When disease is inadequately controlled by, or the patient is intolerant of, a 5-ASA agent
 3. Only after a 5-ASA agent has been used for at least 10 years
 4. Never in combination with any 5-ASA agent
5. Explanation: Immunomodulators and biologic agents are step-up therapies used when 5-ASA agents like mesalamine do not adequately control disease or are not tolerated, reflecting mesalamine's position as typical first-line therapy for mild to moderate disease. [5][6]
6. Question: Why are two Asacol 400 mg tablets not necessarily equivalent to one Asacol HD 800 mg tablet?
 1. Because they contain different active drugs
 2. Because differences in tablet formulation and coating affect the release profile independent of total mesalamine dose
 3. Because Asacol HD is absorbed systemically while Asacol is not
 4. Because the FDA has never evaluated Asacol HD
6. Explanation: The label explicitly states that two 400 mg tablets have not been shown to be bioequivalent to one 800 mg Asacol HD tablet, reflecting how formulation and coating design, not just total dose, determine a pH-dependent-release product's behaviour. [2]

Frequently asked questions

1. Question: Is mesalamine the same drug as sulfasalazine?
 1. Answer: Not exactly. Mesalamine (5-ASA) is the active anti-inflammatory compound in both. Sulfasalazine is an older prodrug that chemically links 5-ASA to a sulfonamide carrier (sulfapyridine) by a bond that colonic bacteria cleave to release the active mesalamine. Mesalamine products such as Lialda, Asacol and Canasa deliver 5-ASA directly, using pharmaceutical formulation rather than bacterial cleavage to control where it is released. [4]
2. Question: Why are there so many different mesalamine brand products?
 2. Answer: Because mesalamine works topically on whichever part of the gut mucosa it contacts, rather than through the bloodstream, getting the drug released at the right location - the colon broadly, the terminal ileum specifically, or the rectum alone - is the main pharmaceutical challenge. Different coatings, release matrices, and rectal formulations are all solving that same location problem for the same active drug. [7]
3. Question: What monitoring does mesalamine require?
 3. Answer: Renal function is checked before starting mesalamine and periodically during treatment, because renal impairment, including minimal change disease and interstitial nephritis, has been reported. New bloody diarrhoea, cramping or fever after starting the drug is also evaluated, since a small proportion of patients develop an acute intolerance reaction to mesalamine itself that can mimic a disease flare. [1][7]
4. Question: When does IBD treatment move beyond mesalamine to drugs like azathioprine or infliximab?
 4. Answer: When mesalamine does not adequately control disease activity, when a patient cannot tolerate it, or when disease is more severe at diagnosis. Azathioprine (an immunomodulator) and infliximab (a TNF-alpha biologic) act by different, broader immunosuppressive mechanisms and are considered step-up therapies rather than alternative aminosalicylates; their full profiles belong to, and are covered on, this site's immunomodulators hub. [5][6]

References

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