

## Frequently Asked Questions – Specific Medications

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Medications to control inflammation are the single most important means of treating IBD.

By bringing the inflammation under control, medications can relieve the symptoms of IBD and reduce the chances of complications developing. Most importantly, controlling the inflammation gives the GI tract an opportunity to heal.

As there is simply not enough space here to include all the available information about each medication, we will present an overview of the most important and relevant information. You should always consult your clinical team or pharmacist if you have any questions about your medications, or if you're concerned about possible side effects. Also, be sure to tell your clinical team if you have any known allergies to medications, or if you have experienced any difficulties when taking medications in the past.

At present, the medications used to treat inflammation in IBD belong to five main categories:

- aminosalicylates
- corticosteroids
- immunomodulators
- biological agents
- antibiotics.

Each of these is described in the following pages. We will also discuss how some non-specific medications are used in managing certain symptoms, treat specific complications, and replace or supplement essential nutrients that are poorly absorbed because of extensive disease or surgery.

### General Considerations About Medication

Several different medications have proved to be effective for the treatment of IBD. The type/s most appropriate for you and the dosage prescribed for you will depend on a number of factors:

- the location of inflammation within your GI tract
- the severity of your symptoms
- whether the medications are being used to treat a flare-up of disease or to prevent further flare-ups
- how well you are able to tolerate certain medications without experiencing undesirable side effects.

Your clinical team will work out a treatment plan based on your own circumstances at a given time. It's quite common for those with IBD to require a combination of medications to achieve the best result.

It is important to remember the following:

- Because IBD is a chronic condition, many people will need to take medications for long periods of time, either to bring the disease under control or to maintain remission once the symptoms have disappeared. It's important to take your medications exactly as prescribed, even if you're feeling well. Stopping your medication can result in a flare-up of symptoms or lead to other problems, including a relapse, sometimes even months later. Always consult with your clinical team before stopping any medication.
- Most of the medications used to treat IBD work by suppressing the immune system. Too much suppression however can reduce the ability of your body to defend itself against infection. Always be sure to report any signs of fever, chills, or sore throat to your clinical team as soon as they appear.
- Depending on the medications used to treat your condition, you might need regular blood tests to assess bone marrow function or to detect signs of infection. You might also need regular tests to monitor the function of your liver and kidneys. These tests are vital to maintaining your long-term health and should never be missed.
- Taking several different medications at the same time also increases the possibility of drug interactions. Drug interactions can decrease the effectiveness of a medication, intensify its action, or cause unexpected side effects. Be sure to tell your clinical team about any other medications you might be taking, including over-the-counter products and complementary or alternative therapies.

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### Aminosalicylates

#### What are they?

Aminosalicylates are a group of medications that contain the active ingredient 5-aminosalicylic acid (5-ASA). **Note:** 5-ASA is chemically related to aspirin but is not the same as aspirin.

To be effective, 5-ASA must reach the area of inflammation within the GI tract. But if 'pure' 5-ASA is taken by mouth, it is absorbed into the bloodstream in the upper GI tract and cannot reach the inflamed area. For this reason, aminosalicylates are formulated in several different ways to best deliver 5-ASA to the actual site of inflammation.

#### How do they work?

Aminosalicylates are thought to work topically (i.e., from the inside) by blocking the effects of inflammatory mediators, which are substances produced by the immune system during the process of inflammation.

#### Who uses them?

Aminosalicylates are used to treat mild to moderate flare-ups of ulcerative colitis and are occasionally used in mild Crohn's disease. Their main role is to maintain remission and prevent relapse in people with ulcerative colitis.

#### Which aminosalicylates are used in Australia to treat IBD?

Aminosalicylates used to treat IBD in Australia are sulfasalazine, olsalazine, mesalazine and balsalazide. You can choose between oral and rectal formulations, depending on the specific aminosalicylate that's prescribed for you.

#### Sulfasalazine

Available as:

- Salazopyrin® oral tablets
- Salazopyrin-EN® oral enteric-coated tablets
- Pyralin EN® oral enteric-coated tablets.

Sulfasalazine is a 'pro-drug,' meaning that it's not active in its ingested form but is chemically linked to another molecule that prevents it from being absorbed until it reaches the area of the body where it is needed. In sulfasalazine, 5-ASA is attached to the sulphur antibiotic sulphapyridine. The link between these two components is broken only when sulfasalazine reaches the large intestine.

Although very little 5-ASA is absorbed into the bloodstream from the large intestine, almost all of the sulphapyridine is absorbed. This is thought to be responsible for most, if not all, of sulfasalazine's side effects. Approximately 10–20% of those with IBD are unable to tolerate sulfasalazine because of its side effects, although these can be managed by starting out with lower doses and gradually building up to an effective dosage.

The most common side effects of sulfasalazine are abdominal pain, nausea, vomiting, and loss of appetite. These can be reduced by taking the medication with food or by using an enteric-coated formulation which helps release the 5-ASA more slowly at the site of inflammation.

Those who are allergic to the sulphapyridine component of sulfasalazine might develop severe inflammation of the liver (hepatitis) or an itchy skin rash (hives), as well as swollen hands and face. These side effects usually occur within about three weeks of first taking the medication. A less common but potentially serious side effect is agranulocytopenia (bone marrow suppression), which also tends to occur within the first month of starting treatment.

Less common side effects of sulfasalazine include: haemolysis (shortening of the normal 4-month lifespan of red blood cells); reduction in the absorption of folic acid; and reduced sperm count in men (which returns to normal once the medication is discontinued). Some might also experience headaches, yellowing of the eyes, and orange-coloured urine (which is no cause for alarm).

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### **Olsalazine**

Available as:

Dipentum® oral tablets and capsules.

Like sulfasalazine, olsalazine is a pro-drug that releases 5-ASA only when it reaches the large intestine. Because the 5-ASA in olsalazine is linked to a molecule other than sulphapyridine, most people who are unable to tolerate sulfasalazine because of its side effects can take olsalazine.

The most common side effect of olsalazine is watery diarrhoea, which tends to develop soon after beginning treatment. This can be lessened by starting with a lower dose and gradually building upwards and/or by taking olsalazine with food. Some people might need to discontinue olsalazine treatment because of the diarrhoea, although the diarrhoea does tend to resolve over time. Less common side effects include nausea, headache, joint pain, abdominal pain, and skin rash.

### **Mesalazine**

Available as:

- Pentasa® oral tablets, sachets, rectal enemas, suppositories
- Salofalk® oral tablets, sachets, rectal enemas, foams
- Mesasal® oral tablets

Mesalazine is available in a number of different formulations:

- orally as tablets or as sachets of microgranules that can be dispersed in water before administration
- rectally as enemas, foams, and suppositories.

The various formulations of tablets, sachets of microgranules that can be dispersed in water before administration, enemas, foams, and suppositories are designed to best deliver an effective dosage of 5-ASA to the site of the inflammation, while at the same time limiting its absorption into the bloodstream. Those who are unable to take sulfasalazine because of its side effects can take mesalazine.

The side effects of mesalazine are relatively uncommon. Nausea, abdominal pain, headaches, and skin rashes are those reported most frequently. There have also been a few reports of associated kidney damage.

### **Balsalazide**

Available as:

Colazide® oral capsules.

Balsalazide is a pro-drug that is formulated to release 5-ASA only when it reaches the large intestine. This mode of delivery results in 99% of the 5-ASA being delivered directly to the colon, allowing for rapid topical treatment of ulcerative colitis with only minimal systemic absorption. Unlike sulfasalazine, the active 5-ASA is attached to an inert carrier molecule, thus avoiding any sulphur-related sensitivity. Balsalazide is well tolerated with relatively few side effects. The most common side effects include diarrhoea and headache.

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### Corticosteroids

#### What are they?

Corticosteroids are medications derived from a natural hormone called cortisol, which is produced by the adrenal gland and is essential for a wide range of bodily functions. Corticosteroids should not be confused with steroid sex hormones (e.g., testosterone or oestrogen) or with anabolic steroids used by body-builders and athletes. Corticosteroids are used in treating a wide range of medical conditions and are among the most effective and fast-acting medications available for treating acute IBD flare-ups.

#### How do they work?

Corticosteroids have a direct anti-inflammatory activity, but also work by suppressing the immune system so that it can no longer mount an inflammatory response. Their action is rapid—which, occasionally, can make some people more susceptible to infection—but is not usually long-lasting. It is also not generally possible to target the action of corticosteroids specifically to the site of inflammation, with the exception of rectally-administered or controlled-release formulations. Many other body systems besides the GI tract react to the presence of corticosteroids, resulting in a wide range of undesirable side effects.

For these reasons, the use of corticosteroids for treating IBD should be limited to the lowest possible dosage for the shortest period of time. Because prolonged use of corticosteroids causes the adrenal glands to either stop producing or to slow down the production of normal internal cortisol, they cannot always be discontinued abruptly. Most often, the dosage must be gradually tapered over time to allow the adrenal glands to begin producing their own cortisol again.

#### Who uses them?

Corticosteroids are used in treating acute moderate to severe ulcerative colitis and acute Crohn's disease. High doses are often given for a short period of time to bring flare-ups of disease under control and to induce remission. The dosage is then gradually tapered over weeks or occasionally months until the corticosteroids can be discontinued altogether. Some people with persistent 'grumbling' disease might need to take corticosteroids for longer periods of time. In these cases, the lowest possible dose is used to keep the disease under control.

The use of corticosteroids as maintenance therapy should be avoided wherever possible, as current research suggests they do not prevent disease flare-ups and, even at low dosages, their long-term use is associated with an increased risk of side effects (see next page).

Combination treatment with immunomodulators (see below) often allows for lower doses of corticosteroids to be used and/or for more a rapid withdrawal of corticosteroids once the inflammation is under control.

#### Which corticosteroids are used to treat IBD in Australia?

The most common corticosteroids used to treat IBD in Australia are prednisolone, budesonide, and hydrocortisone.

- Prednisolone is available in oral formulations (Predsolone®, Panafcortelone®, Solone®), and rectal formulation (Predsol®).
- Hydrocortisone is available as a rectal foam (Colifoam®). It is administered intravenously in hospitals for treating flare-ups.
- Budesonide capsules (Entocort®, Budenofalk®) are a controlled-release formulation that deliver active ingredient to the distal (farthest end) ileum and proximal (nearest end) colon with fewer systemic side effects. Budesonide is also available as a rectal formulation (Budenofalk®).

The type of corticosteroid used to treat IBD will depend on the location and severity of the inflammation at a given time. In acute flare-ups among those with severe and extensive IBD, an intravenous formulation might be needed from time to time to bring the disease under control. For those whose disease is confined to the lower part of the large intestine, formulations that can be administered via the rectum are the preferred option because it limits the absorption of corticosteroid into the bloodstream, producing fewer side effects.

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### **What are the side effects of corticosteroids?**

Because corticosteroids affect a number of different body systems, there is a wide range of possible side effects. While it is important to be aware of the side effects of corticosteroids, it is also important to remember that they don't always occur. The risk of developing side effects depends on the dosage and the length of time that the treatment is administered. In some cases, the side effects of corticosteroids outweigh their anti-inflammatory benefits. For most, however, side effects are temporary problems that tend to resolve once the dosage is reduced or the treatment discontinued altogether.

Some of the more common side effects of corticosteroids include:

- increased appetite
- weight gain, mainly in the face and body (sometimes a 'buffalo hump' of fat develops in the middle of the upper back)
- rounding or 'mooning' of the face
- skin redness
- acne
- increased facial hair
- stretch marks from rapid changes in weight
- thinning of the skin
- easy bruising
- ankle swelling
- weakness and muscle wasting in upper arms and legs
- mood swings
- psychosis and other psychiatric symptoms
- increased risk of infection
- high blood pressure (hypertension)
- high blood sugar levels (hyperglycaemia)
- insomnia (difficulty sleeping)
- growth retardation in children and adolescents
- cataracts
- weakened bones (osteoporosis).

The most effective way to reduce the risk of developing side effects—or to manage certain side effects when they do occur—is to quickly but carefully taper initial high doses of corticosteroids downwards to the lowest effective dosage once the inflammation is under control. In some instances, additional medications might be needed for a time to minimise the side effects of corticosteroids (e.g., bone loss). It is important however to take corticosteroids exactly as prescribed and to never take repeat courses without medical advice and supervision.

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### Immunomodulators

#### What are they? How do they work?

Immunomodulators are a group of medications that modify the normal function of the immune system. More specifically, immunomodulators alter the immune system so that it can no longer mount an inflammatory response in the affected areas of the intestine. Because the process of immune system suppression is slow and gradual, immunomodulators can take up to three months or more to take effect. In general, the immunomodulators used in treating IBD have a corticosteroid sparing effect and are particularly useful in maintaining remission among those with IBD.

#### Who uses them?

Immunomodulators tend to be used for those with more severe IBD and are more commonly used for Crohn's disease than for ulcerative colitis. They are usually most appropriate for those who:

- have had no response or only a partial response to aminosalicylates or corticosteroids
- frequently require corticosteroids or have become dependent on them (i.e., experience disease flare-ups when corticosteroids are withdrawn)
- have perianal disease that is not responding to antibiotics
- have fistulae
- need treatment to maintain remission.

During flare-ups of disease it is common for an immunomodulator to be combined with a corticosteroid to speed up the response. This often allows for lower doses of corticosteroid to be used or for more rapid withdrawal of corticosteroids once the inflammation is under control, resulting in fewer corticosteroid-related side effects. Combination treatment also helps to induce and maintain remission.

#### Which immunomodulators are used to treat IBD in Australia?

The immunomodulators currently used to treat IBD in Australia are:

- azathioprine (AZA, Imuran®, Azahexal®, Azamun®, Azapin®, Thioprine®)
- 6-mercaptopurine (6-MP, Puri-Nethol®)
- cyclosporin (Cicloral®, Neoral®, Sandimmun®)
- methotrexate (Methoblastin®, Ledertrexate®)
- occasionally, 6-thioguanine (Lanvis®).

Increasingly, allopurinol (e.g. Zyloprim®, which is not an immunomodulator) is used to boost the level of active metabolites of azathioprine or 6-mercaptopurine.

#### Azathioprine and 6-mercaptopurine

Azathioprine and 6-mercaptopurine are both available in tablet formulations and are chemically quite similar; in fact, azathioprine is converted to 6-mercaptopurine in the body. These medications are slow-acting and can take up to three to six months to have an effect.

An uncommon but important side effect that can occur because of the accumulation of azathioprine in the body is bone marrow suppression. This causes a decreased production of blood cells, in particular white blood cells, which are the body's

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main defence against infection. It can also cause easy bruising. Bone marrow suppression is reversible once the medication is discontinued but it can take several weeks before the production of blood cells normalises.

Other side effects of azathioprine include nausea, vomiting, loss of appetite, and malaise (a general feeling of illness). These side effects tend to resolve if the dosage is reduced or is divided throughout the day. Some people might also experience allergic reactions such as fever, rashes, joint pain, canker sores in the mouth, and inflammation of the liver (hepatitis) or pancreas (pancreatitis). These usually occur within about three weeks of starting the medication. Approximately 10–20% of individuals are unable to tolerate azathioprine because of its side effects. All of the side effects, however, resolve once the medication is discontinued. Unlike corticosteroids, both azathioprine and 6-mercaptopurine can be discontinued immediately if needed.

### **Methotrexate**

Methotrexate works more rapidly than azathioprine or 6-mercaptopurine and is given weekly via tablets or injections. The most common side effect of methotrexate is nausea, but it can also cause flu-like symptoms (vomiting, headache, fatigue, diarrhoea) and a low white blood cell count. Less common but more serious side effects with long-term use include liver scarring and lung inflammation. Methotrexate can also cause a deficiency of folic acid, which is necessary for blood formation. For this reason, folic acid tablets are often prescribed along with methotrexate. Methotrexate can also lower sperm count among men, but this returns to normal after the medication is discontinued.

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### Biological agents

#### What are they? How do they work?

Biologicals are a newer category of immunomodulator. They are made from living organisms and the products of these organisms such as proteins, genes and antibodies. Biologicals work by blocking the effects of specific substances (inflammatory mediators) that are produced by the immune system during the process of inflammation. An inflammatory mediator known to promote ongoing inflammation in people with Crohn's disease and ulcerative colitis is tumour necrosis factor alpha (TNF- $\alpha$ ). The biological agents used to treat IBD have a selective action in terms of blocking the effects of this particular substance and are sometimes referred to as anti-TNF agents. Similar to corticosteroids, the anti-TNF agents have a rapid onset of action.

#### Who uses them?

Biological agents are used mainly to treat those with moderate to severe Crohn's disease and ulcerative colitis, and whose condition cannot be controlled by other types of medications.

#### Which biologicals are used to treat IBD in Australia?

Infliximab (Remicade®) is currently approved in Australia to treat Crohn's disease and ulcerative colitis, while adalimumab (Humira®) is approved for use in Crohn's disease only.

Vedolizumab is also available for Crohn's disease. Strict eligibility criteria apply for all agents.

Infliximab is a chimeric monoclonal antibody, meaning that it is a hybrid consisting of a protein sequence that is 75% human and 25% mouse. It is given as an intravenous infusion every 8 weeks.

Adalimumab is a fully-human monoclonal antibody that can be self-administered every fortnight by the patient via subcutaneous injection into the fat layer under the skin.

The most common side effects of anti-TNF agents are reactions at the site of infusion or injection. These can appear as redness, swelling, itching, bruising, or rash. Other side effects include upper respiratory tract infections, headaches, generalised rashes, and nausea.

Serious infections, including sepsis and tuberculosis (TB), have been reported in patients receiving anti-TNF agents. Many of these serious infections however occurred in patients also taking immunosuppressive therapy (i.e., immunomodulators) which, along with the disease, can predispose a person to infection. The risk of infection is likely to be related to the total 'burden' of immunomodulatory treatment at a given time, rather than to a specific effect of anti-TNF agents.

Reports of TB involving anti-TNF agents usually involve a reactivation of infection among those who have inactive TB (i.e., those who have been exposed to TB but have not shown any signs or symptoms of the infection). For this reason, all patients starting treatment with infliximab or adalimumab need to undergo TB screening using a TB skin test or blood test (QuantiFERON Gold®), and a chest x-ray. The screening helps determine previous exposure to TB.

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### Antibiotics

#### What are they? How do they work?

Even though no specific infectious agent such as a bacterium or virus has ever been found to be the cause of IBD, antibiotics are sometimes useful as a primary treatment approach, especially among those with Crohn's disease. It is thought that antibiotics help control symptoms in this situation by reducing the level of bacteria found in diseased intestinal tissue.

#### Who uses them?

Antibiotics are used mainly for those with Crohn's disease, especially to treat fistulae (abnormal channels between two loops of intestine or between the intestine and other organs such as skin, vagina, or kidneys), or recurrent abscesses (pockets of pus) that occur near the anus.

Antibiotics are generally not useful for those with ulcerative colitis, with the exception being those who develop toxic megacolon (distended abdomen and an extremely inflated colon). Toxic megacolon is a life-threatening condition that places a person at a high risk for perforation of the large intestine.

#### Which antibiotics are used to treat IBD in Australia?

##### **Metronidazole**

Metronidazole (Flagyl®) is a broad-spectrum antibiotic that, by definition, is useful against a wide range of bacteria. It is used most commonly to treat complications such as fistulae and abscesses in the anal region among those with Crohn's disease. Metronidazole has also yielded benefits in the treatment of Crohn's disease at other sites, particularly the large bowel. It is also useful for the treatment of pouchitis, which can occur following restorative proctocolectomy (otherwise known as ileal pouch-anal anastomosis surgery).

The most common side effects of metronidazole are nausea, vomiting, loss of appetite, diarrhoea, a metallic taste in the mouth, dizziness, headache, and dark or reddish-brown discolouration of the urine. Long-term treatment with metronidazole (i.e., more than eight weeks) is not recommended as it can cause damage to nerves in the feet and arms, leading to a tingling sensation and numbness. Some people taking metronidazole might experience an unpleasant reaction to alcohol (e.g., flushing of the face, headaches, palpitations, nausea, shortness of breath, drowsiness).

##### **Ciprofloxacin**

Ciprofloxacin (Ciproxin®, Cifran®, Ciprol®), like metronidazole, is a broad-spectrum antibiotic used in treating complications arising from Crohn's disease, such as abscesses and fistulae in the anal region, and in the management of pouchitis.

Ciprofloxacin is a well-tolerated medication with the most common side effects being nausea, diarrhoea, elevated liver enzymes, vomiting, and rash. Tendonitis (predominantly the Achilles tendon) can be seen with long-term use of ciprofloxacin. Ongoing use should therefore be avoided if possible.

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### Non-specific medications for IBD

#### Anti-diarrhoeal medications

Medications used to control diarrhoea include loperamide (Imodium®), diphenoxylate and atropine (Lomotil®) and codeine phosphate. These work mainly by reducing muscle contractions in the intestinal wall and thereby slowing down the movement of faecal waste through the intestine. To some extent, anti-diarrhoeal medications also reduce the amount of fluid produced by the lining of the intestine, but have no direct effect on the inflammation itself.

Anti-diarrhoeal agents should not be used in children nor should they be used during a severe flare-up of disease as they can cause the bowel to enlarge and burst. In general, anti-diarrhoeal medications should be used with extreme caution as they do not treat the underlying cause of IBD and are a major cause of toxic megacolon. Their best use is for controlling diarrhoea during milder attacks of disease, or in helping those experiencing diarrhoea even though their disease is inactive.

The main side effect of anti-diarrhoeal agents is constipation. Codeine phosphate can also cause drowsiness, headache, mood changes, and skin rashes. Lomotil® contains atropine, which can cause dry mouth, blurred vision, palpitations, and difficulty passing urine, but these generally occur only when large amounts are taken.

#### Bile salt binders

Bile salts are a normal component of bile, which is produced in the liver, stored in the gallbladder, and secreted into the small intestine to aid in the digestion and absorption of food. Normally, bile salts are reabsorbed in the lower part of the small intestine, the terminal ileum. If, however, the terminal ileum is damaged because of extensive Crohn's disease or, more commonly, as a result of ileal surgery, bile salts can pass into the large intestine and irritate the inner lining, causing diarrhoea.

Cholestyramine (Questran®) and colestipol (Colestid®) are medications that bind to bile salts and prevent them from causing diarrhoea. Both are formulated as powders that need to be dissolved in liquid before swallowing. The most frequent side effects of bile salt binders are constipation, abdominal discomfort, and abdominal distension (bloating). Heartburn, nausea, and loss of appetite can also occur. The medications can also interfere with the absorption of other medications and of food, which worsens the diarrhoea. In addition, many find their taste unpleasant.

#### Analgesics (pain killers)

Pain with IBD most commonly occurs during a flare-up, and is best treated by controlling the inflammation with the use of medications as described above.

For short-term relief of pain only, mild analgesics such as paracetamol (Panadol®) or a combination of paracetamol and codeine (e.g., Panadeine® and Panadeine Forte®) can be used from time to time, as needed. Aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Nurofen®, Brufen®, etc.) should generally be avoided as they can cause bleeding and damage to the lining of the stomach and can exacerbate a flare-up.

Anyone with severe or persistent pain is advised to discuss the symptoms with their clinical team as this might signal the development of a complication that requires specific treatment.

#### Vitamins and minerals

Provided that those with IBD are able to maintain a well-balanced diet that includes items from all major food groups, vitamin and mineral supplements are not usually required, particularly when the disease is inactive. There are however a few exceptions.

- Those who have extensive Crohn's disease of the terminal ileum or have had a significant length of terminal ileum removed by surgery might require regular injections of vitamin B12, which is essential for blood formation and for nerve and brain function.
- Some patients will require folic acid supplements (especially women who are pregnant or are planning to fall pregnant).

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- Some will require iron supplements if there has been significant bleeding in the small or large intestine. Iron supplements can cause one's stool to turn black. It can also cause indigestion and nausea.
- Those with extensive Crohn's disease absorb fat poorly, particularly if they're taking bile salt binders, and might need supplements of the fat-soluble vitamins A, D, or K.

For more information on this topic, refer to the FAQ – Diet and Nutrition.

### Alternative or complementary therapies

Over time, many individuals with chronic conditions grow tired of their disease and its treatment, and look for solutions outside conventional medicine. Some types of alternative therapies, such as relaxation techniques, yoga and meditation, can be helpful.

On the other hand, other alternative solutions such as restrictive diets or homeopathic products in place of usual medications can be detrimental to overall health in both the short and longer term. To ensure that your health and wellbeing are not being compromised in any way, you should discuss these options with your clinical team **before** you try them.