

# SALOFALK® enteric coated tablets

## Mesalazine

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### Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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## 1. Why am I using SALOFALK tablets?

SALOFALK tablets contain the active ingredient mesalazine (5-aminosalicylic acid). SALOFALK tablets are used to treat and prevent relapses of mild to moderate attacks of ulcerative colitis (inflammation of the large bowel) and Crohn's ileitis and colitis (inflammation of the large bowel and last section of the small bowel). For more information, see Section [1. Why am I using SALOFALK tablets?](#) In the full CMI.

## 2. What should I know before I use SALOFALK tablets?

Do not use if you have ever had an allergic reaction to SALOFALK tablets or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use SALOFALK tablets?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with SALOFALK tablets and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use SALOFALK tablets?**

Adults and elderly:

- For acute attacks of ulcerative colitis, take 1.5 g to 3 g SALOFALK tablets once a day or in 2-3 divided doses.
- For acute attacks of Crohn's ileitis and colitis take 3 g to 4.5 g SALOFALK tablets once a day or in 2-3 divided doses.
- For long term treatment of ulcerative colitis take 1.5 g SALOFALK tablets once a day or in 2-3 divided doses.
- For long term treatment of Crohn's ileitis and colitis take 1.5 g to 3 g SALOFALK tablets once a day or in 2-3 divided doses.

Children over 6 years:

- The dose of SALOFALK tablets depends on disease severity and body weight. Your doctor will tell you how much SALOFALK tablets your child should take.

More instructions can be found in Section [4. How do I use SALOFALK tablets?](#) in the full CMI.

## 5. What should I know while using SALOFALK tablets?

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>• <b>Remind any doctor, dentist or pharmacist you visit that you are using SALOFALK tablets.</b></li> <li>• <b>Remind them if any new medicines are about to be started.</b></li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not use SALOFALK tablets to treat any complaint other than that directed by your doctor. It may not be safe to use SALOFALK tablets for another complaint.</li> <li>• Do not give SALOFALK tablets to someone else even if their symptoms are the same. It may not be safe for</li> </ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>● <b>Remind any doctor, dentist or pharmacist you visit that you are using SALOFALK tablets.</b></li> <li>● <b>Remind them if any new medicines are about to be started.</b></li> </ul>
	<p>another person to use SALOFALK tablets.</p>
<p><b>Driving or using machines</b></p>	<p>This medicine is not expected to affect your ability to drive a car or operate machinery.</p> <p>However, you should still be careful before you drive or use any machines or tools until you know how SALOFALK tablets affect you. SALOFALK tablets may cause dizziness in some people.</p>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Keep SALOFALK tablets in their original product pack until it is time to use them. If you take them out of their pack, they may not keep well.</li> <li>● Keep SALOFALK tablets in a cool dry place,</li> </ul>

<p><b>Things you should do</b></p>	<ul style="list-style-type: none"> <li>● <b>Remind any doctor, dentist or pharmacist you visit that you are using SALOFALK tablets.</b></li> <li>● <b>Remind them if any new medicines are about to be started.</b></li> </ul>
	<p>protected from light, where the temperature stays below 25°C.</p> <ul style="list-style-type: none"> <li>● Keep it where children cannot reach it.</li> <li>● A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.</li> </ul>

For more information, see Section [5. What should I know while using SALOFALK tablets?](#) in the full CMI.

## **6. Are there any side effects?**

All medicines can have side effects. If they do occur, they are usually mild and temporary. The most common side effects using SALOFALK tablets are: headache, mild stomach pains, excessive gas in the stomach or bowel, increased number of bowel motions, diarrhoea, nausea and vomiting, rash or itchy skin. For more information, including what to do if you have any side

effects, see Section [6. Are there any side effects?](#) in the full CMI.

# SALOFALK® enteric coated tablets

Active ingredient: *mesalazine*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using SALOFALK tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SALOFALK tablets.**

**Where to find information in this leaflet:**

- [1. Why am I using SALOFALK tablets?](#)
- [2. What should I know before I use SALOFALK tablets?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SALOFALK tablets?](#)
- [5. What should I know while using SALOFALK tablets?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using SALOFALK tablets?

**SALOFALK tablets contain the active ingredient mesalazine (5-aminosalicylic acid).** Mesalazine is an anti-inflammatory agent used to treat inflammatory bowel disease.

**SALOFALK tablets are used to treat and prevent relapse of mild to moderate attacks of ulcerative colitis (inflammation of the large bowel) and Crohn's ileitis and colitis (inflammation of the large bowel and last section of the small bowel).**

**Ask your doctor if you have any questions about why SALOFALK tablets have been prescribed for you.**

Your doctor may have prescribed SALOFALK tablets for another reason.

**Do not give SALOFALK tablets to a child below 6 years of age.** The safety and effectiveness of SALOFALK tablets in this group have not been established.

## **2. What should I know before I use SALOFALK tablets?**

### **Warnings**

#### **Do not use SALOFALK tablets if:**

- you are allergic to mesalazine, to salicylates such as acetylsalicylic acid (e.g. Aspirin®) or any of the ingredients listed at the end of this leaflet. Signs of allergic reactions may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- you suffer from a severe kidney or liver problem.

- the expiry date (EXP) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.
- the package is torn or shows signs of tampering.

Always check the ingredients to make sure you can use this medicine.

### **Check with your doctor if you:**

- have any allergies.
- have or have had any other medical conditions, especially lung or breathing problems such as asthma.
- have kidney problems. Kidney stones may develop with use of mesalazine, the active ingredient in SALOFALK tablets. Symptoms may include pain in the side of abdomen and blood in urine. Take care to drink sufficient amounts of liquid during treatment with SALOFALK tablets.
- have liver problems.
- have phenylketonuria.
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

If you have not told your doctor about any of the above, tell them before you start to use SALOFALK tablets.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) have been reported in association with mesalazine, the active ingredient in SALOFALK tablets. Stop using mesalazine and seek medical attention

immediately if you notice any of the symptoms related to these serious skin reactions described in Side effects section below.

If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.

SALOFALK 500 mg tablets contain 49 mg sodium per tablet. In Ulcerative colitis patients the maximum daily dose of sodium is 294 mg per day, with the maximum daily dose of sodium for Crohn's ileitis and colitis patients being 441 mg per day. This should be particularly taken into account for those on a low salt diet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

People who take medicines containing mesalazine, such as SALOFALK tablets, may notice red-brown discolouration in the toilet bowl. This is due to mesalazine in urine of these people coming in contact with sodium hypochlorite bleach used to clean the toilet. This is the result of a chemical reaction between mesalazine and bleach and is harmless.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using SALOFALK tablets if you are pregnant or breastfeeding.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

SALOFALK tablets may interfere with the action of the following types of medicines:

- anticoagulants which are medicines used to stop blood clots, e.g. warfarin.

#### **Some medicines may interfere with SALOFALK tablets and affect how it works.**

- glucocorticoids which are medicines used to treat inflammation or swelling, e.g. prednisolone
- sulphonylureas which are medicines used to lower blood sugar
- methotrexate which is a medicine used to treat some types of cancer and arthritis.

- probenecid/sulphinpyrazone which are medicines used to treat gout
- spironolactone/frusemide which are medicines which lower blood pressure or increase volume of urine
- rifampicin which is a medicine used to treat tuberculosis
- azathioprine which is a medicine used to suppress the immune system
- mercaptopurine or thioguanine which are medicines used to treat leukaemia.
- lactulose or similar preparations which are medicines which can change the acidity of the content of the bowels.

You may need to use different amounts of the above medicines, or you may need to take different medicines when you are using SALOFALK tablets. Your doctor or pharmacist will advise you.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SALOFALK tablets.**

## **4. How do I use SALOFALK tablets?**

### **How much to use**

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

## Adults and elderly:

### Ulcerative colitis:

- For acute attacks, take 1.5 g to 3 g SALOFALK tablets once a day or in 2-3 divided doses.
- For long term treatment, take 1.5 g SALOFALK tablets once a day or in 2-3 divided doses.

### Crohn's ileitis and colitis:

- For acute attacks, take 3g to 4.5 g SALOFALK tablets once a day or in 2-3 divided doses.
- For long term treatment, take 1.5 g to 3 g SALOFALK tablets once a day or in 2-3 divided doses.

## Children over 6 years old:

The dose of SALOFALK tablets for your child depends on disease, severity and body weight. Your doctor will tell you how much your child should take.

For acute ulcerative colitis, the usual dose for a child is 30-50 mg SALOFALK tablets /kg (body weight)/day in one single or 2-3 divided doses.

For long term treatment of ulcerative colitis, the usual dose for a child is 15-30 mg SALOFALK tablets /kg (body weight)/day in one single or 2 divided doses.

## **When to use SALOFALK tablets**

Swallow the tablet whole with a glass of water.

Take SALOFALK tablets the same time each day. This will help you remember when to take SALOFALK tablets.

## How to use SALOFALK tablets

The tablets should be taken with a glass of water at least one hour before a meal, without chewing or crushing.

## How long to use SALOFALK tablets

This medicine helps control your condition but does not cure it. Therefore, you must use it for as long as your doctor tells you to.

## If you forget to use SALOFALK tablets

SALOFALK tablets should be used regularly at the same time each day. If you miss your dose at the usual time, leave out that dose completely. Take your next dose at the normal time it is due.

**Do not take a double dose to make up for the dose you missed.** If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use SALOFALK tablets, ask your pharmacist for some hints.

## If you use too much SALOFALK tablets

If you think that you have used too much SALOFALK tablets, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, or

- contact your doctor, or
- go to the Accident & Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

**Possible symptoms of overdose may include feeling sick, vomiting and diarrhoea.**

## **5. What should I know while using SALOFALK tablets?**

### **Things you should do**

Make sure that all of your doctors and pharmacists who are treating you know you are using SALOFALK tablets. Remind them if any new medicines are about to be started.

Tell your doctor immediately if you become pregnant while using SALOFALK tablets, or you intend to breastfeed.

### **Things you should not do**

- Do not use SALOFALK tablets to treat any complaint other than that directed by your doctor. It may not be safe to use SALOFALK tablets for another complaint.
- Do not give SALOFALK tablets to someone else even if their symptoms are the same. It may not be safe for another person to use SALOFALK tablets.

Do not stop taking your SALOFALK tablets or change the dosage without checking with your doctor.

## **Driving or using machines**

This medicine is not expected to affect your ability to drive a car or operate machinery. **However, you should still be careful before you drive or use any machines or tools until you know how SALOFALK tablets affects you.**

SALOFALK tablets may cause dizziness in some people.

## **Looking after your medicine**

- Keep SALOFALK tablets in their original product pack until it is time to use them. If you take them out of their packaging they may not keep well.
- Keep SALOFALK tablets in a cool dry place, protected from light, where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• headache</li><li>• mild stomach pain</li><li>• excessive gas in the stomach or bowel</li><li>• increased number of bowel motions</li><li>• diarrhoea</li><li>• dyspepsia</li><li>• nausea (feeling sick)</li><li>• rash or itchy skin</li></ul>	<p><b>Speak to your doctor if you have any of these mild effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dizziness</li> <li>● common cold</li> <li>● fever, muscle aches and pains, painful joints and chest pain (sometimes spreading to the neck and shoulders, and sometimes fever)</li> <li>● mild skin rash, itching or hives</li> <li>● numbness, tingling or weakness of the arms and legs</li> <li>● pain in the upper belly (may be due to inflammation of the pancreas)</li> <li>● worsening of ulcerative colitis.</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● <b>general allergic reaction</b> such as skin rash, fever, joint pain and/or breathing difficulties or a general</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>inflammation of your large bowel (causing severe diarrhoea and abdominal pain)</p> <ul style="list-style-type: none"> <li>● marked reduction of general health, especially if accompanied by fever and/or sore throat or mouth. Very rarely this can be due to a low white blood cell count (<b>agranulocytosis</b>), which may increase the risk of developing a serious infection. Other blood cells may also be affected (e.g. platelets or red cells causing <b>aplastic anaemia</b> or <b>thrombocytopenia</b>) with symptoms which may include unexplained bleeding, purple spots or patches under your skin, anaemia (feeling tired, weak and looking pale, especially on lips and nails). A blood test can confirm whether your symptoms are due</li> </ul>	<p><b>notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>to this medicine. These reactions are very rare.</p> <ul style="list-style-type: none"> <li>● <b>Serious skin rashes</b> with reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes, widespread rash, fever and enlarged lymph nodes. These can be preceded by fever and flu-like symptoms. These reactions occur in an unknown number of patients (frequency not known).</li> <li>● <b>Strong or recurrent headache, disturbed vision, or ringing or buzzing in ears.</b> These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension). These reactions occur in an unknown number of patients (frequency</li> </ul>	

Serious side effects	What to do
<p>not known (cannot be estimated from available data)).</p> <ul style="list-style-type: none"> <li>● Shortness of breath, chest pain or irregular heartbeat, or swollen limbs which may be indicative of <b>cardiac hypersensitivity reactions</b>. These reactions are rare.</li> <li>● <b>Problems with your kidney function</b> (can occur very rarely), e.g. a change in the colour or amount of urine produced and swollen limbs or a sudden flank pain (caused by a kidney stone) (occur in an unknown number of patients (frequency not known)). As a precaution, your doctor may have your blood, liver and kidney tested regularly during treatment with this medicine.</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p data-bbox="199 257 774 414"><b>Other rare events, which have been reported with mesalazine include:</b></p> <ul data-bbox="199 459 782 1993" style="list-style-type: none"> <li data-bbox="199 459 782 560">● changes in liver function tests</li> <li data-bbox="199 582 782 974">● liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine</li> <li data-bbox="199 996 782 1097">● allergic, inflammatory or other lung conditions</li> <li data-bbox="199 1120 782 1568">● shortness of breath, difficulty breathing, cough, wheezing, chest pain that worsens when breathing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions.</li> <li data-bbox="199 1590 782 1814">● increased sensitivity of the skin to sun and ultraviolet light (photosensitivity)</li> <li data-bbox="199 1836 782 1993">● reversible decrease in semen production (oligospermia)</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• hair loss and the development of baldness (alopecia)</li> </ul>	

As a precaution, your doctor may have your blood, liver and kidney tested regularly during treatment with SALOFALK tablets.

**Tell your doctor or pharmacist if you notice anything which is unusual, including anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking/using any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What SALOFALK tablets contain

<b>Active ingredient (main ingredient)</b>	<b>500 mg or 1 g mesalazine</b>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● sodium carbonate (500 mg tablet only)</li><li>● glycine (500 mg tablet only)</li><li>● povidone</li><li>● microcrystalline cellulose</li><li>● croscarmellose sodium</li><li>● colloidal anhydrous silica</li><li>● calcium stearate</li><li>● hypromellose</li><li>● methacrylic acid copolymer</li><li>● purified talc</li><li>● titanium dioxide</li><li>● iron oxide yellow</li><li>● macrogol 6000</li></ul>

<b>Active ingredient (main ingredient)</b>	<b>500 mg or 1 g mesalazine</b>
	<ul style="list-style-type: none"> <li>• eudragit E100 (500 mg tablet only).</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What SALOFALK tablets look like**

SALOFALK 500 mg enteric coated tablets are butter yellow to ochre, oblong tablets.

SALOFALK 1 g enteric coated tablets are yellow to ochre, oblong tablets.

SALOFALK 500 mg enteric coated tablets are available in packs of 100.

SALOFALK 1 g enteric coated tablets are available in starter packs of 10 or packs of 60 tablets.

Australian Registration Numbers:

500 mg: AUST R 133472

1 g: AUST R 285903

## **Who distributes SALOFALK tablets**

Dr Falk Pharma Australia Pty Ltd  
9 Help Street  
Chatswood, NSW 2067

Australia

SALOFALK® is a registered trademark of Dr. Falk  
Pharma GmbH, Germany.

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