

# SALOFALK® GRANULES modified release granules

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 granules?

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

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

Do not use if you have ever had an allergic reaction to SALOFALK granules 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

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information, see Section [2. What should I know before I use SALOFALK granules?](#) in the full CMI.

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

Some medicines may interfere with SALOFALK granules 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 granules?**

Adults and elderly:

- Acute ulcerative colitis: take 1.5 g to 3 g SALOFALK granules a day or in 2-3 divided doses.
- Long term treatment of ulcerative colitis: take 1.5 g SALOFALK granules once a day or in 2-3 divided doses.

Children over 6 years:

- Acute ulcerative colitis: the usual dose for a child is 30-50 mg SALOFALK granules/kg (body weight)/day in one single or 2-3 divided doses.
- Long term treatment of ulcerative colitis: the usual dose for a child is 15-30 mg SALOFALK granules/kg (body weight)/day in one single or 2 divided doses.

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● <b>Remind any doctor, dentist or pharmacist you visit that you are using SALOFALK granules.</b></li><li>● <b>Remind them if any new medicines are about to be started.</b></li></ul>
Things you should not do	<ul style="list-style-type: none"><li>● Do not use SALOFALK granules to treat any complaint other than that directed by your doctor. It may not be safe to use SALOFALK granules for another complaint.</li><li>● Do not give SALOFALK granules to someone else even if their symptoms are the same. It may not be safe for another person to use SALOFALK granules.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>● This medicine is not expected to affect your ability to drive a car or operate machinery.</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 granules.</b></li> <li>● <b>Remind them if any new medicines are about to be started.</b></li> </ul>
	<ul style="list-style-type: none"> <li>● However, you should still be careful before you drive or use any machines or tools until you know how SALOFALK granules affects you. SALOFALK granules may cause dizziness in some people.</li> </ul>
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> <li>● Keep SALOFALK granules in their original package until it is time to use them. If you take them out of their packaging, they may not keep well.</li> <li>● Keep SALOFALK granules in a cool dry place, protected from light, where the temperature stays below 25°C.</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 granules.</b></li> <li>● <b>Remind them if any new medicines are about to be started.</b></li> </ul>
	<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 granules?](#) 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 granules 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® GRANULES modified release granules

Active ingredient: mesalazine

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using SALOFALK granules. **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 granules.**

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

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

## 1. Why am I using SALOFALK granules?

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

**SALOFALK granules are used to treat and prevent relapse of mild to moderate attacks of ulcerative colitis (inflammation of the large bowel).**

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

Your doctor may have prescribed SALOFALK granules for another reason.

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

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

### **Warnings**

**Do not use SALOFALK granules 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 product is torn or shows signs of tampering.

- Always check the ingredients to make sure you can use this medicine. If unsure, speak to your doctor or pharmacist.

### **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 granules. 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 granules.
- 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 granules.

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 granules. 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 granules contain aspartame which is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

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 granules, 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 granules 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 granules 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 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 granules. 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 granules.**

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

### **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:

- For acute ulcerative colitis, take 1.5 g to 3 g SALOFALK granules once a day or in 2-3 divided doses.

- For long term treatment of ulcerative colitis, take 1.5 g SALOFALK granules once a day or in 2-3 divided doses.

### Children over 6 years old:

The dose of SALOFALK granules 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 granules/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 granules/kg (body weight)/day in one single or 2 divided doses.

## **When to use SALOFALK granules**

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

## **How to use SALOFALK granules**

1. Tear open the sachet along the end with the triangular mark.



2. Pour contents of sachet onto tongue.



3. Swallow the modified release granule whole without chewing or crushing.
4. Drink a glass or two of water to wash down the medicine.



The following QR code links to a patient instructions for use video, which covers the same dosing procedure detailed above:



## **How long to use SALOFALK granules**

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 granules**

SALOFALK granules 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 granules, ask your pharmacist for some hints.

## **If you use too much SALOFALK granules**

If you think that you have used too much SALOFALK granules, 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 and 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 granules?**

### **Things you should do**

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

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

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

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

**Do not stop taking your SALOFALK granules 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 granules affects you.**

SALOFALK granules may cause dizziness in some people.

## Looking after your medicine

- Keep SALOFALK granules 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 granules 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>	Speak to your doctor if you have any of these mild effects and they worry you.

Less serious side effects	What to do
<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

Serious side effects	What to do
<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>) and cause 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</li> </ul>	<p><b>notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>symptoms are due 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</li> </ul>	

Serious side effects	What to do
<p>patients (frequency 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><b>Other rare events, which have been reported with mesalazine include:</b></p> <ul style="list-style-type: none"> <li>● changes in liver function tests</li> <li>● 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>● allergic, inflammatory or other lung conditions</li> <li>● 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>● increased sensitivity of the skin to sun and ultraviolet light (photosensitivity)</li> <li>● 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 granules.

**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 granules contain

<b>Active ingredient (main ingredient)</b>	500 mg, 1 g, 1.5 g or 3 g mesalazine
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• microcrystalline cellulose</li><li>• hypromellose</li><li>• colloidal anhydrous silica</li><li>• methacrylic acid copolymer (500 mg, 1 g, 1.5 g only)</li><li>• magnesium stearate</li><li>• simethicone</li><li>• sorbic acid (1.5 g, 3 g only)</li><li>• methylcellulose (1.5 g, 3 g only)</li><li>• triethyl citrate</li><li>• purified talc</li><li>• carmellose sodium</li><li>• aspartame</li><li>• citric acid</li></ul>

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|--|---|
|  | <ul style="list-style-type: none"><li>• vanilla custard flavour<br/>75016-31 (PI 2187)</li><li>• povidone</li><li>• titanium dioxide.</li></ul> |
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What SALOFALK granules look like**

SALOFALK granules are greyish-white cylindrical to round in shape. This medicine is available in 4 different strengths, 500 mg, 1 g, 1.5 g and 3 g.

SALOFALK GRANULES 500 mg modified release granules are available in packs of 100 sachets.

SALOFALK GRANULES 1 g modified release granules are available in packs of 100 sachets.

SALOFALK GRANULES 1.5 g modified release granules are available in packs of 60 sachets.

SALOFALK GRANULES 3 g modified release granules are available in packs of 30 sachets.

Australian Registration Numbers:

500 mg: AUST R 80648

1 g: AUST R 80649

1.5 g: AUST R 143611

3 g: AUST R 214810.

## **Who distributes SALOFALK granules**

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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