

Package Leaflet: Information for the User

# Salofalk® 500mg gastro-resistant tablets

(mesalazine)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The name of your medicine is Salofalk 500mg gastro-resistant tablets but will be referred to as Salofalk throughout the remainder of this leaflet.
- This medicine is also available in another strength.

## What is in this leaflet

1. What Salofalk is and what it is used for
2. What you need to know before you take Salofalk
3. How to take Salofalk
4. Possible side effects
5. How to store Salofalk
6. Contents of the pack and other information

### 1. What Salofalk is and what it is used for

Salofalk contains the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

Salofalk is used for

- the treatment of acute episodes and prevention of further episodes (recurrence) of an inflammatory disease of the large intestine (colon), known by doctors as ulcerative colitis.

### 2. What you need to know before you take Salofalk

#### Do not take Salofalk

- If you are allergic to mesalazine, to salicylic acid, to salicylates such as acetylsalicylic acid (e.g. Aspirin®) or to any of the other ingredients of this medicine (listed in section 6).
- If you have a serious liver or kidney disease.

#### Warnings and precautions

Talk to your doctor before taking Salofalk

- If you have a history of problems with your lungs, particularly if you suffer from **bronchial asthma**.
- If you have a history of allergy to sulphasalazine, a substance related to mesalazine.
- If you suffer with problems of your **liver**.
- If you suffer with problems of your **kidney**.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

#### Further precautions

During treatment your doctor may want to keep you under close medical supervision, and you may need to have regular blood and urine tests.

In rare cases, in patients who have undergone bowel resection/bowel surgery in the ileocaecal area with removal of the ileocaecal valve, it has been observed that Salofalk is excreted undissolved in the stool, due to an excessively rapid passage through the bowel. If you notice this occurrence in your own case, please inform your doctor.

Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.

Serious skin reactions including Drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN) have been reported in association with mesalazine treatment. Stop using mesalazine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

#### Other medicines and Salofalk

Tell your doctor if you take or use any of the medicines mentioned below, as the effects of these medicines may change (interactions):

- **Azathioprine, 6-mercaptopurine or thioguanine** (medicines used to treat immune disorders).
- **Certain agents that inhibit blood clotting** (medicines for thrombosis or to thin your blood, e.g. warfarin)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. It may still be all right for you to use Salofalk and your doctor will be able to decide, what is suitable for you.

#### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should only use Salofalk during pregnancy, if your doctor tells you to.

You should also only use Salofalk during breast-feeding, if your doctor tells you to, as this medicine may pass into breast milk.

#### Driving and using machines

Salofalk has no or negligible influence on the ability to drive or use machines.

#### Salofalk contains sodium

This medicinal product contains 49 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2.5% of the recommended maximum daily dietary intake of sodium for an adult.

### 3. How to take Salofalk

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### Method of administration

Salofalk is for oral use only.

Take the tablets in the morning, at midday and in the evening, 1 hour before meals. They should be swallowed whole, not chewed, and taken with plenty of fluid.

#### Dosage

##### Adults and the elderly

	Ulcerative colitis	
	acute episode	prevention of recurrence/long-term treatment
Mesalazine (active substance)	1.5 g – 3.0 g	1.5 g
Salofalk 500mg gastro-resistant tablets	3 x 1 to 3 x 2	3 x 1

##### Use in children

There is only limited documentation for an effect in children (age 6-18 years).

##### Children 6 years of age and older

Please ask your doctor about the precise dosage of Salofalk for your child.

##### In acute episodes

to be determined individually, starting with 30-50 mg mesalazine per kg body weight per day that should be given in divided doses. The maximum dose is 75 mg mesalazine per kg body weight per day. The total dose should not exceed the maximum adult dose.

##### To prevent a relapse

to be determined individually, starting with 15-30 mg mesalazine per kg body weight per day that should be given in divided doses. The total dose should not exceed the recommended adult dose.

It is generally recommended that half the adult dose should be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg.

### Duration of treatment

The treatment of acute episodes of ulcerative colitis usually lasts 8 weeks. How long you will use the medicine depends upon your condition. Your doctor will decide how long you are to continue the medication.

You should follow the treatment with Salofalk regularly and consistently both during the acute episode of inflammation and also as long-term treatment, because this is the only way to achieve the desired therapeutic effect.

If you think that the effect of Salofalk is too strong or too weak, talk to your doctor.

### If you take more Salofalk than you should

Contact a doctor if you are in doubt, so he or she can decide what to do.

If you use too much Salofalk on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

### If you forget to take Salofalk

Do not take a larger than normal dose of Salofalk next time, but continue treatment at the prescribed dosage.

### If you stop taking Salofalk

Do not stop taking this product until you have talked to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you get any of the following symptoms after taking this medicine, you should contact your doctor and stop the intake of Salofalk tablets immediately:**

- **General allergic reactions** such as skin rash, fever, joint pain and/or breathing difficulties or a general inflammation of your large bowel (causing severe diarrhoea and abdominal pain). These reactions are very rare.
- A marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood, which may make you more prone to developing a serious infection (**agranulocytosis**). Other cells of the blood may also be affected (e.g., platelets or red cells causing aplastic anaemia or **thrombocytopenia**) 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 symptoms are due to an effect of this medicine on your blood. These reactions are very rare.
- **Serious skin rashes** 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).
- Shortness of breath, chest pain or irregular heartbeat, or swollen limbs which may be indicative of **cardiac hypersensitivity reactions**. These reactions are rare.
- **Problems with your kidney function** (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)).

The following side effects have also been reported by patients using mesalazine:

### Common side effects (may affect up to 1 in 10 people)

- Headache
- Rash, itching

### Uncommon side effects (may affect up to 1 in 100 people)

- Abdominal pain, diarrhoea, dyspepsia, wind (flatulence), nausea and vomiting
- Severe abdominal pain because of acute inflammation of the pancreas
- Changes in liver function parameters, changes in pancreatic enzymes

### Rare side effects (may affect less than 1 in 1,000 patients)

- Dizziness
- Jaundice or abdominal pain because of liver and bile flow disorders

- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- Joint pain
- Feeling weak or tired

### Very rare side effects (may affect less than 1 in 10,000 patients)

- Numbness and tingling in the hands and feet (peripheral neuropathy)
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Hair loss and the development of baldness
- Muscle pain
- Reversible decrease in semen production

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Salofalk

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the carton and the blister label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- If your medicine shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Salofalk contains

The active substance is mesalazine.  
Each tablet contains 500mg mesalazine.

**The other ingredients are** calcium stearate; microcrystalline cellulose; sodium carboxymethylcellulose; basic butylated methacrylate copolymer (= Eudragit E); methacrylic acid-methyl methacrylate copolymer 1:1 (= Eudragit L); glycine; silica, colloidal anhydrous; hypromellose; macrogol 6000; sodium carbonate; povidone K25; talc; colouring agents: titanium dioxide (E 171); iron oxide yellow (E 172)

### What Salofalk looks like and contents of the pack

Salofalk 500mg tablets are oval, light yellow to ochre, gastro-resistant tablets, matt with smooth surface; they are not scored.

Salofalk 500mg tablets are available in blister packs of 50 and 100 tablets.

Manufactured by  
DR. FALK PHARMA GmbH, Leinenweberstrasse 5, 79108 Freiburg, Germany.

Procured from within the EU. Repackaged by the Product Licence holder: MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

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Leaflet coded xxxxxxxxxx

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**To request a copy of this leaflet in Braille, large print or audio please call 01922 745645 and ask for the Regulatory Department.**

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# Mesalazine 500mg gastro-resistant tablets

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## What is in this leaflet

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### 1. What Mesalazine is and what it is used for

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Mesalazine is used for

- the treatment of acute episodes and prevention of further episodes (recurrence) of an inflammatory disease of the large intestine (colon), known by doctors as ulcerative colitis.

### 2. What you need to know before you take Mesalazine

#### Do not take Mesalazine

- If you are allergic to mesalazine, to salicylic acid, to salicylates such as acetylsalicylic acid (e.g. Aspirin®) or to any of the other ingredients of this medicine (listed in section 6).
- If you have a serious liver or kidney disease.

#### Warnings and precautions

Talk to your doctor before taking Mesalazine

- If you have a history of problems with your lungs, particularly if you suffer from **bronchial asthma**.
- If you have a history of allergy to sulphasalazine, a substance related to mesalazine.
- If you suffer with problems of your **liver**.
- If you suffer with problems of your **kidney**.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after using mesalazine.

Mesalazine may produce red-brown urine discoloration after contact with sodium hypochlorite bleach in the toilet water. It concerns a chemical reaction between mesalazine and bleach and is harmless.

#### Further precautions

During treatment your doctor may want to keep you under close medical supervision, and you may need to have regular blood and urine tests.

In rare cases, in patients who have undergone bowel resection/bowel surgery in the ileocaecal area with removal of the ileocaecal valve, it has been observed that Mesalazine is excreted undissolved in the stool, due to an excessively rapid passage through the bowel. If you notice this occurrence in your own case, please inform your doctor.

Kidney stones may develop with use of mesalazine. Symptoms may include pain in sides of abdomen and blood in urine. Take care to drink sufficient amount of liquid during treatment with mesalazine.

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You should also only use Mesalazine during breast-feeding, if your doctor tells you to, as this medicine may pass into breast milk.

#### Driving and using machines

Mesalazine has no or negligible influence on the ability to drive or use machines.

#### Mesalazine contains sodium

This medicinal product contains 49 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 2.5% of the recommended maximum daily dietary intake of sodium for an adult.

### 3. How to take Mesalazine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### Method of administration

Mesalazine is for oral use only.

Take the tablets in the morning, at midday and in the evening, 1 hour before meals. They should be swallowed whole, not chewed, and taken with plenty of fluid.

#### Dosage

##### Adults and the elderly

	Ulcerative colitis	
	acute episode	prevention of recurrence/long-term treatment
Mesalazine (active substance)	1.5 g – 3.0 g	1.5 g
Mesalazine 500mg gastro-resistant tablets	3 x 1 to 3 x 2	3 x 1

#### Use in children

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It is generally recommended that half the adult dose should be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg.

### Duration of treatment

The treatment of acute episodes of ulcerative colitis usually lasts 8 weeks. How long you will use the medicine depends upon your condition. Your doctor will decide how long you are to continue the medication.

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If you think that the effect of Mesalazine is too strong or too weak, talk to your doctor.

### If you take more Mesalazine than you should

Contact a doctor if you are in doubt, so he or she can decide what to do.

If you use too much Mesalazine on one occasion, just take your next dose as prescribed. Do not use a smaller amount.

### If you forget to take Mesalazine

Do not take a larger than normal dose of Mesalazine next time, but continue treatment at the prescribed dosage.

### If you stop taking Mesalazine

Do not stop taking this product until you have talked to your doctor.

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## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you get any of the following symptoms after taking this medicine, you should contact your doctor and stop the intake of Salofalk tablets immediately:**

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- A marked reduction of your general health, especially if accompanied by fever, and/or a sore throat and mouth. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood, which may make you more prone to developing a serious infection (**agranulocytosis**). Other cells of the blood may also be affected (e.g., platelets or red cells causing aplastic anaemia or **thrombocytopenia**) 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 symptoms are due to an effect of this medicine on your blood. These reactions are very rare.
- **Serious skin rashes** 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).
- Shortness of breath, chest pain or irregular heartbeat, or swollen limbs which may be indicative of **cardiac hypersensitivity reactions**. These reactions are rare.
- **Problems with your kidney function** (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)).

The following side effects have also been reported by patients using mesalazine:

### Common side effects (may affect up to 1 in 10 people)

- Headache
- Rash, itching

### Uncommon side effects (may affect up to 1 in 100 people)

- Abdominal pain, diarrhoea, dyspepsia, wind (flatulence), nausea and vomiting
- Severe abdominal pain because of acute inflammation of the pancreas
- Changes in liver function parameters, changes in pancreatic enzymes

### Rare side effects (may affect less than 1 in 1,000 patients)

- Dizziness
- Jaundice or abdominal pain because of liver and bile flow disorders

- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)
- Joint pain
- Feeling weak or tired

### Very rare side effects (may affect less than 1 in 10,000 patients)

- Numbness and tingling in the hands and feet (peripheral neuropathy)
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Hair loss and the development of baldness
- Muscle pain
- Reversible decrease in semen production

### Reporting of side effects

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By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Mesalazine

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- Do not store above 25°C.
- If your medicine shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Mesalazine contains

The active substance is mesalazine.  
Each tablet contains 500mg mesalazine.

**The other ingredients are** calcium stearate; microcrystalline cellulose; sodium carboxymethylcellulose; basic butylated methacrylate copolymer (= Eudragit E); methacrylic acid-methyl methacrylate copolymer 1:1 (= Eudragit L); glycine; silica, colloidal anhydrous; hypromellose; macrogol 6000; sodium carbonate; povidone K25; talc; colouring agents: titanium dioxide (E 171); iron oxide yellow (E 172)

### What Mesalazine looks like and contents of the pack

Mesalazine 500mg tablets are oval, light yellow to ochre, gastro-resistant tablets, matt with smooth surface; they are not scored.

Mesalazine 500mg tablets are available in blister packs of 100 tablets.

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