

Package leaflet: information for the user

OSIREC 4 g/60 ml Rectal Suspension

Read all of this leaflet carefully before you start using 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.

1. What OSIREC is and what this is used for

OSIREC 4g/60ml Rectal Suspension contain the active substance mesalazine, an anti-inflammatory agent used to treat inflammatory bowel disease.

OSIREC is used for the treatment of:

Inflammation of the large intestine (colon) and rectum (back passage) known by doctors as ulcerative colitis. It may be used alone or, particularly in the acute phase, with corticosteroids.

2. What you need to know before you use OSIREC

Do not use OSIREC:

- If you are allergic to salicylic acid, to salicylates such as aspirin or to any of the other ingredients of product,
- If you have a serious liver or kidney disease,

Warnings and precautions

Talk to your doctor or pharmacist before using OSIREC

- 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.

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

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.

Other medicines and OSIREC

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

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

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 Osired 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 using this medicine.

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

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

Driving and using machines

There are no effects on the ability to drive and use machines.

OSIREC contains potassium metabisulphite, which may cause breathing difficulties and allergic reactions, particularly if you have asthma or a history of allergies.

OSIREC contains sodium benzoate. This may cause irritation of the skin, eyes and mucous membranes.

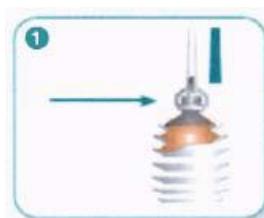
3. How to use OSIREC

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

Method of administration:

This medicine may only be used rectally, so it has to be inserted through the anus. It is not intended to be taken by mouth. Do not swallow. OSIREC should be administered preferably at bedtime.

- Empty your bowels if necessary and wash your hands.
- Shake the bottle for 30 seconds then remove the protective cap from the applicator and hold the bottle by its upper end.



- Lie down on your left side with your left leg outstretched and your right leg bent (this aids the action of the suspension).



- Insert the applicator, which is coated with a lubricant for easy insertion, into the rectum, holding the bottle pointed towards your navel.
- Whilst holding the bottle tightly squeeze slowly.



- Remove the applicator from the rectum when the bottle is empty but maintain this position for at least 30 minutes to allow the suspension to spread throughout the lower part of the large intestine.
- Wash your hands again and try not to empty your bowels again until the next morning.

Dosage:

Adults and the elderly

Unless otherwise prescribed by your doctor, the recommended dose for the treatment of acute episodes of ulcerative colitis is one suspension bottle a day to be used at bedtime

Use in children and adolescents

There is little experience and information about the effect of this medicine when used in children.

Duration of treatment

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 OSIREC regularly and consistently, because this is the only way to achieve the desired therapeutic effect.

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

If you use more OSIREC 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 OSIREC on one occasion, just use your next dose as prescribed.

Do not use a smaller amount.

If you forget to use OSIREC

Do not use a double dose of OSIREC next time, but continue treatment at the prescribed dosage.

If you stop using OSIREC

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

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

4. Possible side effects

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

All medicines can cause allergic reactions although serious allergic reactions are very rare. If you get any of the following symptoms after taking this medicine, you should contact your doctor immediately:

- Allergic skin rash
- Fever
- Breathing difficulties

If you experience a marked reduction of your general health, especially if accompanied by fever and/or sore throat and mouth, stop using the rectal suspension and contact your doctor immediately. These symptoms can, very rarely, be due to a fall in the number of white cells in your blood (a condition called agranulocytosis) which may make you more prone to developing a serious infection. A blood test can confirm whether your symptoms are due to an effect of this medicine on your blood.

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

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

- Abdominal pain, diarrhoea, wind (flatulence), nausea, vomiting, constipation
- Chest pain, breathlessness or swollen limbs because of an effect on your heart
- Headache, dizziness
- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity)

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

- Changes in kidney function, sometimes with swollen limbs or flank pain
- Severe abdominal pain because of acute inflammation of the pancreas
- Shortness of breath, cough, wheezing, lung shadow on x-ray due to allergic and/or inflammatory lung conditions
- Severe diarrhoea and abdominal pain because of an allergic reaction of this medicine within the bowel
- Skin rash or inflammation
- Muscle and joint pain
- Fever, sore throat or malaise because of blood count changes
- Jaundice or abdominal pain because of liver and bile flow disorders

- Hair loss and the development of baldness
- Numbness and tingling in the hands and feet (peripheral neuropathy)
- Reversible decrease in semen production

Not known (frequency cannot be estimated from the available data)

- Kidney stones and associated kidney pain (see also section 2)

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.

5. How to store OSIREC

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the container on the bottom of the bottle and on the carton. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

6. Contents of the pack and other information

What OSIREC contain

The active substance is mesalazine and one bottle contains 4g of mesalazine.

The other ingredients are

Sodium benzoate (E 211), potassium metabisulphite (E 224), carbomer, sodium EDTA, potassium acetate (E 261), xanthan gum and purified water.

What OSIREC look like and contents of the pack

The suspension is a creamy coloured suspension. It is contained in a white, opaque plastic bottle with a lubricated applicator.

Each box of OSIREC contains 7 bottle

Marketing Authorisation Holder

MCG Pharma İlaç San. ve Tic. Ltd. Şti.

Macun Dist. Bati Blvd. No:1/129

Yenimahalle/ANKARA

Manufacturer

Şifa Kimya İlaç Kozmetik San. ve Tic. A.Ş

Büyükkayacık OSB Dist. Kırımlı St. No:15

Selçuklu / KONYA

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