

Zintasa

400mg EC 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.

What is in this leaflet:

1. What Zintasa EC Tablets are and what they are used for
2. What you need to know before you take Zintasa EC Tablets
3. How to take Zintasa EC Tablets
4. Possible side effects
5. How to store Zintasa EC Tablets
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1. What Zintasa EC Tablets are and what they are used for

Zintasa EC Tablets contain the active substance mesalazine (also known as 5-aminosalicylic acid) which is an anti-inflammatory drug used in the treatment of:

Ulcerative colitis: a disease of the large bowel (colon) and back passage (rectum) in which the lining of the bowel becomes inflamed (red and swollen). Symptoms can include rectal bleeding, frequent diarrhoea and abdominal pain. Zintasa EC Tablets act locally in the colon to reduce inflammation and can also prevent further episodes (flares) of ulcerative colitis.

Zintasa EC Tablets can also be used to prevent further attacks of ulcerative colitis.

This medicine is sometimes prescribed for other purposes and you should consult your doctor for more information if necessary.

2. What you need to know before you take Zintasa EC Tablets

TELL YOUR DOCTOR BEFORE TAKING Zintasa EC Tablets:

- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Zintasa EC Tablets.

Do not take Zintasa EC Tablets if you:

- are allergic to mesalazine or any of the other ingredients of Zintasa EC Tablets (see section 6 – What Zintasa EC Tablets contain).
- are allergic to aspirin or any other salicylate.
- have had kidney problems or blood abnormalities while taking other medicines such as sulfasalazine.
- have severe kidney impairment.

DO NOT give the tablets to children under 2 years of age.

Warnings and precautions:

- **Take special care with Zintasa EC Tablets:** 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 Zintasa EC Tablets treatment. Stop using Zintasa EC Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- Zintasa EC Tablets should be used with extreme caution in patients with confirmed mild to moderate kidney impairment.
- Zintasa EC Tablets should be used with extreme caution in the elderly.
- If you become dehydrated (lose too much water), it is important to replace your fluid as soon as possible, contact your doctor or pharmacist for advice.

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.

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.

Other medicines and Zintasa EC Tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Zintasa EC Tablets should NOT be taken with **lactulose** or similar medicines to treat constipation.

Use of **non-steroidal anti-inflammatory drugs** (NSAIDs such as ibuprofen, aspirin, Cox-II inhibitors) and **azathioprine** (used for organ transplant therapy) in particular may increase the risk of kidney reactions.

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.

Tests on your liver, kidney and blood

Before you start treatment with Zintasa EC Tablets you will have a blood and urine test to check how well your kidneys are working and what your blood is doing. During treatment your doctor will check how well your liver, kidney and blood is working by taking blood and urine sample periodically during your treatment.

Driving and using machines

This medicine is not expected to affect your ability to drive or operate machinery.

Important information about Zintasa EC Tablets

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Zintasa EC Tablets

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

The tablets should be swallowed whole with water; do not break, crush or chew them.

The usual dose is:

Adults and the elderly:

- **Treating ulcerative colitis** - 6 tablets each day divided throughout the day, e.g.
 - 2 tablets 3 times a day, or
 - 3 tablets twice a day.
- **Preventing further episodes of ulcerative colitis** – between 3 and 6 tablets each day divided throughout the day, e.g.
 - a daily dosage of 3 tablets may be taken as 1 tablet 3 times a day,
 - a daily dosage of 6 tablets may be taken as 3 tablets twice a day.

DO NOT take more than 6 tablets a day.

Your doctor will need to monitor your kidney function prior to starting Zintasa EC Tablets, every three months for the first year, then 6 monthly for the next four years and annually after that.

Zintasa EC Tablets are not recommended for use in children.

Your doctor may decide to change your dose, it is always important to follow your doctor's directions about when and how to take your medicine. Remember to get a repeat prescription at the right time so that you do not miss a day of treatment.

If you take more Zintasa EC Tablets than you should

Do not exceed the recommended dose. You should only take as many tablets as your doctor has instructed on the pharmacist's label. If you take too many tablets, or someone accidentally swallows some, tell your doctor immediately or go to your nearest Accident & Emergency Department (take the tablet pack with you if possible).

If you forget to take Zintasa EC Tablets

If you forget to take a dose at the required time, take it as soon as you remember and continue taking your tablets as before. DO NOT take more than two doses in one hour. If it is almost time for your next dose, wait until then and carry on as before. If you are at all concerned about this, consult your doctor or pharmacist.

If you stop taking Zintasa EC Tablets

If you suddenly stop taking this medicine your symptoms may come back. You should not stop taking your medicine unless you have been advised to do so by 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 experience any of the following serious side effects **stop taking this medicine** and contact your doctor or go to your nearest hospital casualty department **immediately**:

- 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 serious skin rashes can be preceded by fever and flu-like symptoms.

- allergic reaction. Symptoms include skin rash with flaking, boils or sore lips or mouth, lumps or hives, swelling of the face, lips, hands or feet, sudden wheeziness, tightness of the chest or breathing problems.
- liver problems. Symptoms include feeling tired, feeling sick, pain below the right ribs, your skin or the whites of your eyes turn yellow.
- changes in your blood. Symptoms include unusual bleeding, bruising, rash, fever, sore throat or excessive tiredness, or you become susceptible to infection.
- lupus (a disease where the body attacks internal organs such as lungs, heart, stomach and joints). Symptoms include tiredness, fever, joint pain.

Other side effects:

Common (may affect up to 1 in 10 people)

- headache
- feeling sick, being sick, diarrhoea, stomach pains caused by inflammation (swelling, redness and pain) in the intestines.

Rare (may affect up to 1 in 1,000 people)

- problems with heart, lung, liver or kidney function
- inflammation of the pancreas
- blood abnormalities
- numbness and tingling of the fingers and toes due to damaged nerves
- hair loss
- fever
- skin rash.

Very rare (may affect up to 1 in 10,000 people)

- worsening of symptoms of colitis
- Erythema multiforme and Stevens-Johnson syndrome (skin and mucous membrane disease).

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

- kidney stones and associated kidney pain (see also section 2)
- inflamed lining of the lung, causing sharp chest pain that feels worse with breathing, dry cough, shortness of breath (pleurisy).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Yellow Card Scheme at: 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 your Zintasa EC Tablets

Keep this medicine out of the sight and reach of children.

Store Zintasa EC Tablets at or below 25°C in a dry place and protect from light.

Do not take this medicine after the expiry date shown on the label.

Do not take this medicine if you notice any visible signs of deterioration of these tablets such as cracks in the coat, take them to your pharmacist for advice.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zintasa EC Tablets contain

Each tablet contains 400mg of the active ingredient mesalazine.

The other ingredients are microcrystalline cellulose, sodium carboxymethyl starch, corn starch, magnesium stearate, polyvinyl pyrrolidone, mannitol, precipitated silica, dimethyl phthalate, methacrylic acid copolymer, dimethicone, talc, titanium dioxide and red ferric oxide.

What Zintasa EC Tablets look like and contents of the pack

Zintasa EC Tablets are red-brown, coated and round shaped.

The tablets are available in blister packs of 28, 30, 56, 60, 84, 90, 112, 120, 168 or 240 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder

Morningside Healthcare Ltd.
Unit C, Harcourt Way
Leicester, LE19 1WP, UK

Manufacturer

SOFAR S.P.A., Via Firenze, 40, 20060, Trezzano Rosa (MI) Italy.

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