

# Olsalazine Sodium 250mg Capsules

## Patient Information Leaflet

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 symptoms 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 Olsalazine Sodium Capsules is and what it is used for
- 2 What you need to know before you take Olsalazine Sodium Capsules
- 3 How to take Olsalazine Sodium Capsules
- 4 Possible side effects
- 5 How to store Olsalazine Sodium Capsules
- 6 Contents of the pack and other information

## 1 What Olsalazine Sodium Capsules are for

Olsalazine Sodium Capsules belongs to a group of medicines called aminosalicylates.

Olsalazine Sodium Capsules works by reducing pain and swelling (inflammation) in the intestine. It reduces the actions of substances in the body that cause inflammation.

Olsalazine Sodium Capsules is used to treat an inflammation of your large intestine (colon) called ulcerative colitis. It is used for short-term (acute) attacks (called "flare-ups"), and at a lower dose to maintain the improvement (maintenance treatment) and keep away further "flare-ups". If untreated, a severe attack of ulcerative colitis may cause death due to dehydration and bursting of the colon (peritonitis).

## 2 What you need to know before you take Olsalazine Sodium Capsules

- \* are allergic to olsalazine sodium or any of the other ingredients of this medicine (listed in section 6)
- \* have ever had an allergic reaction to any salicylates (e.g. aspirin and aspirin-containing products, including those bought over the counter)
- \* have severe kidney disease

If any of the above apply to you talk to your doctor or pharmacist.

### Warning and precautions

Before you start taking Olsalazine Sodium Capsules your doctor will do a blood test. This will be repeated every three months for the first year, every six months for the next four years and then once a year. This is to see how well your liver and kidneys are functioning.

You should also check for signs of worsening of allergies such as asthma.

**Tell your doctor immediately** if you develop unexplained bruising or bleeding accompanied with fever, dizziness, sore throat and mouth ulcers. You could have developed a blood disorder.

### Children and adolescents

Do not take Olsalazine Sodium Capsules if you are under 12 years of age.

### Other medicines and Olsalazine Sodium Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might have taken any of the following medicines:

- \* Aspirin or any other aspirin-containing medicines or salicylates
- \* Other drugs to treat ulcerative colitis
- \* Blood thinning agents such as warfarin or heparin or heparinoids
- \* Drugs that treat irritable bowel syndrome and cancer such as thioguanine and 6 mercaptopurine
- \* If you have recently had chickenpox vaccination (taking Olsalazine Sodium Capsules may cause a greater risk of Reye's syndrome; a life threatening condition)
- \* Any other medicine, including medicines obtained without a prescription.

### Olsalazine Sodium Capsules with food and drink

Always take Olsalazine Sodium Capsules with a glass of water **after** food.

### Pregnancy, breast-feeding and fertility

If you are pregnant, or trying to become pregnant or breastfeeding, talk to your doctor before taking Olsalazine Sodium Capsules.

### Driving and using machines

If you experience dizziness and/or blurred vision whilst taking Olsalazine Sodium Capsules do not driver or use machinery.

## 3 How to take Olsalazine Sodium Capsules

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

**Important: Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.**

Remember: Your medicine should always be taken **after** food.

### Adults, children over 12 and the elderly

#### Acute "flare-ups"

- \* The usual starting dose is two capsules twice a day (two in the morning, two in the evening at the end of a meal).
- \* Your doctor may increase your dose until your condition improves.
- \* You must not take more than twelve capsules a day or more than four capsules at a time
- \* If a "flare-up" is severe you are likely to be given additional medicines.

#### Maintenance treatment

- \* Once the "flare-up" is controlled your doctor may gradually reduce your dose to two capsules twice a day (two in the morning, two in the evening at the end of a meal).
- \* This is to prevent further "flare-ups"
- \* You may remain on this treatment, provided it remains effective, for a long period of time.

### If you take more Olsalazine Sodium Capsules than you should

Do not take more Olsalazine Sodium Capsules than you should. If you have taken too much, immediately go to the nearest hospital casualty department or your doctor. Take your capsules and this leaflet with you.

Signs of taking too much Olsalazine Sodium Capsules include nausea, vomiting and diarrhoea.

### If you forget to take Olsalazine Sodium Capsules

Do not take a double dose to make up for a forgotten dose. If you forget a dose take the next one as usual.

### If you stop taking Olsalazine Sodium Capsules

Do not stop taking Olsalazine Sodium Capsules without first talking to your doctor even if your symptoms have improved.

If you have any further questions about 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.

**Seek immediate medical help if you have any of the following symptoms (the frequency of these side effects is unknown):**

- \* Swelling of face, lips, tongue or throat which may cause difficulty in swallowing/breathing
- \* Blood disorders (reduced number of blood cells) where you could have the following symptoms: bruise or bleed easily, have a persistent sore throat, mouth ulcers, dizziness and feeling tired and feverish
- \* Pancreatitis where you could have the following symptoms: severe stomach pain, fever, feeling sick/being sick
- \* Liver disease where you could have the following symptoms: feeling sick/being sick, loss of appetite, feeling generally unwell, itching and the whites of the eyes may become yellow.

# Olsalazine Sodium 250mg Capsules

## Patient Information Leaflet (continued)

### Other possible side effects:

#### Common: may affect up to 1 in 10 people

- \* Headache
- \* Diarrhoea. It does not usually last very long, but taking your medicine at the end of a meal helps to reduce diarrhoea.
- \* Feeling sick
- \* Rash
- \* Joint pain

#### Uncommon: may affect up to 1 in 100 people

- \* Fever
- \* Being sick
- \* Indigestion
- \* Raised liver enzymes (tests your doctor may perform will show changed liver function)
- \* Itching and/or hives, a nettle-like rash
- \* Unusual hair loss
- \* Light sensitivity.
- \* Increased heart rate
- \* Shortness of breath
- \* Muscle pain
- \* Pins and needles
- \* Depression
- \* Dizziness

#### Not known: frequency cannot be estimated from the available data:

- \* Altered breakdown of blood cells in the liver which could result in jaundice (yellowing of skin/eyes)
- \* Stomach pain
- \* Inflammation of heart muscle
- \* Awareness of your heartbeat
- \* Inflammation of sac around heart muscle
- \* Pain in passing urine or blood in the urine
- \* Difficulty in breathing
- \* Blurred vision
- \* Loss of touch sensation/numbness

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 on 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 Olsalazine Sodium Capsules

- \* **Keep out of the sight and reach of children.**
- \* For oral use.
- \* To be taken as directed by your doctor.
- \* Do not store above 25°C.
- \* Keep container tightly closed to protect from moisture.
- \* Do not take Olsalazine after the expiry date shown on the container. The expiry date refers to the last day of that month.
- \* If your doctor tells you to stop using this medicine, take any remaining capsules back to the pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- \* If your capsules become discoloured or show any other signs of deterioration consult your pharmacist who will tell you what to do.
- \* 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 Olsalazine contains:

- \* Each capsule contains olsalazine sodium 250mg.
- \* The other ingredients are magnesium stearate (E572)
- \* Printing Ink: shellac (E904), black iron oxide (E172) and propylene glycol (1520). It may also contain potassium hydroxide.
- \* Capsule shell: caramel (E150), titanium dioxide (E171) and gelatin.

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

- \* Olsalazine is a beige colour hard capsule with 'Dipentum 250mg' printed in black ink.
- \* Each container contains 112 Capsules.

### Manufacturer and Licence Holder

Manufactured by Waymade Plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

**POM** PL 15184/1778 Olsalazine Sodium 250mg Capsules

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