

GLUING AREA

Patient Information leaflet

Olsalazine Sodium 500 mg Tablets



AMM# QP70057A
P/N# CIA00342

GLUING AREA

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- In this leaflet, Olsalazine Sodium 500 mg Tablets will be called Olsalazine Sodium Tablets.

In this leaflet:

1. What Olsalazine Sodium Tablets are for
2. Before you take Olsalazine Sodium Tablets
3. How to take Olsalazine Sodium Tablets
4. Possible side effects
5. How to store Olsalazine Sodium Tablets
6. Further information.

1. What Olsalazine Sodium Tablets are for

Olsalazine sodium belongs to a group of medicines called aminosalicilylates. Olsalazine Sodium Tablets work by reducing pain and swelling (inflammation) in the intestine. They reduce the actions of substances in the body that cause inflammation. Olsalazine Sodium Tablets are used to treat an inflammation of your large intestine (colon) called ulcerative colitis. They are 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. Before you take Olsalazine Sodium Tablets

Do not take if:

- You are allergic to olsalazine sodium or any of the other ingredients of Olsalazine Sodium Tablets (see section 6)
 - You have ever had an allergic reaction to any salicylates (e.g. aspirin and aspirin-containing products, including those bought over the counter)
 - You have severe kidney disease
 - You are a child under 12.
- If any of the above apply to you talk to your doctor or pharmacist.

Take special care

Before you start taking Olsalazine Sodium Tablets 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.

Tell your doctor if you are taking 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 Tablets may cause a greater risk of Reye's syndrome; a life threatening condition)
- Any other medicine, including medicines obtained without a prescription.

Taking Olsalazine Sodium Tablets with food and drink

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

Pregnancy and breast-feeding

If you are pregnant, or trying to become pregnant or breast-feeding, talk to your doctor before taking Olsalazine Sodium Tablets.

Driving and using machines

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

3. How to take Olsalazine Sodium Tablets

Always use Olsalazine Sodium Tablets exactly as your doctor has told you.

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 tablets a day (one in the morning, one 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 six tablets a day or more than two tablets 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 one tablet twice a day (one in the morning, one 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 Tablets than you should

Do not take more Olsalazine Sodium Tablets than you should. If you have taken too many, immediately go to the nearest hospital casualty department or your doctor. Take your tablets and this leaflet with you. Signs of taking too many Olsalazine Sodium Tablets include nausea, vomiting and diarrhoea.

If you forget to take Olsalazine Sodium Tablets

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

If you stop taking Olsalazine Sodium Tablets

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

Information about the ingredients

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per tablet.

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

4. Possible side effects

Like all medicines Olsalazine Sodium Tablets 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.

Other possible side effects:

Common (affects less than 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 (affects less than 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

The frequency of the following side effects is unknown:

- 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.

Also you can help to make sure that medicines remain as safe as possible by reporting any unwanted side effects via the internet at

www.mhra.gov.uk/yellowcard.

Alternatively you can call Freephone 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays) or fill in a paper form available from your local pharmacy.

5. How to store Olsalazine Sodium Tablets

Keep out of the sight and reach of children.

Do not use Olsalazine Sodium Tablets after the expiry date on the carton. The expiry date refers to the last day of that month.

Store in a dry place.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. Further information

What Olsalazine Sodium Tablets contain

The active substance is Olsalazine Sodium 500 mg.

The other ingredients are magnesium stearate, colloidal silicon dioxide, polyvidone 30, crospovidone and ethanol.

What Olsalazine Sodium Tablets look like

Olsalazine Sodium Tablets are yellow, capsule-shaped tablets debossed with 'D500' on one side and scored on the other side.

Olsalazine Sodium Tablets come in plastic bottles containing 60 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Atnahs Pharma UK Limited
Sovereign House, Miles Gray Road,
Basildon, Essex, SS14 3FR, UK.

Manufacturer
Waymade plc,
Sovereign House, Miles Gray Road,
Basildon, Essex SS14 3FR, UK.

This leaflet was last updated on August 2014

If this leaflet is difficult to see or read or you would like it in a different format, please contact Atnahs Pharma UK Limited Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK.

GB 723-0527-APIL

p/n CIA60342

AW# CIP70057A

 **ATNAHS**