

Patient Information Leaflet

Dipentum[®] 250 mg hard Capsules

Olsalazine Sodium

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, Dipentum 250 mg hard Capsules will be called Dipentum.

In this leaflet:

1. What Dipentum is for
2. Before you take Dipentum
3. How to take Dipentum
4. Possible side effects
5. How to store Dipentum
6. Further information.

1. What Dipentum is for

Dipentum belongs to a group of medicines called aminosalicylates.

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

Dipentum 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. Before you take Dipentum

Do not take if:

- You are allergic to olsalazine sodium or any of the other ingredients of Dipentum (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 Dipentum 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 Dipentum may cause a greater risk of Reye's syndrome; a life threatening condition)
- Any other medicine, including medicines obtained without a prescription.

Taking Dipentum with food and drink

Always take Dipentum with a glass of water with or **after** food.

Pregnancy and breast-feeding

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

Driving and using machines

If you experience dizziness and/or blurred vision or any other side effect that might affect the speed of your responses and concentration whilst taking Dipentum do not drive or use machinery.

3. How to take Dipentum

Always use Dipentum 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 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 Dipentum than you should

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

Signs of taking too much Dipentum include nausea, vomiting and diarrhoea.

If you forget to take Dipentum

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 Dipentum

Do not stop taking Dipentum 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 Dipentum 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, 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 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.

5. How to store Dipentum

Keep out of the reach and sight of children.

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

Do not store above 25°C. Keep the container tightly closed to protect from moisture. 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 Dipentum contains

The active substance is olsalazine sodium. Each capsule contains 250 mg olsalazine sodium.

The other ingredients are magnesium stearate (E572). Printing ink: shellac (E904), black iron oxide (E172) and propylene glycol (E1520). It may also contain potassium hydroxide. Capsule shell: Caramel (E150), titanium dioxide (E171), and gelatin.

What Dipentum looks like

Dipentum are beige colour and marked Dipentum 250 mg in black.

Dipentum comes in plastic bottles containing 112 capsules.

Marketing Authorisation Holder

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If this leaflet is difficult to see or read or you would like it in a different format, please contact

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