

Patient Information Leaflet

Dipentum[®] 250mg capsules

(Olsalazine sodium)

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.

The name of your medicine is Dipentum 250mg capsules but will be referred to as Dipentum throughout this leaflet.

What is in this leaflet:

1. What Dipentum is and what it is used for
2. What you need to know before you take Dipentum
3. How to take Dipentum
4. Possible side effects
5. How to store Dipentum
6. Content of the pack and other information

1. What Dipentum is and what it is used 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. What you need to know before you take Dipentum

Do not take Dipentum if you:

- are allergic to olsalazine sodium or any of the other ingredients of Dipentum (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 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.

Children and adolescents

Do not take Dipentum if you are under 12 years of age.

Other medicines and Dipentum

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 Dipentum may cause a greater risk of Reye's syndrome; a life threatening condition)
- Any other medicine, including medicines obtained without a prescription.

Dipentum with food and drink

Always take Dipentum 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 capsule.

Driving and using machines

If you experience dizziness and/or blurred vision whilst taking Dipentum do not drive or use machine.

3. How to take Dipentum

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 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 capsules and this leaflet with you. Signs of taking too much Dipentum include nausea, vomiting and diarrhoea.

If you forget to take Dipentum

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 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.

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: 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 in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

4. How to store Dipentum

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in original container and in dry place.

Do not take the capsules after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.

If the capsules become discoloured or show any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

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.

5. Content of the pack and other information

What Dipentum contains

The active ingredient in Dipentum is olsalazine sodium.

Each capsule contains 250mg olsalazine sodium.

The other ingredients are magnesium stearate, caramel (E150), titanium dioxide (E171) and iron oxide (E172).

The hard capsule shell is made of gelatin.

What Dipentum looks like and contents of the pack

Dipentum are beige coloured capsules marked with 'DIPENTUM 250 mg'.

It is available in plastic bottles containing 100 capsules.

Manufactured by: Waymade plc, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK.

Procured from within the EU and repackaged by the Product Licence holder: Smartway Pharmaceuticals Ltd, 10 Lyon Road, London, SW 19 2RL, UK.

Dipentum® 250mg capsules; PL 42332/0020

Leaflet date: 12.01.2022

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Blind or partially sighted?

Is this leaflet hard to see or read?

Call **0208 545 7711** to obtain the leaflet in a format suitable for you.

Olsalazine sodium 250mg capsules

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- 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.

The name of your medicine is Olsalazine sodium 250mg capsules but will be referred to as Olsalazine sodium throughout this leaflet.

What is in this leaflet:

1. What Olsalazine sodium is and what it is used for
2. What you need to know before you take Olsalazine sodium
3. How to take Olsalazine sodium
4. Possible side effects
5. How to store Olsalazine sodium
6. Content of the pack and other information

1. What Olsalazine sodium is and what it is used for

Olsalazine sodium belongs to a group of medicines called aminosalicylates.

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

Olsalazine sodium 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

Do not take Olsalazine sodium if you:

- are allergic to olsalazine sodium or any of the other ingredients of Olsalazine sodium (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 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 if you are under 12 years of age.

Other medicines and Olsalazine sodium

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 may cause a greater risk of Reye's syndrome; a life threatening condition)
- Any other medicine, including medicines obtained without a prescription.

Olsalazine sodium with food and drink

Always take Olsalazine sodium 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 do not drive or use machine.

3. How to take Olsalazine sodium

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.

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Acute "flare-ups"

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Maintenance treatment

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4. Possible side effects

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