

DIPENTUM®

(pronounced "dye-PENT-um")

Contains the active ingredient olsalazine sodium (pronounced "ole-SAL-a-zeen")

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dipentum. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Dipentum against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Dipentum is used for

This medicine is used to treat a disease of the bowel called ulcerative colitis.

It belongs to a group of medicines called amino salicylates.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Before you take Dipentum

When you must not take it

Do not take Dipentum if you have an allergy to:

- olsalazine, the active ingredient in Dipentum
- medicines containing salicylates e.g. aspirin
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Dipentum if:

- you are taking any medicine for preventing blood clotting
- you have any bleeding disorder
- you have any stomach diseases such as ulcers in the stomach or duodenum.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows sign of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any form of kidney disease
- any problems with your liver
- suffer from severe allergies or asthma as Dipentum may worsen your condition.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Do not use Dipentum if you are pregnant or breast feeding unless your doctor tells you to. Your doctor will discuss with you all the risks and benefits to help decide whether it should be taken.

If you have not told your doctor about any of the above, tell him/her before you start taking Dipentum.

Taking other medicines

Tell your doctor or pharmacist if you are taking other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking:

- heparin or warfarin, which are medicines used to prevent blood clots
- mercaptopurine or thioguanine, which are medicines used to treat leukaemia.

These medicines may cause unwanted side effects when taken with Dipentum. You may need different amounts of your medicine, or you may need to take different medicines.

Tell your doctor if you have recently received a chickenpox vaccination.

How to take Dipentum

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many capsules or tablets you will need to take each day. This may depend on your condition and whether or not you are taking any other medicines.

Your doctor may start you on a low dose of 250 mg to 500 mg a day before gradually increasing your dose to 2 g to 3 g a day (given in divided doses). A single dose should not exceed 1 g.

Once your condition is under control your doctor may reduce your dose to 1 g a day.

Do not switch from Dipentum tablets to capsules or visa versa without first talking to your doctor.

How to take it

Swallow the tablets or capsules whole with a full glass of water.

When to take it

Take Dipentum soon after food.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is

important to keep taking your medicine even if you feel well.

If you forget to take it

If you forget to take your Dipentum dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Dipentum. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include:

- nausea
- vomiting
- diarrhoea.

While you are using Dipentum

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Dipentum.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Go to your doctor immediately if you have a fever, sore throat, mouth ulcers, bruising or bleeding while using Dipentum. These symptoms may indicate that you have developed a blood problem.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some blood tests and may want to check your kidney and liver function from time to time.

Things you must not do

Do not take Dipentum to treat any other complaints unless advised by your doctor.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking Dipentum or change the dose without checking with your doctor.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dipentum,

This medicine helps most people with ulcerative colitis, but it may have unwanted side-effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea
- nausea or vomiting
- stomach pain or upset stomach
- watery diarrhoea
- headache or dizziness
- rash, itching or sensitivity to sunlight
- fever or chills
- joint or muscle pain
- hair loss

Tell your doctor as soon as possible if you notice any of the following:

- increased heart rate or awareness of your heart beat
- blurred vision
- pins and needles
- pain in passing urine
- blood in the urine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fever, sore throat, mouth ulcers, bruising or bleeding
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, mouth, throat or tongue or other parts of the body
- rash, itching or hives on the skin

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Dipentum

Storage

Keep your Dipentum tablets or capsules in the bottle until it is time to take them.

If you take your tablets or capsules out of the bottle they may not keep well.

Keep your tablets or capsules in a cool dry place where the temperature stays below 30°C.

Do not store Dipentum or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

There are two different strengths of Dipentum: 250 mg and 500 mg.

The 250 mg strength is a capsule and is beige in colour and marked 'DIPENTUM 250mg' at one end.

The 500 mg strength is a tablet and is yellow in colour and capsule-shaped. The tablets are debossed with "D500" on one side and scored line on the other side.

Dipentum 250 mg capsules are available in plastic bottles containing 100 capsules.

Dipentum 500mg tablets are available in plastic bottles containing 100 tablets.

Ingredients

Dipentum capsules contain 250 mg of olsalazine sodium as the active ingredient.

The capsules also contain:

- magnesium stearate
- gelatin
- caramel (E150)
- titanium dioxide (E171)
- iron oxide (E172).

Dipentum tablets contain 500 mg of olsalazine sodium as the active ingredient.

The tablets also contain:

- magnesium stearate
- silica-colloidal anhydrous
- povidone
- crospovidone.

Dipentum tablets and capsules do not contain gluten, lactose, sucrose, tartrazine or other azo dyes.

Supplier

Dipentum is supplied in Australia by:

UCB Pharma
A division of UCB Australia Pty Ltd
Level 1, 1155 Malvern Road
Malvern VIC 3144
Australia

Dipentum 250 mg capsules:
- AUST R 14466
Dipentum 500 mg tablets:
- AUST R 53582

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