

Asamax[®] 500

500mg gastro-resistant tablets

Mesalazine

What is in this leaflet?

This leaflet answers some common questions about Asamax tablets.

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 using Asamax against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Asamax tablets are used for

This medicine is used to treat Crohn's disease affecting the colon and ulcerative colitis, diseases associated with inflammation, ulcers and sores in the bowel causing bleeding, stomach pain, and diarrhoea.

The active ingredient in this medicine is mesalazine. It is an anti-inflammatory agent, chemically similar to aspirin and is thought to work by reducing inflammation in the bowel.

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 not addictive.

It is available only with a doctor's prescription.

Before you take Asamax tablets

When you must not take it

Do not take Asamax if you have:

- an allergy* to any medicine containing mesalazine or aspirin-like medicines, or any of the ingredients listed at the end of this leaflet
- a severe kidney or liver problem
- problems with the clotting of your blood or you tend to bleed easily
- a stomach or duodenal ulcer

*Some of the 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 give this medicine to a child under 2 years of age.

Safety and effectiveness in children younger than 2 years have not been established.

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

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

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:

- a known allergy to Asamax, sulfasalazine or aspirin-like medicines, or any of the ingredients listed at the end of this leaflet
- a kidney or liver problem
- problems with the clotting of your blood or you tend to bleed easily
- a stomach or duodenal ulcer
- lung or breathing problems such as asthma

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

Your doctor can discuss with you the risks and benefits involved. Asamax should be used with caution during pregnancy and lactation and only if the potential benefits outweigh the possible hazards in the opinion of the doctor.

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

Taking other medicines

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

Some medicines and Asamax may interfere with each other. These include:

- azathioprine, used to suppress the immune system
- mercaptopurine, used to treat leukaemia
- sulphonylureas, used to lower blood sugar and treat diabetes (e.g. glibenclamide, glipizide)
- anti-coagulants, used to thin blood or stop blood clots (e.g. warfarin)
- methotrexate, used to treat arthritis and some forms of cancer
- probenecid or sulfinpyrazone, used to treat gout
- spironolactone or furosemide, used to increase the amount of urine produced, and to lower blood pressure
- rifampicin, used to treat tuberculosis
- glucocorticoids, used to treat inflammation, swelling or allergies (e.g. prednisolone).

These medicines may be affected by Asamax or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Asamax tablets

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 box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many Asamax tablets to take each day.

The usual dose can be up to 8 tablets per day.

Your doctor may adjust the dose depending on the particular disease you have and/or your response.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Asamax may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew or break them.

These tablets have a special coating to stop them dissolving until they have gone through the stomach and into the intestines, where they start to work. If you chew them, the coating is destroyed.

When to take it

Take the tablets after meals.

How long to take it

Continue using 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 using your medicine even if you feel well.

If you forget to use it

If it is almost time for your next 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 have missed.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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 use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Asamax. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Asamax tablets

Things you must do

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

Have all blood tests recommended by your doctor.

Asamax may cause kidney, liver or blood problems in a few people. You should have regular blood tests to check your kidney function.

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

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

It may affect other medicines used during surgery.

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

Things you must not do

Do not use Asamax to treat any other complaints unless your doctor tells you to.

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

Do not stop using your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen.

Do not swap between brands of mesalazine tablets without talking to your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how Asamax tablets affect you.

This medicine may cause dizziness and headache in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous if you have a headache or feel dizzy.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Asamax.

This medicine helps most people 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 experience some of the side effects.

Do not be alarmed by the following lists of possible side effects.

You may not experience any of them.

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

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

- headache
- diarrhoea

- abdominal or stomach pain
- nausea (feeling sick)
- vomiting
- mood swings
- dizziness

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- bruising easily, unusual bleeding (e.g. nosebleeds), or frequent signs of infection such as fever, chills, sore throat and mouth ulcers
- painful joints
- fever
- severe upper stomach pain, nausea and vomiting
- chest pain, sometimes spreading to the neck and shoulders, or with fever
- mild skin rash, hives or itching
- yellowing of the skin or eyes, dark coloured urine
- worsening of your condition

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

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

- sudden signs of allergic reactions such as rash, itching or hives, shortness of breath, wheezing, coughing, or swelling of limbs, face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing
- severe stomach cramps and/or pain, bloody diarrhoea, fever, severe headache and skin rash
- rash with severe blisters and bleeding of the eyes, mouth, lips, nose and genitals.

The above list includes very serious side effects, which may need urgent medical attention or hospitalisation. These side effects are very rare.

Other rare side effects that have been reported with Asamax include:

- changes in kidney function
- changes in liver function
- changes in the blood

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 Asamax tablets

Storage

Keep your Asamax tablets in the blister pack until it is time to take your next dose.

If you take Asamax out of the packaging it may not keep well.

Keep your Asamax tablets in a cool dry place where the temperature stays at or below 25°C.

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

Heat and dampness can affect 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 using 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

Asamax 500 tablets are supplied in a pack of 100. The tablets are oval and of a yellow ochre colour.

Each tablet is protected in a PVC/PVDC-Aluminium foil blister.

Ingredients

Asamax 500 tablets contain 500mg mesalazine as the active ingredient, as well as the following inactive ingredients:

- microcrystalline cellulose
- povidone
- colloidal silicon dioxide
- crospovidone
- magnesium stearate
- hypromellose
- polyethylene glycol
- methacrylic acid copolymer
- triethyl citrate
- talc
- titanium dioxide
- yellow iron oxide

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes. Ethanol is used during the manufacturing process of this medicine and trace amounts may be present in the final product.

Distributor

CSL Biotherapies (NZ) Ltd
666 Great South Road
Penrose, Auckland 1544
New Zealand

Ph: 0800 502 757

This leaflet was prepared in March 2009.

Asamax® is a registered trademark of Astellas Pharma Europe B.V.