

# Axanum 81 mg/20 mg hard capsules

acetylsalicylic acid (aspirin)/esomeprazole

## 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 further questions, please ask your doctor or your 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.
- 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 your pharmacist.

### In this leaflet:

1. What Axanum is and what it is used for
2. Before you take Axanum
3. How to take Axanum
4. Possible side effects
5. How to store Axanum
6. Further information

## 1. WHAT AXANUM IS AND WHAT IT IS USED FOR

### What Axanum is

Axanum contains two different medicines called acetylsalicylic acid (aspirin) and esomeprazole.

### What Axanum is used for

The two medicines in Axanum are used for different things:

- **acetylsalicylic acid** prevents recurrence of heart attacks or strokes by thinning the blood. In some people it can cause stomach ulcers.
- **esomeprazole** stops stomach ulcers from forming. It belongs to a group of medicines called "proton pump inhibitors". Esomeprazole works by reducing the amount of acid that your stomach produces.

Follow your doctor's advice and if you want more information ask your doctor or pharmacist.

## 2. BEFORE YOU TAKE AXANUM

### Do not take Axanum if:

- you are allergic to acetylsalicylic acid, esomeprazole, or any of the other ingredients of Axanum (listed in Section 6: Further information)
- you are allergic to other proton pump inhibitor medicines
- you are taking a medicine containing nelfinavir (used to treat HIV)
- you have ever had symptoms of asthma, a runny nose (rhinitis) or a raised, red, itchy skin rash (urticaria) when taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs
- you have bleeding disorders (haemophilia or low platelets), bleeding in your intestines or brain, severe liver problems, severe heart failure or a severe kidney problem

Do not take Axanum if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Axanum.

### Take special care with Axanum

Check with your doctor or pharmacist before taking Axanum if:

- you plan on having surgery
- you have liver problems
- you have kidney problems
- you have asthma, hay fever or any other airway disease or allergy
- you are taking medicines such as Selective Serotonin Reuptake inhibitors (SSRIs) or medicines for thinning the blood.
- you have problems with gout
- you are pregnant

Axanum may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Axanum or while you are taking it, talk to your doctor straight away:**

- you lose a lot of weight for no reason and have problems swallowing
- you get stomach pain or indigestion
- you begin to vomit food or blood
- you pass black stools (blood-stained faeces)

Taking a proton pump inhibitor (which is a component of Axanum), especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take Axanum if you are taking a medicine containing nelfinavir (used to treat HIV).

The effect of treatment may be influenced if Axanum is taken at the same time as some other medicines for:

- HIV (e.g. atazanavir)
- thinning of the blood/prevention of clots (e.g. warfarin, clopidogrel)

- high blood pressure (e.g. diuretics, beta blockers and ACE-inhibitors)
- pain and inflammation (e.g. anti-inflammatory medicines such as ibuprofen, corticosteroids)
- gout (e.g. probenecid)
- cancer or rheumatoid arthritis (e.g. methotrexate). If you are taking a high dose of methotrexate, your doctor may temporarily stop your Axanum treatment.
- diabetes (oral hypoglycemics)
- epilepsy (e.g. phenytoin or sodium valproate)
- glaucoma (e.g. acetazolamide)
- fungal infections (e.g. itraconazole, ketoconazole, voriconazole)
- cancer (e.g. erlotinib)
- anxiety (diazepam)
- infections (claritromycin)
- intermittent claudication (cilostazol)
- heart problems (digoxin)
- speeding up stomach emptying (cisapride)
- organ transplantation (tacrolimus)
- tuberculosis (rifampicin)
- depression (St. John's wort)

### Pregnancy

Before taking Axanum, tell your doctor if you are pregnant or trying to become pregnant. Do not take Axanum if you are pregnant, unless it is on your doctor's advice. If you are in the last trimester of pregnancy do not take more than one tablet Axanum per day. If delivery is expected in the next days you should not take Axanum.

### Breast-feeding

Before taking Axanum tell your doctor if you are breast-feeding. Your doctor will decide whether you should stop breast-feeding or stop taking Axanum.

### Driving and using machines

Axanum is unlikely to affect your ability to drive or to operate machinery.

### Important information about some of the ingredients in Axanum

Axanum contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3. HOW TO TAKE AXANUM

Always take Axanum exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell how many capsules to take and when to take them. The usual dose is 1 capsule once daily. The strength of the capsule you take and the length of time you take them for will depend on what conditions you are suffering from. You can take your capsules with food or on an empty stomach. The capsules should not be chewed or crushed. They should be swallowed whole, with half a glass of liquid.

Axanum should not be used in children.

Axanum can be used in the elderly.

If you have the impression that the effect of Axanum is too strong or too weak, talk to your doctor or pharmacist.

### If you take more Axanum than you should

If you may have taken more Axanum than you should, talk to a doctor or pharmacist immediately. Symptoms of an overdose may include dizziness, tinnitus, impaired hearing, irritation, anxiety, hallucinations, hyperventilation, upper abdominal pain and/or discomfort, nausea, confusion, vomiting, loss of consciousness, rash and uncontrolled movements of the body.

### If you forget to take Axanum

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose, just take the next dose on time. Do not take a double dose to make up for forgotten individual doses.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Axanum can cause side effects, although not everybody gets them.

**Stop taking Axanum and see a doctor immediately if you notice any of the following serious side effects – you may need urgent medical treatment:**

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- symptoms of liver problems (e.g. dark urine, yellow skin).
- You pass black sticky bowel motions (stools) or have bloody diarrhoea.
- You vomit any blood or dark particles that look like coffee grounds.



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Schawk Job No.: 368229-A02  
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#### Printable Colours:



Black

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Technical Info



Profile

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Body text size

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Smallest text size

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Other possible side effects include:

**Common (affects 1 to 10 users in 100)**

- headache
- diarrhoea
- wind
- stomach pain and stomach discomfort
- feeling sick/being sick
- constipation

**Uncommon (affects 1 to 10 users in 1,000)**

- disturbed sleep or trouble sleeping (insomnia)
- dizziness
- tingling feeling such as "pins and needles"
- drowsiness
- spinning feeling (vertigo)
- stuffy nose
- asthma
- dry mouth
- itchy skin and skin rashes
- allergic reactions
- peripheral oedema, i.e. swelling of e.g. hands and feet
- increased liver values
- low blood sugar
- nosebleed
- gout

**Rare (affects 1 to 10 users in 10,000)**

- blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely
- fever, swelling of the skin, anaphylactic reaction/ shock(hypersensitivity reactions)
- low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- depression
- appetite problems or taste changes
- difficulty breathing
- stomach ulcer
- duodenal ulcer
- bleeding in your stomach
- an infection called "thrush" which can affect the gut and is caused by a fungus
- pale coloured stools and dark urine which are signs of serious liver problems (hepatitis)
- hair loss
- joint pain (arthralgia)
- muscle pain (myalgia)
- generally feeling unwell, week or lack of energy
- ringing in the ears (tinnitus)

The substances included in Axanum, acetylsalicylic acid and esomeprazole have been observed to cause the following side effects when used as single substances. These side effects, have however, up to date not been observed during combination therapy:

- increased bleeding time
- agitation
- confusion
- sore mouth
- blurred vision
- sensitive to light
- increased sweating
- very low levels of all blood cells
- low number of all blood cells
- aggression
- hallucinations – seeing, feeling, or hearing things that are not there
- severe liver failure
- severe skin reactions with redness, blisters and skin exfoliation
- muscular weakness
- kidney problems
- enlarged breasts in men
- inflammation in the gut (leading to diarrhoea)

**Not known (frequency cannot be estimated from the available data)**

- If you are on Axanum for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

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 AXANUM**

Keep out of the reach and sight of children.

Do not use Axanum after the expiry date which is stated on the carton and blister foil after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Store in the original package in order to protect from moisture.

Do not use Axanum if you notice damaged capsules and/or free pellets.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**What Axanum contains**

The active substances are acetylsalicylic acid (aspirin) and esomeprazole.

Each hard-capsule contains 81 mg acetylsalicylic acid (aspirin) immediate release and 20 mg esomeprazole as esomeprazole magnesium trihydrate (gastro-resistant pellets).

The other ingredients are:

**Esomeprazole component**

glycerol monostearate 40-55  
hydroxypropylcellulose  
hypromellose  
magnesium stearate  
methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent (may contain sodium dodecyl sulphate and polysorbate 80)  
polysorbate 80  
sodium stearyl fumarate  
sugar spheres (contain sucrose and maize starch)  
talc  
triethyl citrate

**Acetylsalicylic acid component**

low-substituted hydroxypropylcellulose

**Hard gelatine capsule, reddish pink/grey size 3**

gelatine  
iron oxide red (E172)  
iron oxide black (E172)  
titanium dioxide (E171)

**Ink black, SW-9008**

iron oxide black (E172)  
potassium hydroxide  
shellac  
propylene glycol

**What Axanum looks like and the contents of the pack**

This medicinal product is presented as a hard gelatine capsule with reddish pink body and grey cap. Cap is marked E 20 mg and A 81 mg printed in black in radial format.

Aluminium/aluminium perforated blister pack of 10 capsules per blister.

Pack sizes of 10, 30 and 90 capsules in perforated blister.

Pack sizes of 30x1 and 90x1 capsules in perforated unit dose blister.

Not all pack sizes may be marketed.

**Marketing authorisation holder**

AstraZeneca UK Ltd  
600 Capability Green,  
Luton, LU1 3LU,  
United Kingdom.

**Manufacturer**

AstraZeneca AB,  
Gärtunavägen, SE-151 85 Södertälje  
Sweden.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria	Axanum
Belgium	Aspaxa
Bulgaria	Axanum
Cyprus	Axanum
Czech Republic	Axanum
Denmark	Axanum
Estonia	Axanum
Finland	Asariex
France	Axanum
Germany	Axanum
Greece	Axanum
Hungary	Aspaxa
Ireland	Axanum
Italy	Onnua
Latvia	Axanum
Lithuania	Axanum
Luxembourg	Aspaxa
Malta	Axanum
The Netherlands	Axanum
Norway	Axanum
Poland	Axanum
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