

## What is in this leaflet

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## What Axiago MUPS is used for

Axiago MUPS is used to treat the following conditions in Adults and young people aged 12 years and above:

- ‘Gastro-oesophageal reflux disease’ (GERD). This is where acid from the stomach escapes into the oesophagus (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn. Axiago MUPS is used for symptomatic and long-term management of patients with healed esophagitis to prevent recurrence.

Axiago MUPS is also used to treat the following conditions in Adults:

- In combination with an appropriate antibacterial medication to eradicate *Helicobacter pylori*, promote healing of these duodenal ulcers and prevent relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcers.
- Patients who need continued (Non-Steroidal Anti-Inflammatory Drugs) NSAID therapy for the healing of stomach ulcers associated with NSAID therapy and to prevent stomach and duodenal ulcers associated with NSAID therapy in patients at risk.

- Prolonged treatment after intravenous induced prevention of re-bleeding of peptic ulcers.
- Zollinger Ellison Syndrome, which is a rare condition where one or more tumors form in the pancreas or upper part of the small intestine (duodenum). These tumors, called gastrinomas, secrete large amounts of the hormone gastrin, which causes the stomach to produce too much acid.

## How Axiago MUPS works

Axiago MUPS contains a medicine called esomeprazole. This belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

## Before you use Axiago MUPS

### - When you must not use it

- You are allergic to esomeprazole or any of the other ingredients of this medicine.
- You are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are taking a medicine containing nelfinavir (used to treat HIV).

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

### - Before you start to use it

Check with your doctor or pharmacist before taking Axiago MUPS if:

- You have severe liver problems.
- You have severe kidney problems.

Axiago MUPS may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Axiago MUPS 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).

Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

If you have been prescribed Axiago MUPS “on demand” you should contact your doctor if your symptoms continue or change in character.

### - Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription. This is because Axiago MUPS can affect the way some medicines work and some medicines can have an effect on Axiago MUPS.

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

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Atazanavir (used to treat HIV).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat lung cancer)
- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Axiago MUPS.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to

monitor you when you start or stop taking Axiago MUPS.

- Cisapride (used for indigestion and heartburn).
- Clopidogrel (used to prevent heart attack or stroke)
- Digoxin (used for heart problems).
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).
- Tacrolimus (used in organ transplant)
- Methotrexate (used in cancer treatment)

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Axiago MUPS to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

### How to use Axiago MUPS

#### - How much to use

The usual doses are given below for adults and children aged 12 or above:

#### To treat heartburn caused by gastro-oesophageal reflux disease (GERD):

If your doctor has found that your oesophagus has been slightly damaged, the usual dose is one Axiago MUPS 40 mg tablet once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your oesophagus has not yet healed.

The usual dose once the oesophagus has healed and to prevent recurrence, is one Axiago MUPS 20 mg tablet once a day. If your oesophagus has not been damaged, the usual dose is one Axiago MUPS 20 mg tablet each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one Axiago MUPS 20 mg tablet each day.

The usual doses are given below for adults:

#### To treat ulcers caused by *Helicobacter pylori* infection and prevent recurrence:

One Axiago MUPS 20 mg tablet together with a suitable antibiotic such as 1g of Amoxycillin and 500mg of Clarithromycin. You need to take these medications twice a day for one week.

#### To treat stomach ulcers caused by NSAIDs:

One Axiago MUPS 20 mg tablet once a day for 4 to 8 weeks. For the prevention of ulcers from recurring, one Axiago MUPS 20 mg tablet once a day.

#### Prolonged treatment after prevention of rebleeding of ulcers with intravenous treatment:

One Axiago MUPS 40 mg tablet once a day for 4 weeks.

#### To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):

One Axiago MUPS 40 mg tablet twice a day.

Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. The maximum dose is 80 mg twice a day.

Axiago MUPS are not recommended for children less than 12 years old.

If you have severe liver problems, the maximum dose should be one Axiago MUPS 20 mg tablet daily.

#### - When to use it

You can take your tablets at any time of the day.

You can take your tablets with food or on an empty stomach. Swallow your tablets whole with a glass of water. Do not chew or crush the tablets. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

#### What to do if you have trouble swallowing the tablets

If you have trouble swallowing the tablets:

- Put them into a glass of still (non-fizzy) water. Do not use any other liquids.
- Stir until the tablets break up (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.

If you cannot swallow at all, the tablet can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ('gastric tube').

#### - How long to use it

Always take Axiago MUPS exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).

If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition, how old you are and how well your liver works.

#### - If you forget to use it

If you forget to take a dose, take it as soon as you remember it.

However, if it is almost time for your next dose, skip the missed dose.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

#### - If you use too much (overdose)

If you take more Axiago MUPS than prescribed by your doctor, talk to your doctor or pharmacist straight away.

**While you are using it**

- Things you must do

Take your medication daily as prescribed. If your doctor prescribed antibiotics for your together with Axiago MUPS, ensure that you complete the whole course of medication as advised.

- Things you must not do

Do not take other medications together with Axiago MUPS without speaking to your doctor or pharmacist first.

- Things to be careful of

Pregnancy and breast-feeding

Before taking Axiago MUPS, tell your doctor if you are pregnant or trying to get pregnant. Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will decide whether you can take Axiago MUPS during this time.

It is not known if Axiago MUPS passes into breast milk.

Therefore, you should not take Axiago MUPS if you are breastfeeding.

Taking Axiago MUPS with food and drink

You can take your tablets with food or on an empty stomach.

Driving and using machines

Axiago MUPS is not likely to affect you being able to drive or use any tools or machines. However, side effects such as dizziness and blurred vision may uncommonly or rarely occur. If affected, you should not drive or use machines.

Important information about some of the ingredients of Axiago MUPS

Axiago MUPS contain sucrose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Axiago MUPS tablets contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

**Side effects**

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

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints (Subacute Lupus Erythematosus, SCLE)
- Fever, extreme tiredness, pus/blood in urine
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- Fracture in the hip, wrist or spine
- Watery stool, stomach pain and fever that do not go away
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes)

If you also notice any of the following serious side effects, stop taking Axiago MUPS and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Sudden onset of severe rash or reddening of the skin with blisters or peeling may occur even after several weeks of treatment. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. The skin rashes may develop into serious widespread skin damage

(peeling of the epidermis and superficial mucous membranes) with life threatening consequences. This could be 'Stevens-Johnson syndrome', 'toxic epidermal necrolysis', 'acute generalised exanthematous pustulosis', or 'drug reaction with eosinophilia and systemic symptoms'.

- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Other side effects include:

*Common (affects less than 1 in 10 people)*

- Headache.
- Effects on your stomach or gut: diarrhea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Fundic gland polyps (benign polyps in the stomach).

*Uncommon (affects less than 1 in 100 people)*

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Dry mouth.
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Fracture. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

*Rare (affects less than 1 in 1,000 people)*

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or

- short of breath (bronchospasm).
- An inflammation of the inside of the mouth.
  - An infection called “thrush” which can affect the gut and is caused by a fungus.
  - Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
  - Hair loss (alopecia).
  - Skin rash on exposure to sunshine.
  - Joint pains (arthralgia) or muscle pains (myalgia).
  - Generally feeling unwell and lacking energy.
  - Increased sweating.

*Very rare (affects less than 1 in 10,000 people)*

- Changes in blood count including agranulocytosis (lack of white blood cells)
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms)
- Muscle weakness.
- Severe kidney problems (interstitial nephritis).
- Enlarged breasts in men.

*Unknown frequency (cannot be estimated from available data)*

- Subacute cutaneous lupus erythematosus (SCLE)
- Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood (Hypomagnesaemia)
- Inflammation in the large bowel, that causes persistent watery diarrhea.

Other possible side effects include Clostridium difficile diarrhea and Vitamin B12 deficiency.

Axiago MUPS may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medication at this time.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage & Disposal of Axiago MUPS

#### - Storage

- Keep out of the reach and sight of children.
- Do not store above 30°C.
- Keep this medicine in the original container (blister).
- Do not take your tablets after the expiry date (EXP) shown on the carton or blister foil. The expiry date refers to the last day of that month.

#### - Disposal

- Remember to return any unused medicine to your pharmacist (chemist).
- 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.

### Product Description

#### - What it looks like

- Axiago MUPS 20 mg tablets are light pink with an A/EH on one side and 20 mg on the other side.
- Axiago MUPS 40 mg tablets are pink with an A/EI on one side and 40 mg on the other side.

Axiago MUPS 20 mg & 40 mg tablets come in blister packs containing 14 tablets in strips of 7 tablets.

#### - Ingredients

- The active ingredient is esomeprazole.
- The inactive ingredients are glycerol monostearate 40-55, hyprolose, hypromellose, iron oxide (reddish-brown, yellow) (E172, 20 mg tablet only), magnesium stearate, methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30 percent, microcrystalline cellulose, synthetic paraffin, macrogol, polysorbate 80, crospovidone, sodium stearyl fumarate, sugar spheres (sucrose and maize starch), talc, titanium dioxide (E171), triethyl citrate.

#### - MAL number

20mg: MAL17055017AZ  
40mg: MAL17055018AZ

### Manufacturer

AstraZeneca AB  
Gärtnavägen,  
SE-152 57 Södertälje,  
Sweden.

### Product Registration Holder

Zuellig Pharma Sdn. Bhd.  
15 Persiaran Pasak Bumi, Seksyen U8, Perindustrian Bukit Jelutong, 40150 Shah Alam, Selangor Darul Ehsan Malaysia.

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