PACKAGE LEAFLET

Package leaflet: Information for the user

Axympa 180mg gastro-resistant tablets
mycophenolic acid

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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Axympa is and what it is used for

Axympa contains a substance called mycophenolic acid. This belongs to a group of medicines called immunosuppressants.

Axympa is used to stop the body's immune system from rejecting a kidney transplant. It is used together with other medicines containing ciclosporin and corticosteroids.

2. What you need to know before you take Axympa

WARNING
Mycophenolate causes birth defects and miscarriage. If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor.
Your doctor will speak to you and give you written information, particularly on the effects of mycophenolate on unborn babies. Read the information carefully and follow the instructions.
If you do not fully understand these instructions, please ask your doctor to explain them again before you take mycophenolate. See also further information in this section under "Warnings and precautions" and "Pregnancy, breast-feeding and fertility".

Do not take Axympa
- if you are allergic to mycophenolic acid, mycophenolate sodium, mycophenolate mofetil or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman who could be pregnant and you have not provided a negative pregnancy test before your first prescription, as mycophenolate causes birth defects and miscarriage.
- if you are pregnant or planning to become pregnant or think you may be pregnant.
- if you are not using effective contraception (see Pregnancy, breast-feeding and fertility).
- if you are breast-feeding.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Axympa.

Axympa

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Axympa:

- if you have or have ever had serious digestive problems, such as stomach ulcer.
- if you have a rare hereditary enzyme deficiency of hypoxanthine-guanine phosphoribosyl-transferase (HGPRT) such as Lesch-Nyhan or Kelley-Seegmiller syndrome.
- if you are planning to become pregnant, or if you get pregnant while taking Axympa.

You should also be aware that

- Axympa lowers the skin´s level of protection from the sun. This increases the risk of skin cancer. You should limit your exposure to sunlight and ultraviolet (UV) light by covering exposed skin areas as much as possible and regularly applying sunscreen with a high protective factor. Ask your doctor for advice on protection from the sun.
- if you get any signs of infection (such as fever or a sore throat) or unexpected bruising or bleeding you should tell your doctor straight away.
- your doctor may want to check your white blood cell count during treatment with Axympa, and will tell you whether you can continue taking Axympa.
- the active substance, mycophenolic acid, is not the same as other similar-sounding medicines such as mycophenolate mofetil. You should not switch between medicines unless your doctor tells you to.

Axympa

You must not donate blood during treatment with Axympa and for at least 6 weeks after stopping treatment. Men must not donate semen during treatment with Axympa and for at least 90 days after stopping treatment.

Children and adolescents

The use of Axympa in children and adolescents is not recommended due to lack of data.

Other medicines and Axympa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, you should talk to your doctor if you are taking any of the following:

- other immunosuppressant medicines such as azathioprine or tacrolimus.
- medicines used to treat high blood cholesterol levels such as cholestyramine.
- activated charcoal used to treat digestive problems such as diarrhoea, upset stomach, and gas.
- antacids that contain magnesium and aluminium.
- medicines used to treat viral infections such as aciclovir or ganciclovir.

You should also tell your doctor if you plan to have any **vaccinations**.

Axympa with food and drink and alcohol

Axympa can be taken with or without food. You need to choose whether to take your tablets with or without food and then take them in the same way each day. This is to make sure that the same amountof your medication is absorbed into your body each day.

Elderly patients

Elderly people (age 65 years or older) can take Axympa without any need to adjust the usual recommended dose.

Pregnancy and breast-feeding and fertility

If you are a woman you should make sure that you are not pregnant, by means of a negative pregnancy test, before you start taking Axympa. Because mycophenolic acid may harm the foetus and increase the risk of pregnancy loss, Axympa should not be used during pregnancy unless clearly necessary.

Contraception in women taking Axympa

If you are a woman, who could become pregnant you must always use two effective methods of contraception with Axympa.Axympa You must use contraception before and while taking it and for 6 weeks after you have stopped taking it. Axympa
Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation. **Contact your doctor as soon as possible, if you think your contraception may not have been effective or if you have forgotten to take your contraceptive pill.**

Contraception in men taking Axympa
If you are a sexually active man it is recommended to use condoms during treatment, and for a total of 90 days after your last dose of Axympa. In addition, your female partners are recommended to use highly effective contraception during your treatment and for a total of 90 days after the last dose of Axympa. If you are planning to have a child, your doctor will talk to you about the risks and the alternative treatments you can take to prevent rejection of your transplant organ.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will talk to you about the risks in case of pregnancy and the alternatives you can take to prevent rejection of your transplant organ if:

- You plan to become pregnant.
- You miss or think you have missed a period, or you have unusual menstrual bleeding, or suspect you are pregnant.
- You have sex without using an effective method of contraception.

If you do become pregnant during the treatment with mycophenolate, you must inform your doctor immediately. However, keep taking Axympa until you see your doctor.

Mycophenolate causes a very high frequency of miscarriage (50%) and of severe birth defects (23-27%) in the unborn baby. Birth defects which have been reported include anomalies of ears, of eyes, of face (cleft lip/palate), of development of fingers, of heart, oesophagus (tube that connects the throat with the stomach), kidneys and nervous system (for example spina bifida (where the bones of the spine are not properly developed)).Your baby may be affected by one or more of these.
If you are a woman who could become pregnant, you must provide a negative pregnancy test before starting treatment and must follow the contraception advice given to you by your doctor. Your doctor may request more than one test to ensure you are not pregnant before starting treatment.

Do not take Axympa if you are breast-feeding. This is because small amounts of the medicine can pass into the mother's milk.AxympaAxympaAxympa
Driving and using machines
Axympa has not been shown to affect your ability to drive or use machines.

Axympa contains sodium
This medicinal product contains 0.61 mmol (13.9 mg) sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

3. How to take Axympa

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Axympa will only be prescribed for you by a doctor with experience in treating transplant patients. Check with your doctor or pharmacist or nurse if you are not sure.

How much to take

The recommended daily dose of Axympa is 1440 mg (8 tablets of 180 mg). This is taken as 2 separate doses of 720 mg each (4 tablets of 180 mg).
Take your tablets in the morning and in the evening.

The first dose of 720 mg will be given within 72 hours after transplantation.

If you have severe kidney problems
Your daily dose should not be more than 1440 mg (8 tablets of 180 mg).

Taking Axympa
Swallow the tablets whole with a glass of water.
Do not break or crush the tablets.
Do not take any tablets that are broken or split.
Treatment will continue for as long as you need immunosuppression to stop your body rejecting your transplant.

If you take more Axympa than you should
If you take more Axympa than you should, or if someone else has taken your tablets, talk to a doctor or go to a hospital straight away. Medical attention may be necessary. Take the tablets with you and show them to your doctor or to the hospital staff. If you have run out of tablets, take the empty packaging with you.

If you forget to take Axympa
If you forget to take Axympa, take it as soon as you remember unless it is almost time for your next dose. Then take your next dose at the usual time. Ask your doctor for advice. Do not take a double dose to make up for a forgotten dose.

If you stop taking Axympa
Do not stop taking Axympa unless your doctor tells you to. Stopping Axympa may increase the chance of your body rejecting your kidney transplant.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Elderly patients may experience more side effects due to a reduced immune defence.

Immunosuppressants, including Axympa, reduces your body's own defence mechanisms to stop you rejecting your transplanted organ. Consequently your body will not be as good as normal at fighting infections. So if you are taking Axympa, you may therefore catch more infections than usual such as infections of the brain, skin, mouth, stomach and intestines, lungs and urinary tract.

Your doctor will perform regular blood tests to monitor any changes in the number of your blood cells or in the levels of substances carried in your blood, such as sugar, fat and cholesterol.

Some effects could be serious:
- signs of infection including fever, chills, sweating, feeling tired, drowsy, or lack of energy. If you are taking Axympa you may be more likely to get an infection than usual. Such infections could affect various parts of your body, but the parts most commonly affected are the kidneys, bladder, upper and/or lower airways.
- vomiting blood, black or bloody stools, stomach or intestinal ulcer.

- swelling of your glands, development of a new skin growth or enlargement of an existing skin growth, or changes in an existing mole. As can happen in patients taking immunosuppressants, a very small number of Axympa patients have developed cancer of the skin or lymph nodes.

If you experience any of the above after taking Axympa, talk to your doctor straight away.

Other side effects may include:
Very common (*may affect more than 1 in 10 people*)
- diarrhoea
- low level of white blood cells.

Common (*may affect up to 1 in 10 people*)
- low level of red blood cells which can result in tiredness, breathlessness and looking pale (anaemia)
- unexpected bleeding and bruising (possible signs of a low level of blood platelets)
- headache
- cough
- abdominal or stomach pain, inflammation of the lining of the stomach, abdominal bloating, constipation, indigestion, wind (flatulence), loose stools, feeling sick (nausea), being sick (vomiting)
- tiredness, fever
- abnormal results of liver or kidney function tests
- respiratory infections.

Uncommon (may affect up to *1 in 100 people*)
- fast or irregular heart beat, fluid in the lungs
- a growth that looks like a sac (cyst) containing fluid (lymph)
- trembling, difficulty in sleeping
- itching, redness and swelling of eyes, blurred vision
- wheezing
- belching, bad breath, bowel blockage, lip ulcers, heartburn, tongue discolouration, dry mouth, inflammation of the gums, inflammation of the pancreas leading to severe upper stomach pain, blockage of the salivary glands, inflammation of the inner lining of the abdomen
- infection of the bones, blood and the skin
- blood in urine, damage to the kidney, pain and difficulty passing urine
- hair loss, skin bruising
- inflammation of the joints, back pain, muscle cramps
- loss of appetite, increased level of lipids, sugar, cholesterol, or decreased level of phosphate in the blood
- signs of flu (such as tiredness, chills, sore throat, aching joints or muscles), swelling of ankles and feet, feeling thirsty or weak
- strange dreams, believing things that aren´t true (delusions)
- inability to get or keep an erection.

Not known *(frequency cannot be estimated from the available data)*
- rash
- lung problems such as:
  - shortness of breath, cough, which can be due to bronchiectasis (a condition in which the lung airways are abnormally dilated), and other less common bacterial infections usually resulting in a serious lung disorder (tuberculosis and atypical mycobacterial infection). Talk to your doctor if you develop a persistent cough or breathlessness.

Other side effects reported with medicines similar to Axympa

Additional side effects have been reported with the group of medicines that Axympa belongs to: inflammation of the colon (large intestine), inflammation of the stomach lining caused by cytomegalovirus, development of a hole in the intestinal wall, resulting in severe abdominal pain with possible bleeding, stomach or duodenal ulcers, a low level of specific white blood cells or of all blood cells, serious infections such as inflammation of the heart and its valves and of the membrane that covers the brain and spinal cord, and other less common bacterial infections usually resulting in a serious lung disorder (*tuberculosis and atypical mycobacterial infection*).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Axympa

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light.
Do not use this medicine if you notice description of the visible signs of deterioration.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Axympa contains
- The active substance is mycophenolic acid (as mycophenolate sodium).

Each tablet contains 180 mg of mycophenolic acid.

The other ingredients are:
Tablet core: Cellulose Microcrystalline (E460), Croscarmellose sodium (E468), Povidone K30 (E1201), Talc (E553b), Silica, colloidal anhydrous (E551), Magnesium stearate (E470b).

Tablet Coating:
Methacrylic acid - ethyl acrylate copolymer (1:1), talc (E553b), titanium dioxide (E171), triethyl citrate (E1505), silica, colloidal anhydrous (E551), sodium hydrogen carbonate (E500), iron oxide yellow (E172), indigo carmine aluminium lake (E132), sodium laurilsulfate (E487).

Tablet Imprinting:
Shellac glaze, partially esterified (E904), iron oxide black (E172), propylene glycol (E1520).

What Axympa looks like and contents of the pack

Axympa are Lime Green colored, round shaped, biconvex bevelled edged enteric-coated tablets imprinted with M1 on one side with black ink and plain on the other side

Axympa are available in blister packs containing 20, 50, 100, 120 and 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva Pharma B.V
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer
Accord Healthcare Limited
Sage house,
319 Pinner Road, North Harrow
Middlesex, HA1 4HF
United Kingdom

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000
Malta

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

Country	**Proposed Name**
ES	Axympa 180 mg comprimidos gastrorresistentes EFG
AT	Axympa 180 mg magensaftresistente Tabletten
BG	Axympa 180 mg gastro-resistant tablets
CZ	Axympa 180 mg enterosolventní tablety
EE	Axympa
HU	Axympa 180 mg gyomornedv-ellenálló tabletta
IE	Axympa 180 mg Gastro-resistant Tablets
LT	Axympa 180 mg skrandyje neirios tabletės
LV	Axympa 180 mg zarnās šķīstošās tabletes
MT	Axympa 180 mg Gastro-resistant Tablets
PL	Axympa
PT	Axympa
RO	Axympa 180 mg comprimate gastro-rezistente
SI	Axympa 180 mg gastrorezistentne tablete
SK	Axympa 180 mg gastrorezistentné tablety

This leaflet was last revised in January 2017.