

## **Package leaflet: Information for the user**

### **Mycophenolate mofetil Clonmel 500 mg, film-coated tablets**

Mycophenolate mofetil

**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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Mycophenolate mofetil is and what it is used for
2. What you need to know before you take Mycophenolate mofetil
3. How to take Mycophenolate mofetil
4. Possible side effects
5. How to store Mycophenolate mofetil
6. Contents of the pack and other information

#### **1. What Mycophenolate mofetil is and what it is used for**

The full name of your medicine is Mycophenolate mofetil Clonmel 500 mg, film-coated tablets.

- In this leaflet the shorter name Mycophenolate mofetil is used.

This medicine contains mycophenolate mofetil.

- This belongs to a group of medicines called “immunosuppressants”.

Mycophenolate mofetil is used to prevent your body rejecting a transplanted organ:

- A kidney, heart or liver.

Mycophenolate mofetil should be used together with other medicines:

- Ciclosporin and corticosteroids.

#### **2. What you need to know before you take Mycophenolate mofetil**

##### **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, contraception and breast-feeding”.

##### **DO NOT take Mycophenolate mofetil**

- If you are allergic to mycophenolate mofetil, mycophenolic acid 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, contraception and breast-feeding”).
- 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 Mycophenolate mofetil.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Mycophenolate mofetil

- If you have a sign of infection such as a fever or sore throat.
- If you have any unexpected bruising or bleeding.
- If you have ever had a problem with your digestive system such as a stomach ulcer.
- If you are planning to become pregnant or if you get pregnant while taking Mycophenolate mofetil.

If any of the above apply to you (or you are not sure), talk to your doctor straight away before taking Mycophenolate mofetil.

### **The effect of sunlight**

Mycophenolate mofetil reduces your body’s defences. As a result, there is an increased risk of skin cancer. Limit the amount of sunlight and UV light you get. Do this by:

- Wearing protective clothing which also covers your head, neck, arms and legs.
- Using a sunscreen with a high protection factor.

### **Other medicines and Mycophenolate mofetil**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Mycophenolate mofetil can affect the way some other medicines work. Also other medicines can affect the way Mycophenolate mofetil works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Mycophenolate mofetil:

- Azathioprine or other medicines which suppress your immune system – given after a transplant operation.
- Colestyramine – used to treat high cholesterol.
- Rifampicin – an antibiotic used to prevent and treat infections such as tuberculosis (TB).
- Antacids or proton pump inhibitors – used for acid problems in your stomach such as indigestion.
- Phosphate binders – used by people with chronic kidney failure to reduce how much phosphate gets absorbed into their blood.

### **Vaccines**

- If you need to have a vaccine (a live vaccine) while taking Mycophenolate mofetil, talk to your doctor or pharmacist first. Your doctor will have to advise you on what vaccines you can have.

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

### **Mycophenolate mofetil with food and drink**

Taking food and drink has no effect on your treatment with mycophenolate mofetil.

### **Pregnancy, contraception and breast-feeding**

### Contraception in women taking Mycophenolate mofetil

If you are a woman who could become pregnant you must use an effective method of contraception with Mycophenolate mofetil. This includes:

- Before you start taking Mycophenolate mofetil.
- During your entire treatment with Mycophenolate mofetil.
- For 6 weeks after you stop taking Mycophenolate mofetil.

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation. Two forms of contraception are preferable as this will reduce the risk of unintended pregnancy. **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.**

You are a woman who is not capable of becoming pregnant if any of the following applies to you:

- You are post-menopausal, i.e. at least 50 years old and your last period was more than a year ago (if your periods have stopped because you have had treatment for cancer, then there is still a chance you could become pregnant).
- Your fallopian tubes and both ovaries have been removed by surgery (bilateral salpingo-oophorectomy).
- Your womb (uterus) has been removed by surgery (hysterectomy).
- Your ovaries no longer work (premature ovarian failure, which has been confirmed by a specialist gynaecologist).
- You were born with one of the following rare conditions that make pregnancy impossible: the XY genotype, Turner's syndrome or uterine agenesis.
- You are a child or teenager who has not started having periods.

### Contraception in men taking Mycophenolate mofetil

The available evidence does not indicate an increased risk of malformations or miscarriage if the father takes mycophenolate. However, a risk cannot be completely excluded. As a precaution you or your female partner are recommended to use reliable contraception during treatment and for 90 days after you stop taking Mycophenolate mofetil.

If you are planning to have a child, talk to your doctor about the potential risks.

### 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 Mycophenolate mofetil until you see him or her.

### Pregnancy

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.

#### Breast-feeding

Do not take Mycophenolate mofetil if you are breast-feeding. This is because small amounts of the medicine can pass into the mother's milk.

#### **Driving and using machines**

Mycophenolate mofetil is not likely to affect you being able to drive or use any tools or machines.

### **3. How to take Mycophenolate mofetil**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### **How much to take**

The amount you take depends on the type of transplant you have had. The usual doses are shown below. Treatment will continue for as long as you need to prevent you from rejecting your transplant organ.

#### Kidney transplant

##### *Adults*

- The first dose is given within 3 days of the transplant operation.
- The daily dose is 4 tablets (2 g of the medicine) taken as 2 separate doses.
- Take 2 tablets in the morning and then 2 tablets in the evening.

##### *Children (aged 2 to 18 years)*

- The dose given will vary depending on the size of the child.
- Your doctor will decide the most appropriate dose based on your child's height and weight (body surface area – measured as square metres or "m<sup>2</sup>"). The recommended dose is 600 mg/m<sup>2</sup> taken twice a day.

#### Heart transplant

##### *Adults*

- The first dose is given within 5 days of the transplant operation.
- The daily dose is 6 tablets (3 g of the medicine) taken as 2 separate doses.
- Take 3 tablets in the morning and then 3 tablets in the evening.

##### *Children*

- There is no information for the use of mycophenolate mofetil in children with a heart transplant.

#### Liver transplant

##### *Adults*

- The first dose of oral mycophenolate mofetil will be given to you at least 4 days after the transplant operation and when you are able to swallow oral medicines.
- The daily dose is 6 tablets (3 g of the medicine) taken as 2 separate doses.
- Take 3 tablets in the morning and then 3 tablets in the evening.

##### *Children*

There is no information for the use of mycophenolate mofetil in children with a liver transplant.

**Taking the medicine**

Swallow your tablets whole with a glass of water

- Do not break or crush them.

**If you take more Mycophenolate mofetil than you should**

If you take more Mycophenolate mofetil than you should, talk to a doctor or go to a hospital straight away. Also do this if someone else accidentally takes your medicine. Take the medicine pack with you.

**If you forget to take Mycophenolate mofetil**

If you forget to take your medicine at any time, take it as soon as you remember. Then continue to take it at the usual times. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Mycophenolate mofetil**

Do not stop taking Mycophenolate mofetil unless your doctor tells you to. If you stop your treatment you may increase the chance of rejection of your transplant organ.

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

**4. Possible side effects**

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

**Talk to a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:**

- You have a sign of infection such as a fever or sore throat.
- You have any unexpected bruising or bleeding.
- You have a rash, swelling of your face, lips, tongue or throat, with difficulty breathing - you may be having a serious allergic reaction to the medicine (such as anaphylaxis, angioedema).

**Usual problems**

Some of the more usual problems are diarrhoea, fewer white cells or red cells in your blood, infection and vomiting. Your doctor will do regular blood tests to check for any changes in:

- The number of your blood cells.
- The amount in your blood of things like sugar, fat or cholesterol.

Children may be more likely than adults to have some side effects. These include diarrhoea, infections, fewer white cells and fewer red cells in the blood.

**Fighting infections**

Mycophenolate mofetil reduces your body's defences. This is to stop you rejecting your transplant. As a result, your body will not be as good as normal at fighting infections. This means you may catch more infections than usual. This includes infections of the brain, skin, mouth, stomach and gut, lungs and urinary system.

**Lymph and skin cancer**

As can happen in patients taking this type of medicine (immune-suppressants), a very small number of mycophenolate mofetil patients have developed cancer of the lymphoid tissues and skin.

**General unwanted effects**

You may get general side effects affecting your body as a whole. These include serious allergic reactions (such as anaphylaxis, angioedema), fever, feeling very tired, difficulty sleeping, pains (such as stomach, chest, joint or muscle, pain on passing urine), headache, flu symptoms and

swelling.

*Other unwanted effects may include:*

**Skin problems** such as:

- Acne, cold sores, shingles, skin growth, hair loss, rash, itching.

**Urinary problems** such as:

- Kidney problems or the urgent need to pass water (urine).

**Digestive system and mouth problems** such as:

- Swelling of the gums and mouth ulcers.
- Inflammation of the pancreas, colon or stomach.
- Gut problems including bleeding, liver problems.
- Constipation, feeling sick (nausea), indigestion, loss of appetite, flatulence.

**Nervous system problems** such as:

- Feeling dizzy, drowsy or numb.
- Tremor, muscle spasms, convulsions.
- Feeling anxious or depressed, changes in your mood or thoughts.

**Heart and blood vessel problems** such as:

- Change in blood pressure, unusual heartbeat, widening of blood vessels.

**Lung problems** such as:

- Pneumonia, bronchitis.
- Shortness of breath, cough, which can be due to bronchiectasis (a condition in which the lung airways are abnormally dilated) or pulmonary fibrosis (scarring of the lung). Talk to your doctor if you develop a persistent cough or breathlessness.
- Fluid on the lungs or inside the chest.
- Sinus problems.

**Other problems** such as:

- Weight loss, gout, high blood sugar, bleeding, bruising.

### **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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Mycophenolate mofetil**

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C.

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

Do not use Mycophenolate mofetil if you notice any visible signs of deterioration.

Do not use this medicine after the expiry date which is stated on the carton, blister and bottle after "EXP". The expiry date refers to the last day of that month.

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 Mycophenolate mofetil contains**

The active substance is mycophenolate mofetil.

Each film-coated tablet contains 500 mg mycophenolate mofetil.

The other ingredients are:

- Tablet core: cellulose microcrystalline, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate
- Tablet coating: opadry purple 20B50135IH (composed of hypromellose 3cP (E464), hydroxypropylcellulose (E463), titanium dioxide (E171), macrogol 400, hypromellose 50cP (E464), iron oxide black (E172) and iron oxide red (E172))

### **What Mycophenolate mofetil looks like and contents of the pack**

Mycophenolate mofetil Clonmel 500 mg film-coated tablets are lavender coloured, capsule shaped, tablets, engraved with “APO” on one side and “MYC500” on the other.

The tablets are available in blister packs containing 50, 150 and 250 tablets and bottles containing 50 and 100 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer:

Apotex Nederland B.V., Archimedesweg 2, 2333 CN Leiden, The Netherlands

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Denmark	Mycophenolatmofetil STADA
France	MYCOPHENOLATE MOFETIL EG 500 mg comprimé pelliculé
Germany	Mycophenolatmofetil AL 500 mg Filmtabletten
Iceland	Mycophenolatmofetil Stada 500 mg filmuhúðaðar töflur
Ireland	Mycophenolate mofetil Clonmel 500 mg film-coated tablets
Portugal	Micofenolato de Mofetil Stada
Romania	Micofenolat mofetil Stada 500 mg comprimate filmate
The Netherlands	Mycofenolaat mofetil STADA 500 mg, filmomhulde tabletten

**This leaflet was last revised in March 2018.**