

REFRAT

Mycophenolate Mofetil Capsules USP 250mg / Tablets USP 500mg

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What Refrat Capsule/ Tablet is used for

Refrat is used to prevent your body rejecting a transplanted organ; i.e. kidney, heart or liver.

Refrat is indicated for induction and maintenance treatment of lupus nephritis (inflammation of the kidney caused by systemic lupus erythematosus (SLE)), a disease of the immune system. Refrat is used together with other medicines:

- Cyclosporine
- corticosteroids.

How Refrat Capsule/ Tablet works

Refrat contains mycophenolate mofetil, This belongs to a group of medicines called “immune - suppressants”.

This medication works by lowering your body's immune system activity.

Before you use Refrat Capsule/ Tablet

-When you must not take it

Do not take Refrat if:

- you are allergic (hypersensitive) to mycophenolate mofetil, mycophenolic acid or any of the other ingredients of Refrat

If you are not sure, talk to your doctor or pharmacist before taking Refrat.

Before you start to take it

Take special care with Refrat

Talk to your doctor straight away before taking Refrat if:

- you have a sign of infection such as a fever or sore throat
- you have any unexpected bruising or bleeding
- you have ever had a problem with

your digestive system such as a stomach ulcer

- you have increased risk for cancer especially skin cancer.

Taking Refrat with food and drink

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

Pregnancy, contraception and breast- feeding

Pregnancy

If you are pregnant, do not take Refrat. This is because Refrat may harm your unborn baby.

- **If you plan to become pregnant,** talk to your doctor first. Your doctor will talk to you about other medicines you can take to prevent rejection of your transplant organ.
- In certain situations, you and your doctor may decide that the benefits of taking Refrat for your health are more important than the possible risks to your unborn baby.
- **If you think you may be pregnant, tell your doctor straight away.**
- However, keep taking Refrat until you see him or her.

If you are able to become pregnant, you must have a pregnancy test before you start Refrat. You can only start Refrat if the result is negative.

Contraception

You must always use an effective method of contraception with Refrat. This includes:

- before you start taking Refrat
- during your entire treatment with Refrat
- for 6 weeks after you stop taking Refrat.

Talk to your doctor about the most suitable contraception for you. This will depend on your individual situation.

Breast-feeding

Do not take Refrat if you are breast-feeding. This is because the medicine can pass into the mother's milk.

Driving and using machines

This medicine may or may not affect your ability to drive or use machines. If the capsules make you

feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

-Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Refrat can affect the way some other medicines work. Also, other medicines can affect the way Refrat works.

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

- antivirals such as acyclovir and Ganciclovir
- cholestyramine – used to treat high cholesterol
- Antacids with magnesium and aluminium hydroxides – used for acid problems in your stomach such as indigestion
- Immunosuppressive agents (medicine that reduce the activity of the immune system) such as azathioprine, cyclosporin and tacrolimus.
- Probenecid – a type of medicine to treat gout
- Vaccines - If you need to have a vaccine (a live vaccine) while taking Refrat, talk to your doctor or pharmacist first. Your doctor will have to advise you on what vaccines you can have.

How to take Refrat Capsule/ Tablet

-How much to take

Kidney Transplant Adults

- The daily dose is 8 capsules (2 g of the medicine) taken as 2 separate doses.
- Take 4 capsules in the morning and then 4 capsules in the evening.

Heart transplant Adults

- The daily dose is 12 capsules (3 g of the medicine) taken as 2 separate doses.
- Take 6 capsules in the morning and then 6 capsules in the evening.

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Liver

transplant

Adults

- The daily dose is 12 capsules (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 Refrat in children.

Elderly (>65 years)

- For kidney transplant, the daily dose is 4 tablets (2 g of the medicine) taken as 2 separate doses.
- For heart transplant, the daily dose is 6 tablets (3 g of the medicine) taken as 2 separate doses.

For starting and maintenance treatment of lupus nephritis:

- 1g taken twice a day (daily dose of 2g).

People with neutropenia (low white blood cell count)

Dosing with mycophenolate mofetil should be stopped or reduced.

People with Kidney Problems

- For kidney transplant, the daily dose should not exceed 4 tablets (2 g of the medicine) taken as 2 separate doses.
- Limited data available for these people with heart and liver transplant

People with Liver Problems

- For kidney transplant, no dose adjustment required.
- Limited data available for these people with heart and liver transplant

-When to take it

Swallow your tablets whole with a glass of water.
Do not break or crush them.

-How long to take it

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

-If you forget to take it

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 missed dose.

-If you take too much (overdose) If you take more Refrat 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.

While you are taking Refrat Capsules / Tablets

-Things you must do

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

-Things you must not do

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

-Things to be careful of

Refrat can increase the risk of you getting cancer, particularly skin cancer, as it reduces your body's defense mechanism. To reduce the risk of skin cancer, exposure to sunlight and UV light should be avoided by wearing protective clothing and using a sunscreen with a high protection factor.

Side Effects

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

The most common side effects includes:

- diarrhoea
- changes in white blood cell count
- vomiting
- higher frequency of infections, including opportunistic infections (caused by pathogens that usually do not cause infections).

The other side effects include: pain (e.g. abdominal, chest, back), fever, headache, anaemia (decreased red blood cells), thrombocytopenia (low platelet cells), urinary tract infection, abnormal kidney function, high or

low blood pressure, heart problems, tachycardia (rapid heartbeat), oedema (water retention), hypercholesteremia (high cholesterol), hypokalemia or hyperkalemia (low or high potassium levels in blood), hyperglycemia (high blood sugar levels), increases in blood urea nitrogen (BUN) and blood creatinine concentration, increased lactic dehydrogenase (a type of enzyme in the blood), hypomagnesemia (low levels of magnesium in blood), hypocalcemia (low calcium levels in the blood), constipation, indigestion, nausea, anorexia (eating disorder), abnormal liver function test results, cough, dyspnea (breathing difficulty), lung problems, sinusitis (inflammation of sinus tissue), pleural effusion (excess fluid surrounding the lungs), rash, tremor, insomnia (unable to sleep), dizziness, anxiety, and paresthesia (tingling, prickling).

Not all side effects are listed in the leaflet. Please visit your doctor or pharmacist immediately if you experience any side effects after taking the medicine.

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.moh.gov.my (Consumers -> Reporting->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Refrat Capsules / Tablets

-Storage

Store below temperature 30°C.
Protect from light.

-Disposal

Do not use after the expiry date stated on the label.

Return any unused tablets to your pharmacist to be disposed of. Only keep the tablets if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

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Product Description

-What it looks like

Refrat Capsule USP 250mg are White to off white blend of Mycophenolate Mofetil filled in size 1 hard gelatin capsules with ivory Cap and ivory body printed "SAL" on cap & "726" on body in black.

Refrat Tablet USP 500mg is mauve colored, capsule shaped, film coated tablets with engraved REFRAT on one side and plain on other side.

-Ingredients

Active ingredient

Refrat Capsule USP 250mg

Each capsule contains

Mycophenolate Mofetil 250 mg.

Refrat Tablet USP 500mg

Each tablet contains

Mycophenolate Mofetil 500 mg

Inactive ingredients

Refrat Capsule USP 250mg

Microcrystalline cellulose, Croscarmellose sodium, Povidone (K-30), Magnesium Stearate, and Purified water.

Refrat Tablet USP 500mg

Microcrystalline cellulose, Croscarmellose sodium, Povidone (K-30), Magnesium Stearate, Opadry Brown (03B 86660), Isopropyl Alcohol and Purified water.

-MAL Number

Refrat Capsule USP 250mg

MAL10070580AZ

Refrat Tablet USP 500mg

MAL10070550AZ

Manufacturer

Strides Pharma Science Limited
36/7, Suragajakkanahalli, Indlavadi
Cross, Anekal Taluk, Bangalore-
562 106, India.

Product Registration Holder

Unimed Sdn Bhd.
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09/07/2022

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