

Proprietary name:	Transwel 180 mg and Transwel 360 mg
Dosage form:	Tablets
Active Ingredient:	Mycophenolic acid (as mycophenolate sodium)
Strength per dosage unit:	180 mg and 360 mg per tablet

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

Transwel 180 mg tablets

Transwel 360 mg tablets

180 mg and 360 mg of mycophenolic acid (as mycophenolate sodium).

Contains sugar.

Transwel 180 mg: Each tablet contains 23,10 mg of lactose anhydrous.

Transwel 360 mg: Each tablet contains 46,20 mg of lactose anhydrous.

Please read this leaflet carefully before taking Transwel.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care giver.
- **Transwel** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **Transwel** is and what it is used for
2. What you need to know before you take **Transwel**
3. How to take **Transwel**

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4. Possible side effects
5. How to store **Transwel**
6. Contents of the pack and other information

1. WHAT TRANSWEL IS AND WHAT IT IS USED FOR:

Transwel contains an active ingredient called mycophenolate sodium, which is broken down to the potent mycophenolic acid. **Transwel** belongs to a group of medicines called immunosuppressants. Immunosuppressants are medicines that lower the body's ability to reject a transplanted organ. The cells in the immune system that are responsible for regulating and triggering immune responses are white blood cells called T- and B-lymphocytes. **Transwel** works by reducing the production of these white blood cells. It does this by blocking the action of a compound called inosine monophosphate dehydrogenase, which is needed for their production.

Transwel is used to prevent the body's immune system from rejecting organs in patients receiving kidney transplants. **Transwel** should be used together with ciclosporin and steroid.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRANSWEL:

Do not take Transwel:

- If you are allergic to mycophenolic acid, mycophenolate sodium, mycophenolate mofetil or any of the inactive ingredients on **Transwel** (see **WHAT TRANSWEL CONTAINS**).
- If you are pregnant or breastfeeding.

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

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Warnings and Precautions

WARNING 1: Cancer-causing effects:

Treatment with **Transwel** can result in increased infection and development of cancers, especially of the skin due to lowered immunity. Inform your doctor immediately if you develop unexpected bruising or bleeding.

Only doctors specializing in transplant and immunosuppression therapy can prescribe **Transwel**.

WARNING 2: Birth defects and malformations:

Mycophenolic acid causes inherited birth defects and spontaneous abortions when used during pregnancy.

The doctor will conduct two pregnancy tests. The second test will be performed 8 – 10 days after the first one and before starting the treatment with **Transwel**. Repeat pregnancy test will be conducted routinely.

Women who are still capable of having babies should use two type of contraceptive at the same time before, during and 6 weeks after **Transwel** treatment.

Female patients should use intra-uterine devices (a form of birth control) with caution as it may also increase the risk of infection.

Female partners of male patients should use very effective contraception during treatment for a total of 90 days after treatment.

Sexually active men should use condom during treatment and for at least 90 days after stopping treatment. Condom must be used by both fertile and sterilized men.

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Take special care with Transwel:

- Elderly patients may experience an increased risk of side effects compared to younger adult patients.
- You should limit the exposure to sunlight and UV light by wearing protective clothing and using sunscreen with high protection factor while taking **Transwel**, as skin diseases may develop.
- Your doctor will request blood tests during your treatment in order to monitor any blood changes.
- Do not receive live vaccines (immunisations) due to an increased risk of infection.
- Inform your doctor if you have an active digestive system disease. Transwel is associated with an increased incidence of digestive system adverse events.

Taking Transwel with food and drink:

Transwel should be taken on an empty stomach and should be swallowed whole with a glass of water.

Using other medicines with Transwel:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Always inform your doctor if you take any medicine as this may interact with **Transwel**.

The use of **Transwel** with the following medicines may cause undesirable interactions:

- Acyclovir or valacyclovir; ganciclovir or valganciclovir (antiviral medicines)
- Cholestyramine (used for high cholesterol levels in the bloodstream)

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- Antacids with magnesium and aluminium hydroxides
- Azathioprine, tacrolimus (medicine used to suppress the immune system)
- Oral contraceptives (used to prevent unplanned pregnancies)
- Live vaccines (used to prevent certain diseases)
- Rifampicin (used to treat tuberculosis (TB))
- Tobramycin, cefuroxime, norfloxacin, ciprofloxacin, metronidazole, amoxicillin and clavulanic acid (used to treat bacterial infections)
- Probenecid (used to treat gout and hyperuricaemia)

Not all the medicines that may interact with Transwel are listed above.

Pregnancy and breastfeeding:

Transwel should not be taken when you are pregnant.

If you are planning to become pregnant, please consult your doctor.

Transwel is excreted into breast milk and may affect your baby. Do not breastfeed your baby whilst taking the treatment of **Transwel**.

Driving and using machinery:

Transwel may cause dizziness or sleepiness.

Do not drive a vehicle or operate any machinery until you know how **Transwel** affects you.

Important information about some of the ingredients of Transwel:

Transwel tablets contain a sugar called lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **Transwel**.

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3. HOW TO TAKE TRANSWEL

Treatment with **Transwel** should be initiated and maintained by appropriately qualified transplant specialists.

Transwel should be initiated in new patients within 48 hours following transplantation.

The recommended dose is 720 mg (four 180 mg or two 360 mg **Transwel** tablets) given twice daily (1440 mg daily dose).

The product can be taken with or without food. The tablet should be swallowed whole with a glass of water. Tablet should not be crushed.

Avoid inhalation or direct contact with skin or mucous membrane of the powder, in case of accidental breakage of the **Transwel**.

Kidney transplant patients with serious kidney damage should be carefully observed. No dose adjustment is required for the elderly and patients with delayed renal graft function post-transplant. Patients with severe chronic renal damage, however, should be carefully monitored.

If you take more Transwel than you should:

In the event of an overdosage contact your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and any remaining capsules or tablets with you, so that the doctor knows what you have taken.

If you forget to take Transwel:

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the capsule(s) or tablet(s) at the usual time.

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Do not take a double or larger dose to make up for the forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

Transwel can have side effects.

Not all side effects reported for Transwel are included in this leaflet. Should your general health worsen while taking **Transwel** please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **Transwel** and tell your doctor immediately or go to the casualty department at your nearest hospital:

Less frequent side-effects:

- Fast or irregular breathing and/or heartbeat
- Hive-like swelling on face, eyelids, mouth, lips or tongue
- Shortness of breath or difficulty breathing.

These are all serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following:

Frequent side-effects:

- Signs of blood disorders such as excessive tiredness, dizziness, unexplained bleeding, bruising or looking pale
- High or low blood pressure
- High levels of cholesterol (fat) in your blood (which is determined by a blood cholesterol test by your doctor)
- Diabetes (characterised by frequent urination, excessive thirst, unusual tiredness)

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- Low potassium levels in your blood (characterised by vomiting, nausea, constipation, low blood pressure) or abnormally high potassium levels in your blood (characterised by nausea, unusual weakness or tiredness, muscle weakness)
- Abnormally low levels of magnesium in your blood (characterised by weakness, muscle cramps or irregular heartbeats)
- Abnormally low levels of sodium (salt) in your blood (characterised by nausea and vomiting,
- Headache, confusion, unusual weakness or tiredness, appetite loss, restlessness, irritability, muscle weakness, spasms or cramps),
- Abnormally low levels of phosphate in your blood (characterised by muscle dysfunction and weakness, irritability, confusion),
- Nervous excitement, anxiety, confusion, depression
- Blood in your urine
- Bladder infection (characterised by burning when you are urinating), difficulty with urination, white foam in your urine, intense pain in the area between your hips and ribs
- Pneumonia (inflammation of the lungs caused by a bacterial or viral infection, characterised by coughing, fever, shaking, chills, shortness of breath and sharp or stabbing chest pain during deep breaths)
- Sepsis (bacterial infection in your bloodstream or body tissues, characterised by fever, low body temperature and fast breathing)
- Dizziness, trouble in sleeping, trembling or shaking of hands or feet
- Swelling of lower legs or feet
- Diarrhoea, nausea, vomiting, constipation, heartburn
- Unusual weakness or tiredness, fever, headache, stomach pain, back pain, chest pain
- Hay fever.

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Less frequent side-effects

- Discolouration of the skin due to blood disorders
- Underactive thyroid gland (characterised by weight gain, unusual weakness and depression) or overactive thyroid gland (characterised by irritability, fast irregular heartbeat, increased sweating and weight loss)
- Cushing's syndrome (high levels of cortisol, characterised by upper body obesity, a rounded face, increased fat around the neck and thinning arms and legs)
- Seizures (fits), mood changes, seeing or hearing things that does not exist, nerve damage (characterised by muscle weakness, cramps and spasms or tingling, numbness and pain), abnormal thinking, an abnormal increase in sensitivity to stimuli of your senses, loss of contact with reality.
- Acidosis (too much acid in your body, after your doctor performed a urine test that checks your body's pH levels), dehydration (when your body loses more fluid than it takes in), increased weight
- Increased tightness of muscle tone
- Sensation of tingling, burning, pricking or numbness of the skin ("pins and needles"), sleepiness
- Vision disturbances, infection in the eye, cataract (cloudiness of the eye)
- Hearing loss
- Disturbances of your heart beat, heart disorders, heart failure, abnormally slow or fast heart beat
- Light headedness when standing up from a lying or sitting position

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- Asthma, lung disorders (characterised by difficulty breathing, coughing up blood (classically seen as pink, frothy sputum), excessive sweating, anxiety, pale skin, flu-like symptoms, chest pain)
- Blood in your stools, fungus infection in your mouth, inflammation of the gums, mouth, oesophagus or pancreas, overgrowth of the gum tissue
- Skin cancers
- Liver disease (characterised by yellow colouration of the skin and eyes)
- Painfully or difficult urination, need to urinate more often than usual, loss of bladder control, production of abnormally small amounts of urine, excessive urination at night
- Feeling an abnormal lump beneath the skin, enlarged stomach, swelling of the face, flu-like symptoms, unusual weakness or tiredness, seeing or feeling a bulge in your stomach area, stomach pressure
- Leg cramps, muscle pain, joint pain, abnormal weakness of certain muscles
- Acne, temporary hair loss, skin rash, infection of the skin
- Runny nose, sore throat.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE TRANSWEL:

Store at or below 25 °C in a cool dry place.

Store in the original package until ready for use.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the medicine after the expiry date shown on the label or carton.

Return the expired medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

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6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Transwel contains:

The active substance :

Mycophenolic acid (as mycophenolate sodium)

The other ingredients are: Colloidal silicone dioxide, crospovidone, anhydrous lactose, magnesium stearate, maize starch and povidone.

Contains Lactose.

What Transwel looks like and contents of the pack:

PRODUCT NAME] 180: Lime green colored, round shaped, biconvex, film coated tablets, imprinted "MA 180" with black ink on one side and plain on other side.

Transwel 360: Pale orange-red colored, oval shaped, biconvex, film coated tablets, imprinted "MA 360" with black ink on one side and plain on other side.

Transwel 180 is packed into plain aluminium foil / aluminium foil blister strips containing 10 tablets packed in an outer carton.

Transwel 360 is packed into plain aluminium foil / white opaque PVC blisters strips containing 10 tablets. 5 blister strips of 10 tablets each packed in an outer carton.

REGISTRATION NUMBER:

To be allocated by Council.

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

Alkem Laboratories (Pty) Ltd.

Route 21 Corporate Park,

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121 Sovereign Drive, Block A, Office A202

Irene Ext. 30, Centurion, 0157

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