
What is in this leaflet

1. What **RANOZYP TABLETS** are used for
2. How **RANOZYP TABLETS** work
3. Before you use **RANOZYP TABLETS**
4. How to use **RANOZYP TABLETS**
5. While you are using it
6. Side Effects
7. Storage and disposal of **RANOZYP TABLETS**
8. Product description
9. Manufacturer and Product registration holder
10. Date of revision

This leaflet answers some common questions about **RANOZYP TABLETS**.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking **RANOZYP TABLETS** against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What RANOZYP TABLETS are used for

RANOZYP TABLETS belong to a group of medicines called antipsychotics. These help to correct chemical imbalances in the brain, which may cause mental illness.

RANOZYP TABLETS are used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.

RANOZYP TABLETS are used to treat a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It is also a mood stabiliser that prevents further occurrences of the disabling high and low (depressed) extremes of mood associated with this condition.

Your doctor may have prescribed **RANOZYP TABLETS** for another reason.

Ask your doctor if you have any questions about why RANOZYP TABLETS have been prescribed for you.

This medicine is available only with a doctor's prescription.

How RANOZYP TABLETS work

RANOZYP TABLETS contain the active ingredient, olanzapine which is a type of medicine called antipsychotics.

RANOZYP TABLETS help to correct chemical imbalances in the brain, which may cause mental illness.

Before you use RANOZYP TABLETS

When you must not use it

Do not use RANOZYP TABLETS

if you are allergic (hypersensitive) to olanzapine or any of the other ingredient of **RANOZYP TABLETS** listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

Shortness of breath wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body, rash, itching or hives on the skin

- if you have been previously diagnosed with eye problems such

as certain kinds of glaucoma (increased pressure in the eye).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

The expiry date refers to the last day of that month. If it has expired or is damaged; return it to your pharmacist for disposal.

If you are not sure whether you should start taking RANOZYP TABLETS, talk to your doctor or pharmacist

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- disease of the blood with a reduced number of white blood cells
- disease of the blood vessels of the brain, including stroke
- prostate problems
- liver disease
- parkinson's disease
- high blood sugar, diabetes or a family history of diabetes (your doctor will advise you to monitor your blood sugar levels and weight regularly)
- paralytic ileus, a condition where the small bowel does not work properly
- epilepsy (seizures or fits)
- heart disease, including irregular heart rhythm (QT-prolongation).
- neuroleptic malignant syndrome, a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- tardive dyskinesia, a reaction to some medicines with

uncontrollable twitching or jerking movements of the arms and legs. If this happens after you have been given **RANOZYP TABLETS** tell your doctor

The use of **RANOZYP TABLETS** in elderly with dementia is not recommended as it may have serious side effects.

Taking **RANOZYP TABLETS** may lead to increase in body weight. Your doctor will advise you to monitor your weight regularly.

In case if you are at high risk of developing thromboembolism (blockage of a blood vessel by a blood clot formed elsewhere in the body) due to being bedridden etc. your doctor would advise you to take certain preventive measures.

The use of **RANOZYP TABLETS** may produce symptoms associated with difficulty in swallowing (dysphagia) and inflammation of lungs from breathing in foreign material (aspiration pneumonia). Aspiration pneumonia is complication associated with Alzheimer disease (dementia with loss of memory and other mental abilities). Aspiration pneumonia is a common cause of mortality and morbidity in patients with advanced Alzheimer disease. The use of **RANOZYP TABLETS** is not recommended in patients with Alzheimer disease.

The use of **RANOZYP TABLETS** may produce high prolactin levels (a chemical secreted by Pituitary glands) in the blood. High prolactin levels in blood may lead to:

- unusual secretion of breast milk (galactorrhoea)
- no menstrual periods
- breast enlargement in men (gynecomastia)
- impotence
- decrease in bone density

If you are above 65 years of age, your blood pressure should be monitored regularly as **RANOZYP TABLETS** can cause decrease in blood pressure.

Your doctor will advise you regarding appropriate care in avoiding overheating and dehydration. You are advised to call your doctor right away if you become severely ill and have some or all of these symptoms of dehydration: sweating too much or not at all, dry mouth, feeling very hot, feeling thirsty, not able to produce urine

If you have not told your doctor about any of the above, tell them before you start taking RANOZYP TABLETS.

Taking RANOZYP TABLETS with drink

Do not drink any alcohol if you have been given **RANOZYP TABLETS** as **RANOZYP TABLETS** and alcohol together may make you feel drowsy.

Pregnancy and breast-feeding

Tell your doctor as soon as possible if you are pregnant or think you may be pregnant. You should not take this medicine when pregnant, unless you have discussed this with your doctor. You should not be given this medicine when breast-feeding, as small amounts of **RANOZYP TABLETS** can pass into breast milk.

The following symptoms may occur in newborn babies, of mothers that have used **RANOZYP TABLETS** in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Important information about some of the ingredients of RANOZYP TABLETS

RANOZYP TABLETS contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Tell your doctor if you smoke.

Smoking may affect **RANOZYP TABLETS** or may affect how it works.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines,

including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **RANOZYP TABLETS** may interfere with each other. These include:

- fluvoxamine (a medicine used for depression)
- carbamazepine, a medicine used for mood stabilisation and to treat epilepsy
- other centrally acting medicines (eg. tranquillisers)
- diazepam (medicine used to treat anxiety)
- ciprofloxacin, a medicine used to treat bacterial infections
- ketoconazole, a medicine used to treat fungal infections
- medicines that lower blood pressure
- medicines used for Parkinson's disease
- medicines that can change the heart's electrical activity or make it more likely to change
- activated charcoal
- omeprazole, medicine used to treat acidity
- rifampin, medicine used to treat tuberculosis

You should know that alcohol can add to the orthostatic hypotensive effect (dizziness on standing up, especially when getting up from a sitting or lying position) caused by this medication. Do not drink alcohol while taking olanzapine.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking **RANOZYP TABLETS**.

How to use RANOZYP TABLETS

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to use it

Your doctor will tell you how many **RANOZYP TABLETS** you should take. The dose your doctor will prescribe for you will be as follows:

Schizophrenia

The usual starting dose for the treatment is 10 mg daily.

Manic episodes

The usual starting dose for the treatment of manic episodes is 15 mg daily when used alone and 10 mg daily when used in combination with other medicines used to treat manic episodes.

Preventing recurrence in bipolar disorder

The usual starting dose is 10 mg daily.

During the treatment of above mentioned disease, your doctor may increase or decrease your dose in order to find the appropriate dose for your condition and this may usually be in the range 5 mg to 20 mg per day.

Elders

A lower starting dose may be prescribed for elderly patients (over the age of 65 years).

Children

RANOZYP TABLETS are not recommended for use in children under the age of 18 years as there is not enough information on its effects in this age group.

Kidney/ Liver problems

In patients with kidney or liver disease a lower dose (5 mg) may be prescribed.

How to use it

RANOZYP TABLETS should be swallowed whole with a glass of water.

When to use it

RANOZYP TABLETS should be taken once a day as advised by your doctor.

Take your prescribed dose at the same time each day.

RANOZYP TABLETS can be taken with or without food.

How long to take it

Do not stop taking **RANOZYP TABLETS** just because you feel better. It is important that you do NOT stop taking **RANOZYP TABLETS** unless your doctor tells you.

If you forget to take it

If it is almost time for your next dose, **skip the dose you missed and take your next dose when you are meant to.**

Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much RANOZYP TABLETS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too many **RANOZYP TABLETS** the most common signs are fast heart beat, agitation/ aggression, difficulty speaking, uncontrollable movements and reduced level of consciousness ranging from sedation to coma.

Other symptoms may be: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart

While you are taking RANOZYP TABLETS

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RANOZYP TABLETS.

Tell all doctors, dentists and pharmacists who are treating you that you are taking RANOZYP TABLETS.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

- Your doctor should monitor your weight while you are taking **RANOZYP TABLETS**.
- Patients with diabetes or who have a higher chance of developing diabetes should have their blood sugar checked often.
- **RANOZYP TABLETS** may alter the lipid profile, if you are on **RANOZYP TABLETS** your doctor will monitor your lipid profile from time to time
- If you are over 65 years of age, your doctor may measure your blood pressure from time to time.

Talk to your doctor or mental health professional if you have thoughts or talk about death or suicide; or thoughts or talk about self-harm or doing harm to others.

These may be signs of changes or worsening in your mental illness.

Things you must not do

Do not stop taking **RANOZYP TABLETS** abruptly. This may lead to sweating, difficulty in sleeping, tremor, nervousness, feeling sick (nausea) or being sick (vomiting). Your doctor may suggest you to reduce the dose gradually before stopping treatment.

Do not give RANOZYP TABLETS to anyone else even if their symptoms seem similar or they have the same condition as you.

Your doctor has prescribed **RANOZYP TABLETS** for you and your condition.

Things to be careful of

Be careful when drinking alcohol while taking RANOZYP TABLETS.

The effects of alcohol could be made worse while taking **RANOZYP TABLETS**.

Your doctor may suggest you avoid alcohol while you are being treated with **RANOZYP TABLETS**.

If **RANOZYP TABLETS** makes you feel lightheaded, dizzy or faint, be careful when getting up from a sitting or lying position. Getting up slowly may help. This effect may increase if you are concomitantly using diazepam (medicine used to treat anxiety) or alcohol.

Be careful while driving or operating machinery

There is a risk of feeling drowsy or dizzy when you are given **RANOZYP TABLETS**. If this happens do not drive or operate any tools or machines. Tell your doctor.

Side Effects

Like other medicines, RANOZYP TABLETS may cause some unwanted side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Serious side effects

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following

- Sudden signs of an allergic reaction such as a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.
- Very rare: Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver

enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia).

- Very high levels of blood sugar which may lead to excessive thirst, being sick (vomiting), breathing difficulty, confusion and unconsciousness (diabetic ketoacidosis or coma).
- Sudden increase in body temperature, sweating, fast heart beat, muscle stiffness, high blood pressure and convulsions
- Abnormal rhythms of the heart
- Suicide attempt
- Uncontrollable muscle spasms
- Worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to the arms and legs
- Trembling, rigid posture, slow movements and a shuffling, unbalanced walk (Parkinsonism)
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers, bleeding or bruising more easily than normal
- fits
- Reaction following abrupt discontinuation (profuse sweating, nausea or vomiting)
- liver disease appearing as yellowing of the skin and white parts of the eyes
- Severe upper stomach pain often with nausea and vomiting (inflammation of the pancreas)
- Temporary paralysis or weakness of muscles
- Blood clots in the veins especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.

Sudden death due to cardiac disorder has also been reported.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Weight gain
- Sleepiness
- Feeling more hungry, constipation, dry mouth, increased thirst, indigestion

- Water retention leading to swelling of the hands, ankles or feet
- Dizziness, restlessness
- Unusual tiredness or weakness
- Dizziness on standing up, especially when getting up from a sitting or lying position
- Sensitivity to sunlight
- Unusual hair loss or thinning
- Change in body temperature
- Difficulty in initiating urination, involuntary passing of urine
- Prolonged and/or painful erection
- Loss of memory
- Feeling of extreme happiness
- Painful menstrual periods, absence of menstrual periods
- Vaginal infection
- Lack of emotion or feeling;
- Speech disorder
- Confusion, incoordination
- Increased blood pressure
- Unusual behaviour
- Back pain, chest pain, pain in the legs and hands, joint pain
- Abnormal vision
- Nose bleeding
- Cough, difficulty in breathing
- Sore throat and discomfort when swallowing
- Increased salivation
- Acne, dry skin, rash
- Nasal dripping
- feeling of tension or fullness in the nose
- Tingling or numbness of the hands or feet (paraesthesia)
- Accidental injury
- Purple discoloration of the skin

Additional side effects reported in older patients include stroke, pneumonia, , falls and visual hallucinations, .

Effect on laboratory tests

- Increase in prolactin levels
- Changes in the levels of some blood cells and circulating fats
- Increase in the levels of glucose in blood and urine
- Abnormal total bilirubin levels (liver test)
- Elevated liver enzymes

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected

with this medicine and are not referred to in this leaflet.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of RANOZYP TABLETS

Storage

Store Below 30°C, protected from moisture

Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product description

What RANOZYP TABLETS looks like

For 5 mg strength: Light Yellow to Yellow coloured, round, biconvex tablets debossed with 'O5' on one side and plain on other side.

For 10 mg strength: Light Yellow to Yellow coloured, round, biconvex tablets debossed with 'O7' on one side and plain on other side.

Ingredients**Active ingredient:**

Ranozyp Tablets 5 mg

Each tablet contains:

Olanzapine.....5 mg

Ranozyp Tablets 10 mg

Each tablet contains:

Olanzapine.....10 mg

Inactive ingredients:**RANOZYP TABLETS contains:**

Lactose anhydrous (Pharmatose DCL 21)

Microcrystalline Cellulose (PH 112)

L-Hydroxy propyl cellulose (LH 21)

Magnesium Stearate (Veg)

MAL No.

10 mg: MAL14035011AZ

5 mg: MAL14035010AZ

Manufacturer

SUN PHARMACEUTICAL INDUSTRIES LIMITED

Paonta Sahib, Dist. Sirmour,
Himachal Pradesh – 173 025

Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

Lot 23, Bakar Arang Industrial Estate,
08000 Sungai Petani, Kedah

Date of Revision:

October 2018