

TORQUITE TABLETS

Quetiapine Fumarate (25 mg, 300 mg)

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What Torquite is used for

Torquite can be used to treat several illnesses, such as:

- Bipolar depression: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Schizophrenia: where you may hear or feel things that do not there, believe in things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.

Your doctor may continue to prescribe Torquite even when you are feeling better.

How Torquite works

Torquite contains a medicine called quetiapine. This belongs to a group of medicines called antipsychotics. Torquite helps to correct chemical imbalances in the brain.

Before you use Torquite

- When you must not use it

- If you are allergic (hypersensitive) to quetiapine or any of the other ingredients of Torquite (see Section 8: Further information).
- If you are taking any of the following medicines:
 - Some medicines for HIV.
 - Azole medicines (for fungal infections).
 - Erythromycin or clarithromycin (for infections).
 - Nefazodone (for depression).

Do not take Torquite if the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Torquite.

Pregnancy and lactation

Do not take Torquite if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Torquite, stop taking it immediately and contact your doctor.

Do not take Torquite until you and your doctor have discussed the risks and benefits involved.

The following extrapyramidal and/or withdrawal symptoms may occur in newborn babies, of mothers that have used Torquite in the last trimester (last three months of their pregnancy):

- Agitation.
- Muscle stiffness and/or weakness.
- Shaking.
- Sleepiness.
- Breathing problems.
- Difficulty in feeding.

If your baby develops any of these symptoms you may need to contact your doctor.

Do not take Torquite if you are breast-feeding. This is because small amounts of Torquite may pass into the mother's milk. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Before you take your medicine, tell your doctors if:

- You, or someone in your family, have or have had any heart problems, for example heart rhythm problems, weakening of the heart muscle or inflammation of the heart or if you are taking any medicines that may have an impact on the way your heart beats.
- You have low blood pressure.
- You have had a stroke, especially if you are elderly.
- You have problems with your liver.
- You have ever had a fit (seizure).
- You have diabetes or have a risk of getting diabetes. If you do, your doctor may check your blood sugar levels while you are taking Torquite.

- You know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- You are an elderly person with dementia (loss of brain function). If you are, Torquite should not be taken because the group of medicines that Quetiapine belongs to may increase the risk of stroke or in some cases the risk of death, in elderly people with dementia.
- You or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

Tell your doctor immediately if you experience:

- A combination of fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome"). Immediate medical treatment may be needed.
- Uncontrollable movements, mainly of your face or tongue.
- Dizziness or a severe sense of feeling sleepy. This could increase the risk of accidental injury (fall) in elderly patients.
- Fits (seizures).
- A long-lasting and painful erection (Priapism).

These conditions can be caused by this type of medicine.

Tell your doctor as soon as possible if you have:

- A fever, flu-like symptoms, sore throat, or any other infection, as this could be a result of a very low white blood cell count, which may require Torquite to be stopped and/or treatment to be given.
- Constipation along with persistent abdominal pain, or constipation which has not responded to treatment, as this may lead to a more serious blockage of the bowel.

Tell your doctor if you are lactose intolerant because Torquite contains lactose.

Talk to your doctor or pharmacist if you:

- Have or are at risk of having diabetes (e.g. being overweight or

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a family history of diabetes). Your doctor should check your blood sugar before you start taking Torquite and regularly during treatment.

- Taking other medicines

Do not take Torquite if you are taking any of the following medicines:

- Some medicines for HIV.
- Azole medicines (for fungal infections).
- Erythromycin or clarithromycin (for infections).
- Nefazodone (for depression).

Tell your doctor if you are taking any of the following medicines:

- Epilepsy medicines (like phenytoin or carbamazepine).
- High blood pressure medicines.
- Barbiturates (for difficulty sleeping).
- Thioridazine or lithium (other anti-psychotic medicines).
- Medicines that have an impact on the way your heart beats, for example, drugs that can cause an imbalance in electrolytes (low levels of potassium or magnesium) such as diuretics (water pills) or certain antibiotics (drugs to treat infections).
- Medicines that can cause constipation.

Before you stop taking any of your medicines, please talk to your doctor first.

How to use Torquite

- How much to use

- Always take Torquite exactly as your doctor has told you.
- You should check with your doctor or pharmacist if you are not sure.
- Your doctor will decide on your starting dose and may gradually increase it.
- Torquite can be taken with or without food.
- Torquite should generally be administered with an initial dose of 25 mg two times a day, with increases in increments of 25-50 mg two times a day or three times a day on the second and third day, as tolerated, to a target dose range of 300 to 400 mg daily by the fourth day, given two times a day or three times a day. Further dosage

adjustments if indicated, should generally occur at Intervals of not less than 2 days, as steady state for Torquite would not be achieved for approximately 1 - 2 days in the typical patient when dosage adjustments are necessary, dose increments/decrements of 25 - 50 mg two times a day are recommended.

- When to use it

- Swallow your tablets whole with a drink of water.
- Do not split, chew or crush the tablets.
- Do not stop taking your tablets even if you feel better, unless your doctor tells you.

- How long to use it

Continue taking Torquite for as long as your doctor recommends.

If you suddenly stop taking Torquite you may feel nauseous or vomit, or be unable to sleep or have jerky movements, or your original illness might come back. Your doctor may suggest you reduce the dose gradually before stopping treatment.

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

- If you forget to use it

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you take more Torquite than prescribed by your doctor, you may feel sleepy, feel faint or dizzy and decrease in blood pressure. Contact your doctor or nearest hospital straight away. Take the Torquite tablets with you.

While you are using it

- Things you must do

- Take Torquite at about the same time each day.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Torquite.

- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking your medicine unless your doctor tells you to.
- Do not take any new medicines without consulting your doctor.
- Do not give Torquite to anyone else, even if they have the same symptoms or condition as you.
- Do not drink grapefruit juice while you are taking Torquite. It can affect the way the medicine works.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablet make you feel sleepy, do not drive or use machines and contact your doctor immediately.

Alcohol Consumption

Be careful how much alcohol you drink. This is because the combined effect of Torquite and alcohol can make you sleepy.

Side effects

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

Very common:

- Dizziness (may lead to falls).
- Headache.
- Dry mouth.
- Feeling sleepy (this may go away with time, as you keep taking Torquite) (may lead to falls).
- Discontinuation symptoms (symptoms which occur when you stop taking Torquite) include:
 - Not being able to sleep (insomnia).
 - Nausea.
 - Headache.
 - Diarrhea.
 - Vomiting.
 - Dizziness.
 - Irritability.

Gradual withdrawal over a period of at least 1 to 2 weeks is advisable.

- Putting on weight.
- Abnormal muscle movements. These include:

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- Difficulty starting muscle movements.
- Shaking.
- Feeling restless or muscle stiffness without pain.
- Changes in the amount of certain fats (triglycerides and total cholesterol).

Common:

- Rapid heartbeat feeling like your heart is pounding, racing or has skipped beats.
- Constipation, indigestion.
- Feeling weak.
- Swelling of arms or legs.
- Low blood pressure when standing up. This may make you feel dizzy or faint (may lead to falls).
- Increased levels of sugar in the blood.
- Blurred vision.
- Abnormal dreams and nightmares.
- Feeling more hungry.
- Feeling irritated.
- Disturbance in speech and language.
- Thoughts of suicide and worsening of your depression.
- Shortness of breath.
- Vomiting (mainly in the elderly).
- Fever.
- Changes in the amount of thyroid hormones in your blood.
- Decreases in the number of certain types of blood cells.
- Increases in the amount of liver enzymes measured in the blood.
- Increases in the amount of the hormone prolactin in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
 - Men and women to have swelling breasts and unexpectedly produce breast milk.
 - Women to have no monthly periods or irregular periods.

Side effects in children and adolescents:

The same side effects that may occur in adults may also occur in children and adolescents.

The following side effects have been seen more often in children and adolescents or have not been seen in adults:

Very Common side effects:

- Increase in the amount of a hormone called prolactin, in the blood. Increases in the hormone prolactin could in rare cases lead to the following:
 - Boys and girls to have swelling of breasts and unexpectedly produce breast milk.
 - Girls to have no monthly period or irregular periods.
- Increased appetite.
- Vomiting.
- Abnormal muscle movements. These include difficulty starting muscle movements, shaking, feeling restless or muscle stiffness without pain.
- Increase in blood pressure.

Common side effects:

- Feeling weak, fainting (may lead to falls).
- Stuffy nose.
- Feeling irritated.

You should seek immediate medical advice.

Talk to your doctor or pharmacist if you experience:

- Increase in blood sugar level and / or symptoms of high blood sugar (e.g. increased thirst, increased hunger and frequent urination).
- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome).
- Trouble breathing during sleep (sleep apnoea).
- Difficulty or inability to pass urine (urinary retention).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

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.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Torquite

- Storage

- Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

TORQUITE TABLETS 25 MG

Brownish red coloured, round, biconvex, film coated tablets plain on both sides.

TORQUITE TABLETS 300 MG

White to off white, capsule shaped, biconvex, film coated tablets with break line on both sides.

- Ingredients

Active ingredient:

- Quetiapine Fumarate.

Inactive ingredients:

- Calcium Hydrogen Phosphate Dihydrate.
- Microcrystalline Cellulose.
- Lactose Monohydrate.
- Sodium Starch Glycolate (Type-A).
- Povidone (K-30).
- Purified Water.
- Colloidal silicone dioxide.
- Magnesium Stearate.
- Hypromellose 2910 (6cps).
- Polyethylene Glycol 400.
- Titanium Dioxide.
- Ferric Oxide Yellow (*For Torquite Tablets 25 mg only*).
- Ferric Oxide Red (*For Torquite Tablets 25 mg only*).

- MAL number(s):

TORQUITE 25MG TABLETS

MAL18016052AZ

TORQUITE 300 MG TABLETS

MAL18016049AZ

Manufacturer

Torrent Pharmaceuticals Limited
Indrad 382 721, Tal: Kadi,
City: Indrad, Dist. Mehsana,

TORQUITE TABLETS

Quetiapine Fumarate (25 mg, 300 mg)

India

Product Registration Holder

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