

TORQUITE SR TABLETS

Quetiapine Fumarate 200mg

What is in this leaflet

1. What is Torquite SR used for
2. How Torquite SR works
3. Before you use Torquite SR
4. How to use Torquite SR
5. While you are using it
6. Side effects
7. Storage and Disposal of Torquite SR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Torquite SR is used for

Torquite SR contains a medicine called quetiapine.

Torquite SR can be used to treat conditions such as:

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

When Torquite SR is being taken to treat major depressive episodes in major depressive disorder, it will be taken in addition to another drug being used to treat this illness.

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

How Torquite SR works

Torquite SR contains a medicine called quetiapine. This belongs to a group of medicines called antipsychotics.

Torquite SR helps to correct chemical imbalances in the brain.

Before you use Torquite SR

- When you must not use it

- If you are allergic (hypersensitive) to quetiapine or any of the other ingredients of Torquite SR.
- If you are taking any of the following medicines:
 - Protease inhibitors, such as nelfinavir (for HIV infection).
 - Azole medicines (for fungal infections).
 - Medicines for an infection (like erythromycin or clarithromycin).
 - Nefazodone (for depression).

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

Pregnancy and lactation

Do not take Torquite SR if you are pregnant or plan to become pregnant or think you might be pregnant.

Do not take Torquite SR if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Before you take your medicine, tell your doctor if:

- You, or someone in your family, have or have had any heart problems such as a very fast heart beat or prolonged QT on an ECG (heart tracing), 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 problems with your liver.
- You have ever had a fit (seizure).
- 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 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 SR
- You are an elderly person with dementia. If you are, Torquite SR should not be taken because the group of medicines that Torquite SR 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 feeling very drowsy.
- This could increase the risk of accidental injury (fall) in elderly patients.

These conditions can be caused by this type of medicine.

- Thoughts of suicide and worsening of your depression.
- If you are depressed you may sometimes have thoughts of harming or killing yourself.
- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.
- Weight gain has been seen in patients taking Torquite SR. You and your doctor should check your weight regularly.
- Tell your doctor if you are lactose intolerant because Torquite SR contains lactose.

Talk to your doctor or pharmacist if you:

- Have or are at risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking Torquite SR and regularly during treatment.

- Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines because it may affect the way the medicines work. This includes medicines obtained without a prescription and herbal medicines.

TORQUITE SR TABLETS

Quetiapine Fumarate (200mg)

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

- Epilepsy medicines (like phenytoin or carbamazepine).
- Rifampicin (for tuberculosis).
- Thioridazine (another anti-psychotic medicine).
- Medicines that affect the heart, for example, drugs that can cause an imbalance in some of the chemicals in your blood such as diuretics (water pills) or certain antibiotics.

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

If you have a urine drug screen, taking Torquite SR could cause positive results for methadone or drugs for depression called tricyclic antidepressants (TCAs), even though you may not be taking methadone or TCAs. The result will need to be confirmed by a more specific test.

How to use Torquite SR

- How much to use

Always take Torquite SR 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.

For the treatment of schizophrenia and moderate to severe manic episodes associated with bipolar disorder:

The daily dose at the start of therapy is 300 mg on Day 1 and 600 mg on Day 2. The recommended daily dose is 600 mg.

For the treatment of depressive episodes associated with bipolar disorder:

Quetiapine should be administered once daily at bedtime. The total daily dose for the first four days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4). The recommended daily dose is 300 mg.

For preventing recurrence in bipolar disorder:

The dose may be adjusted depending on clinical response and tolerability of the individual patient within the dose range of 300 mg to 800 mg/day.

- When to use it

- You will take your tablets once a day.
- 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 SR for as long as your doctor recommends.

If you suddenly stop taking Torquite SR 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 this product, 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 SR 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 SR tablets with you.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Torquite SR.
- 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 SR to anyone else, even if they have the same symptoms or condition as you.
- Do not drink grapefruit juice while you are taking Torquite SR. 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 dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

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

Side effects

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

If any of the following happens, stop taking Torquite SR and contact a doctor or go to the nearest hospital straight away, as you may need urgent medical attention:

- Somnolence.
- Dizziness.
- Dry mouth.
- Mild weakness.
- Constipation.
- Fast heart rate (tachycardia).
- Orthostatic hypotension (occurs when a person's blood pressure falls when suddenly standing up from a lying or sitting).
- Indigestion (dyspepsia).
- Weight gain.
- Syncope.
- Neuroleptic malignant syndrome.
- Decrease in the number of white blood cells (leukocytes) found in the blood (leucopenia).
- Abnormally low level of neutrophils which are type of white blood cells (neutropenia).
- Accumulation of fluid causing swelling in tissues usually in the lower limbs.

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

TORQUITE SR TABLETS

Quetiapine Fumarate (200mg)

The following side effect has been seen only in children and adolescents:

- Increase in blood pressure.
- 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.

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 calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Torquite SR

- Storage

- Store below 30°C.
- Keep medicines out of reach of children.

- 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 SR 200 MG TABLETS

Yellow coloured, capsule shaped biconvex film coated tablets, printed with '243'.

- Ingredients

Active ingredient

- Quetiapine Fumarate.

Inactive ingredients

- Lactose Monohydrate.
- Microcrystalline Cellulose (Avicel pH 101).
- Magnesium Oxide light compacted.
- Carrageenan Lambda (Viscarin PH 209).
- Povidone (K-30).
- Methylene Chloride (does not exist in finished product).
- Magnesium Stearate.
- Titanium Dioxide.
- Ferric Oxide Yellow.
- Polyethylene Glycol 400.
- Isopropyl Alcohol (does not exist in finished product).
- Purified Water (does not exist in finished product).

- MAL number:

TORQUITE SR 200 MG TABLETS

MAL17107010AZ

Manufacturer

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

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn. Bhd.
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara Mont Kiara,
50480 Kuala Lumpur,
Malaysia.

Date of revision

10/04/2019

Serial Number

NPRA(R2/1)190403/102