

PACKAGE LEAFLET: INFORMATION FOR THE USER

TORENDQ Q-TAB

1mg orodispersible tablets

RISPERIDONE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TORENDQ Q-TAB is and what it is used for
2. Before you take TORENDQ Q-TAB
3. How to take TORENDQ Q-TAB
4. Possible side effects
5. How to store TORENDQ Q-TAB

1. WHAT TORENDQ Q-TAB IS AND WHAT IS IT USED FOR

TORENDQ Q-TAB belongs to a group of medicines called 'anti-psychotics'.

TORENDQ Q-TAB is used to treat the following:

- Schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, or confused
- Mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called "bipolar disorder"
- Short-term treatment (up to 6 weeks) of long-term aggression in people with Alzheimer's dementia, who harm themselves or others. Alternative (non-drug) treatments should have been used previously
- Short-term treatment (up to 6 weeks) of long-term, aggression in intellectually disabled children (at least 5 years of age) and adolescents with conduct disorder.

2. BEFORE YOU TAKE TORENDQ Q-TAB

Do not take TORENDQ Q-TAB if

- You are allergic (hypersensitive) to risperidone or any of the other ingredients of TORENDQ Q-TAB.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using TORENDQ Q-TAB.

Take special care with TORENDQ Q-TAB

Check with your doctor or pharmacist before taking TORENDQ Q-TAB if:

- You have a heart problem. Examples include an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. TORENDQ Q-TAB may cause low blood pressure. Your dose may need to be adjusted
- You know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain
- You have Parkinson's disease or dementia
- You are diabetic
- You have epilepsy
- You are a man and you have ever had a prolonged or painful erection. If you experience this while taking TORENDQ Q-TAB, contact your doctor straight away
- You have problems controlling your body temperature or overheating
- You have kidney problems
- You have liver problems
- You have an abnormally high level of the hormone prolactin in your blood or if you have a tumour, which is possibly dependent on prolactin.
- 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

- involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of TORENDQ Q-TAB may be needed
- fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome). Immediate medical treatment may be needed.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using TORENDQ Q-TAB.

TORENDQ Q-TAB may cause you to gain weight.

Elderly people with dementia

In elderly patients with dementia, there is an increased risk of stroke. You should not take TORENDQ Q-TAB if you have dementia caused by stroke.

During treatment with TORENDQ Q-TAB you should frequently see your doctor.

Medical treatment should be sought straight away if you or your care-giver notice a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke.

Children and adolescents

Before treatment is started in conduct disorder, other causes of aggressive behaviour should have been ruled out.

If during treatment with TORENDQ Q-TAB tiredness occurs, a change in the time of administration might improve attention difficulties.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines.

It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- Medicines that work on your brain such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as TORENDQ Q-TAB may increase the sedative effect of all of these
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems (such as quinidine), allergies (anti-histamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heart beat
- Medicines that cause low blood potassium (e.g. certain diuretics)
- Medicines to treat elevated blood pressure. TORENDQ Q-TAB can lower blood pressure
- Medicines for Parkinson's disease (such as levodopa)
- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build up of too much fluid (such as furosemide or chlorothiazide). TORENDQ Q-TAB taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

The following medicines may reduce the effect of TORENDQ Q-TAB

- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin (medicines for epilepsy)
- Phenobarbital

If you start or stop taking such medicines you may need a different dose of TORENDQ Q-TAB.

The following medicines may increase the effect of TORENDQ Q-TAB

- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants
- Medicines known as beta blockers (used to treat high blood pressure)
- Phenothiazines (e.g. used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)

If you start or stop taking such medicines you may need a different dose of TORENDQ Q-TAB.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using TORENDQ Q-TAB.

Taking TORENDQ Q-TAB with food and drink

You can take this medicine with or without food. You should avoid drinking alcohol when taking TORENDQ Q-TAB.

Pregnancy and breast-feeding

- Talk to your doctor before using TORENDQ Q-TAB if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will decide if you can take it
- Shaking, muscle stiffness and problems feeding, all of which are reversible, have been seen in newborn babies when TORENDQ Q-TAB was used during the last trimester of pregnancy.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Dizziness, tiredness, and vision problems may occur during treatment with TORENDQ Q-TAB. Do not drive or use any tools or machines without talking to your doctor first.

3. HOW TO TAKE TORENDQ Q-TAB

How much to take
For the treatment of schizophrenia

Adults

- The usual starting dose is 2 mg per day, this may be increased to 4 mg per day on the second day
- Your dose may then be adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with daily doses of 4 to 6 mg
- This total daily dose can be divided into either one or two doses a day. Your doctor will tell you which is the best for you.

Elderly people

- Your starting dose will normally be 0.5 mg twice a day
- Your dose may then be gradually increased by your doctor to 1 mg to 2 mg twice a day
- Your doctor will tell you which is the best for you.

Children and adolescents

- Children and adolescents under 18 years old should not be treated with TORENDO Q-TAB for schizophrenia.

For the treatment of mania

Adults

- Your starting dose will usually be 2 mg once a day
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with doses of 1 to 6 mg once a day.

Elderly people

- Your starting dose will usually be 0.5 mg twice a day
- Your dose may then be gradually adjusted by your doctor to 1 mg to 2 mg twice a day depending on how much you respond to the treatment.

Children and adolescents

- Children and adolescents under 18 years old should not be treated with TORENDO Q-TAB for bipolar mania.

For the treatment of long-standing aggression in people with Alzheimer's dementia

Adults (including elderly people)

- Your starting dose will normally be 0.25 mg twice a day
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment
- Most people feel better with 0.5 mg twice a day. Some patients may need 1 mg twice a day
- Treatment duration in patients with Alzheimer's dementia should be not more than 6 weeks.

For the treatment of conduct disorder in children and adolescents

The dose will depend on your child's weight: For children who weigh less than 50 kg

- The starting dose will normally be 0.25 mg once a day
- The dose may be increased every other day in steps of 0.25 mg per day.
- The usual maintenance dose is 0.25 mg to 0.75 mg once a day. For children who weigh 50 kg or more
- The starting dose will normally be 0.5 mg once a day

- The dose may be increased every other day in steps of 0.5 mg per day.
- The usual maintenance dose is 0.5 mg to 1.5 mg once a day.

Treatment duration in patients with conduct disorder should be not more than 6 weeks. Children under 5 years old should not be treated with TORENDQ Q-TAB for conduct disorder. **People with kidney or liver problems** Regardless of the disease to be treated, all starting doses and following doses of TORENDQ Q-TAB should be halved. Dose increases should be slower in these patients.

TORENDQ Q-TAB should be used with caution in this patient group.

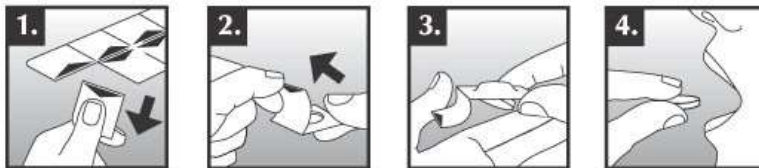
How to take TORENDQ Q-TAB

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

Your doctor will tell you how much medicine to take and for how long. This will depend on your condition and varies from person to person. The amount of medicine you should take is explained under the 'How much to take' sub-heading below.

TORENDQ Q-TAB orodispersible tablets are fragile. They should not be pushed through the foil in the blister pack as this will cause damage to the tablet. Remove a tablet from the package as follows:

1. Hold the blister at the edges and separate one blister cell from the rest of the blister by gently tearing along the perforations around it.
2. Pull up the edge of the foil and peel foil off completely.
3. Tip the tablet out onto your hand.
4. Put the tablet on the tongue as soon as it is removed from the packaging.



In a few seconds it begins disintegrating in the mouth and subsequently can be swallowed with or without water. The mouth should be empty before placing the tablet on the tongue.

If you take more TORENDQ Q-TAB than you should

- See a doctor right away. Take the medicine pack with you
- In case of overdose you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heart beats or fits.

If you forget to take TORENDQ Q-TAB

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor
- **Do not take a double dose (two doses at the same time) to make up for a forgotten dose**

If you stop taking TORENDQ Q-TAB

You should not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medicine, your dose may be decreased gradually over a few days. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TORENDO Q-TAB can cause side effects, although not everybody gets them. Very common: affects more than 1 user in 10

Common: affects 1 to 10 users in 100

Uncommon: affects 1 to 10 users in 1,000

Rare: affects 1 to 10 users in 10,000

Very rare: affects less than 1 user in 10,000

Not known: frequency cannot be estimated from the available data.

The following side effects may happen:

Very Common (affects more than 1 user in 10):

- Parkinsonism. This is a medical term that includes many symptoms. Each individual symptom may occur less frequently than in 1 in 10 people. Parkinsonism includes: increase in saliva secretion or watery mouth, musculoskeletal stiffness, drooling, jerks when bending the limbs, slow, reduced or impaired body movements, no expression on the face, muscle tightness, stiff neck, muscle stiffness, small, shuffling, hurried steps and lack of normal arm movements when walking, persistent blinking in response to tapping of the forehead (an abnormal reflex)
- Headache, difficulty falling or staying asleep.

Common (affects 1 to 10 users in 100):

- Drowsiness, fatigue, restlessness, inability to sit still, irritability, anxiety, sleepiness, dizziness, poor attention, feeling exhausted, sleep disorder
- Vomiting, diarrhoea, constipation, nausea, increased appetite, abdominal pain or discomfort, sore throat, dry mouth
- Weight increased, increase in body temperature, decreased appetite
- Difficulty breathing, lung infection (pneumonia), flu, infection of the breathing passages, blurred vision, nose congestion, nose bleeding, cough
- Urinary tract infection, bed wetting
- Muscle spasm, involuntary movements of face or arms and legs, joint pain, back pain, swelling of arms and legs, pain in arms and legs
- Rash, skin redness
- Fast beating heart, chest pain
- Blood prolactin hormone level increased.

Uncommon (affects 1 to 10 users in 1000):

- Excessive drinking of water, stool incontinence, thirsty, very hard faeces, hoarseness or voice disorder
- Lung infection caused by inhaling of food into the breathing passages, bladder infection, 'pink eye', sinus infection, viral infection, ear infection, tonsil infection, infection under the skin, eye infection, stomach infection, eye discharge, yeast infection of nails
- Abnormal electrical conduction of the heart, drop in blood pressure after standing, low blood pressure, feeling dizzy after changing body position, abnormal electric activity tracing of the heart (ECG), abnormal heart rhythm, awareness of heart beating, heart rate increased or decreased
- Urinary incontinence, pain when passing urine, frequent passing of urine
- Confused, disturbance in attention, low level of consciousness, excessive sleep, nervousness, elated mood (mania), lack of energy and interest
- Blood sugar increased, liver enzymes increased, white blood cell count decreased, low haemoglobin or red blood cell count (anaemia), increase in eosinophils (special white blood cells), blood creatinine phosphokinase increased, decrease in platelets (blood cells that help you stop bleeding)
- Muscle weakness, muscle pain, ear pain, neck pain, joint swelling, abnormal posture, joint stiffness, musculoskeletal chest pain, chest discomfort
- Skin lesion, skin disorder, dry skin, intense itching of skin, acne, hair loss, skin inflammation caused by mites, skin discoloration, thickening of skin, flushing, reduced skin sensitivity to pain or touch, inflammation of oily skin

- No menstruation, sexual dysfunction, erectile dysfunction, ejaculation disorder, breast discharge, enlargement of breast in men, decreased sexual drive, irregular menstruation, vaginal discharge
- Fainting, gait disturbance, sluggishness, decreased appetite resulting in malnutrition and low body weight, feeling 'out of sorts', balance disorder, allergy, edema, speech disorder, chills, abnormal coordination
- Painful oversensitivity to light, increased blood flow to the eye, eye swelling, dry eye, increase in tears
- Breathing passage disorder, lung congestion, crackly lung noise, congestion of breathing passages, trouble speaking, difficulty swallowing, cough with sputum, coarse/whistling sound during breathing, flu-like illness, sinus congestion
- Unresponsive to stimuli, loss of consciousness, sudden swelling of lips and eyes along with difficulty breathing, sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech that last for less than 24 hours (these are called mini-strokes or strokes), involuntary movements of face, arms, or legs, ringing in ears, face edema.

Rare (affects 1 to 10 users in 10,000):

- Inability to reach orgasm, menstrual disorder
- Dandruff
- Drug allergy, coldness in arms and legs, lip swelling, lip inflammation
- Glaucoma, reduced visual clarity, eyelid margin crusting, eye rolling
- Lack of emotion
- Change in consciousness with increased body temperature and twitching of muscles, edema all over the body, drug withdrawal syndrome, body temperature decreased
- Fast shallow breathing, trouble breathing during sleep, chronic otitis media
- Obstruction of intestine,
- Reduced blood flow to the brain
- Decrease in white blood cells, inappropriate secretion of a hormone that controls urine volume
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis), movement disorder
- Coma due to uncontrolled diabetes
- Yellowing of the skin and the eyes (jaundice)
- Inflammation of the pancreas.

Very rare (affects less than 1 user in 10,000):

- Life threatening complications of uncontrolled diabetes.

Unknown frequency of occurrence (frequency cannot be estimated from the available data):

- Severe allergic reaction resulting in difficulty in breathing and shock
- No granulocytes (a type of white blood cell to help you against infection)
- Prolonged and painful erection
- Dangerously excessive intake of water.
- 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. If you notice any of these symptoms seek medical advice immediately.

Long-acting injectable TORENDO Q-TAB formulation

The following side effects have been reported with the use of long-acting injectable TORENDO Q-TAB formulation. Even if you are not being treated with long acting injections of TORENDO Q-TAB but you experience any of the following, talk to your doctor.

- Infection of the intestine
- Abscess under the skin, tingling pricking or numbness of skin, inflammation of the skin
- Decrease in white blood cell counts that helps to protect you against bacterial infection
- Depression
- Convulsion
- Eye blinking

- Sensation of spinning or swaying
- Slow beating heart, high blood pressure
- Toothache, tongue spasm
- Buttock pain
- Weight decreased.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE TORENDO Q-TAB

Keep out of the reach and sight of children.

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

This medicinal product does not require any special storage conditions.

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.