

Tapentadol 50mg, 100mg, 150mg, 200mg extended- release tablets

Tapentadol

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 (see section 4).

What is in this leaflet:

1. What Tapentadol ER is and what it is used for
2. What you need to know before you take Tapentadol ER
3. How to take Tapentadol ER
4. Possible side effects
5. How to store Tapentadol ER
6. Contents of the pack and other information

1. What Tapentadol ER is and what it is used for

The full name of your medicine is ' Tapentadol ER 50mg , 100mg , 150mg , 200mg extended-release tablets'. It is

referred to as ' Tapentadol ER' in the rest of this leaflet.

Tapentadol - the active substance in Tapentadol ER - is a strong painkiller which belongs to the class of opioids. Tapentadol ER is used in adults for the treatment of severe long-term pain that can only be adequately managed with an opioid painkiller.

2. What you need to know before you take Tapentadol ER

Do not take Tapentadol ER

- if you are allergic to tapentadol or any of the other ingredients of this medicine (listed in section 6)
- if you have asthma or if your breathing is dangerously slow or shallow (respiratory depression, hypercapnia)
- if you have no bowel movement as shown by severe constipation and bloating which may be accompanied by pain or discomfort in the lower stomach
- if you have poisoning with alcohol, sleeping pills, pain relievers or medicines that affect mood and emotions (see 'Other medicines and Tapentadol ER')

Warnings and precautions

Talk to your doctor or pharmacist before taking Tapentadol ER if you:

- have slow or shallow breathing
- suffer from increased pressure in the brain or are not fully conscious
- have had a head injury or brain tumors

- suffer from liver or kidney problems (see 'How to take Tapentadol ER')
- suffer from a pancreatic disease including inflammation of the pancreas (pancreatitis) or disease of the bile duct (biliary tract disease)
- are taking medicines referred to as mixed opioid agonist/antagonists (e.g., pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine)
- have a tendency towards epilepsy or fits or if you are taking other medicines known to increase the risk of seizures because the risk of a fit may increase.
- have a tendency to abuse medicines or if you are dependent on medicines, as Tapentadol ER may lead to addiction. In this case, you should only take these tablets for short periods of time and under strict medical supervision.

Other medicines and Tapentadol ER

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor will tell you which medicines are safe to take with Tapentadol ER.

- The risk of side effects increases if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take Tapentadol ER at the same time. Your doctor will tell you whether Tapentadol ER is suitable for you.
- Concomitant use of Tapentadol ER and sedative medicines such as benzodiazepines or related drugs (certain

sleeping pills or tranquillizers (e.g. barbiturates) or pain relievers such as opioids, morphine and codeine (also as cough medicine), antipsychotics, H1-antihistamines, alcohol) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Tapentadol ER together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

- If you are taking a type of medicine that affects serotonin levels (e.g. certain medicines to treat depression), speak to your doctor before taking Tapentadol ER as there have been cases of "serotonin syndrome". Serotonin syndrome is a rare, but life-threatening condition. The signs include involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension and body temperature above 38°C. Your doctor can advise you on this.
- Tapentadol ER may not work as well if taken with opioid like medicines (e.g. those containing pentazocine,

nalbuphine or buprenorphine). Tell your doctor if you are currently being treated with one of these medicines.

- Taking Tapentadol ER with products (e.g. rifampicin, phenobarbital or St John's Wort) that affect the enzymes required to remove Tapentadol ER from the body, may affect how well Tapentadol ER works or may cause side effects. The effects may occur especially when the other medication is started or stopped.
- Tapentadol ER should not be taken together with monoamine oxidase inhibitors (MAOIs - certain medicines for the treatment of depression). Tell your doctor if you are taking MAO inhibitors or have taken these during the last 14 days.

Please keep your doctor informed about all medicines you are taking.

Taking Tapentadol ER with food, drink and alcohol

Do not drink alcohol whilst you are taking Tapentadol ER, because some side effects such as drowsiness may be increased. You can take Tapentadol ER with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Tapentadol ER:

- if you are pregnant, unless your doctor has instructed you to do so

- if you become pregnant during treatment with Tapentadol ER. Check with your doctor.
- during childbirth, as it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn
- if you are breast-feeding, as it may pass into the breast milk.

Driving and using machines

If you feel drowsy, dizzy, have blurred vision or a slow reaction time whilst taking Tapentadol ER, then do not drive, use tools or machinery.

Any such effects are more likely to occur when you start taking Tapentadol ER, when the dose of Tapentadol ER is changed, or when you drink alcohol or take tranquilizers.

Please ask your doctor before driving a car or using machinery.

Tapentadol ER contains lactose.

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to take Tapentadol ER

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will change the dose and time between doses of Tapentadol ER according to your pain level and your needs. Generally, the lowest pain-relieving dose should be taken.

Adults

The usual dose is 1 tablet every 12 hours.

Daily doses of Tapentadol ER greater than 500mg tapentadol are not recommended.

Your doctor may prescribe a different, more appropriate dose or timing of dosing, if this is necessary for you. If you feel that the effect of these tablets is too strong or weak, talk to your doctor or pharmacist.

How and when should you take Tapentadol ER

Tapentadol ER is for oral use.

Swallow the tablets with a glass of water. You may take the tablets either on an empty stomach or with food. Do not chew, break or crush the tablet, as it may result in overdose due to quick release of tapentadol in your body.

The empty shell of the tablet may not be digested completely and thus be seen in stool. This should not worry you, since the drug (active substance) of the tablet has already been absorbed in your body and what you see is just the empty shell.

How long should you take Tapentadol ER

Do not take the tablets for longer than your doctor has told you.

Elderly patients

In elderly patients (above 65 years) usually no dose adjustment is necessary. However, your doctor may adjust your dose or time between doses if required.

Patients with liver or kidney problems (insufficiency)

Do not take Tapentadol ER if you have severe liver or kidney problems.

If you have moderate liver problems, your doctor will adjust your dose or time between doses.

If you have mild liver problems or mild to moderate kidney problems, a dose adjustment is not required.

Children and adolescents

Tapentadol ER is not recommended for children and adolescents below the age of 18 years.

If you take more Tapentadol ER than you should

Taking too much Tapentadol ER may be life-threatening.

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Very high doses of Tapentadol ER may cause the following:

- pin-point pupils in the eyes
- being sick (vomiting)
- drop in blood pressure
- fast heart beat
- altered consciousness, collapse or deep unconsciousness (coma)
- epileptic fits
- dangerously slow or shallow breathing or stopping breathing.

If you forget to take Tapentadol ER

If you forget to take the tablets, your pain is likely to return. Do not take a double dose to make up for a forgotten dose; simply continue taking the tablets as before.

If you stop taking Tapentadol ER

If you interrupt or stop treatment too soon, your pain is likely to return. If you wish to stop treatment, please tell your doctor first before stopping treatment.

Generally there will be no withdrawal effects when treatment is stopped. However, on uncommon occasions, people who have been taking the tablets for some time may feel unwell if they suddenly stop taking them.

Symptoms may be:

- feeling restless, irritable, anxious, weak or sick (nausea), loss of appetite, being sick (vomiting), diarrhoea
- watery eyes, runny nose, increase in size of the pupils in the eyes (dilated pupils)
- difficulty in sleeping, yawning
- sweating, shivering
- muscle or joint pain, backache, abdominal cramps
- increase in blood pressure, breathing or heart rate.

If you experience any of these complaints after stopping Tapentadol ER, please contact your doctor.

Do not stop taking this medicine unless your doctor tells you to. If your doctor wants you to stop taking your tablets, he/she will tell you how to do this. This may include a gradual reduction of the dose.

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

4. Possible side effects

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

Important side effects or symptoms to look out for and what to do if you are affected:

- This medicine may cause allergic reactions including swelling beneath the skin, hives, and in severe cases difficulty breathing, a fall in blood pressure, collapse, or shock (uncommon). Symptoms may be wheeziness, difficulty breathing, swelling of the eyelids, face or lips, or rash or itching, which may cover your whole body.
- Another serious side effect is a condition where you breathe more slowly or weakly than expected (rare). It mostly occurs in elderly and weak patients.

If you are affected by these important side effects contact a doctor immediately.

Other side effects that may occur:

Very common (may affect more than 1 in 10 people)

- feeling sick (nausea)
- constipation
- dizziness, drowsiness, headache.

Common (may affect up to 1 in 10 people)

- decreased appetite, anxiety, being sick (vomiting), diarrhoea, indigestion

- sleep problem, tiredness or exhaustion (fatigue), feeling of weakness, trembling, muscle twitches, shortness of breath
- feeling depressed, nervousness, restlessness, lack of attention
- feeling hot (flushing), increased sweating, feeling of body temperature change, dry areas like nostrils, mouth, lips, eyelids, ears, genitals and anus
- itching, rash
- water retention (oedema).

Uncommon (may affect up to 1 in 100 people)

- weight loss
- low awareness of time, place or identity (disorientation), confusion, excitable (agitated), disturbances in perception, abnormal dreams, forgetfulness, mental impairment
- very happy (euphoria), less consciousness, fainting, sedation, feeling unsteady, difficulty in speaking, numbness
- abnormal sensations of the skin (e.g. tingling, prickling), skin reactions (hives)
- abnormal vision
- faster or slower heart beat, palpitations, low blood pressure
- stomach discomfort, delay in passing urine, passing urine more often than usual
- sexual dysfunction

- drug withdrawal effects (see 'If you stop taking Tapentadol ER')
- feeling strange, irritable.

Rare (may affect up to 1 in 1,000 people)

- addiction
- thinking abnormal, epileptic fits, near fainting, uncoordinated, feeling drunk or relaxed
- delayed emptying of the stomach (impaired gastric emptying).

Unknown

- Delirium

In general, the likelihood of having suicidal thoughts and behaviour is increased in patients suffering from chronic pain. In addition, certain medicines for the treatment of depression (which have an impact on the neurotransmitter system in the brain) may increase this risk, especially at the beginning of treatment. Although tapentadol also affects neurotransmitters, data from human use of tapentadol do not provide evidence for an increased risk.

Reporting of side effects

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

5. How to store Tapentadol ER

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister.

The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Tapentadol ER contains

The **active** ingredient is tapentadol.

Tapentadol ER 50mg extended-release tablet contains 50mg tapentadol (as hydrochloride).

Tapentadol ER 100mg extended-release tablet contains 100mg tapentadol (as hydrochloride).

Tapentadol ER 150mg extended-release tablet contains 150mg tapentadol (as hydrochloride).

Tapentadol ER 200mg extended-release tablet contains 200mg tapentadol (as hydrochloride).

The **other** ingredients are:

- Tablet core: hypromellose, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.
- tablet coat: hypromellose, lactose monohydrate, talc, macrogol, propylene glycol, titanium dioxide.

What Tapentadol ER looks like and contents of the pack

- Tapentadol ER 50mg, 100mg, 150mg, 200mg extended-release tablets

Tapentadol ER are packed in blisters.

7. Manufactured By: Taj Pharmaceuticals Ltd.

at: Plot. No. 220, Mahagujarat
Industrial Estate, At & Post-Moraiya,
Tal-Sanand, Dist- Ahmedabad Gujarat (India)