PACKAGE LEAFLET: INFORMATION FOR THE USER

Tapentadol 50 mg film-coated tablets
Tapentadol 75 mg film-coated tablets
Tapentadol 100 mg film-coated tablets

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

1. WHAT TAPENTADOL IS AND WHAT IT IS USED FOR

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TAPENTADOL

Do not take Tapentadol
- 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 paralysis of the gut.
- If you have acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions) (see "Other medicines and Tapentadol").

Warnings and precautions
Talk to your doctor or pharmacist before taking Tapentadol
- If you have slow or shallow breathing.
- If you suffer from increased pressure in the brain or disturbed consciousness up to coma.
- If you have had a head injury or brain tumors.
- If you suffer from a liver or kidney disease (see "How to take Tapentadol").
- If you suffer from a pancreatic or biliary tract disease, including pancreatitis.
- If you are taking medicines referred to as mixed opioid agonist/antagonists (e.g., pentazocine, nalbuphine) or partial mu-opioid agonists (e.g., buprenorphine).
- If you 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.

Tolerance, dependence and addiction
This medicine contains tapentadol, which is an opioid. It can cause dependence and/or addiction.

This medicine contains tapentadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of tapentadol can also lead to dependence, abuse and addiction which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.
The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to tapentadol if:
- you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- you are a smoker.
- you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking tapentadol, it could be a sign that you have become dependent or addicted:
- You need to take the medicine for longer than advised by your doctor.
- You need to take more than the recommended dose.
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (see section 3, If you stop taking tapentadol).

Sleep-related breathing disorders
Tapentadol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and Tapentadol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 at the same time. Your doctor will tell you whether Tapentadol is suitable for you.

Concomitant use of tapentadol 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 together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening.
Please tell your doctor if you are taking gabapentin or pregabalin or any sedative medicines 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 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 may advise you on this.

Taking tapentadol together with other types of medicines referred to as mixed mu-opioid agonist/antagonists (e.g., pentazocine, nalbuphine) or partial mu-opioid agonists (e.g., buprenorphine) has not been studied. It is possible that tapentadol will not work as well if given together with one of these medicinal products. Tell your doctor in case you are currently treated with one of these medicinal products.

Taking tapentadol together with strong inhibitors or inducers (e.g. rifampicin, phenobarbital, St John's Wort) of certain enzymes that are necessary to eliminate tapentadol from your body, may influence how well tapentadol works or may cause side effects, especially when this other medication is started or stopped. Please keep your doctor informed about all medicines you are taking.

Tapentadol should not be taken together with MAO inhibitors (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.

If you use tapentadol together with the below medicines that have anticholinergic effects the risk of side effects may be increased:
- medicines to treat depression.
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics).
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics);
- muscle relaxants.
- medicines to treat Parkinson's disease.

Tapentadol with food, drink and alcohol
Do not drink alcohol whilst taking Tapentadol, because some side effects such as drowsiness may be increased. Food does not influence the effect of this medicine.

Pregnancy, breast-feeding and fertility
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 these tablets:
- if you are pregnant, unless your doctor has instructed you to do so, if used over prolonged periods during pregnancy, tapentadol may lead to withdrawal symptoms in the newborn baby, which might be life-threatening for the newborn if not recognized and treated by a doctor.
- during childbirth because it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn,
- during breast-feeding, because it may be excreted in the breast milk.

Driving and using machines
Tapentadol may cause drowsiness, dizziness and blurred vision and may impair your reactions. This may especially happen when you start taking Tapentadol, when your doctor changes your dosage or when you drink alcohol or take tranquillizers. Please ask your doctor whether it is permitted to drive a car or use machines.

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected. There is further information for patients who are intending to drive in Great Britain - go to https://www.gov.uk/drug-driving-law.

Tapentadol 50 mg, 75 mg and 100 mg film-coated tablets contain 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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE TAPENTADOL

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

Your doctor will adjust the dosage according to the intensity of your pain and your individual pain sensitivity. In general, the lowest pain-relieving dose should be taken.

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Artwork Specification Item(s): Tapentadol 50, 57 & 100 mg film-coated tablets Size: 155 x 550 mm Software: InDesign CC	**Fonts** Helvetica Neue 9pt (min)	**Colours** Black	**Designed by** **Version** Number: 01 Date: 22 Oct 2025

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using tapentadol when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also "If you stop taking tapentadol" below).

Use in adults
The recommended dose is 1 tablet every 4 to 6 hours. Total daily doses greater than 700 mg tapentadol on the first day of treatment and daily doses greater than 600 mg tapentadol on the following days of treatment are not recommended.
Your doctor may prescribe a different, more appropriate dose or interval of dosing, if this is necessary for you.
If you feel that the effect of these tablets is too strong or too weak, talk to your doctor or pharmacist.

Use in elderly
In elderly patients (above 65 years) usually no dose adjustment is necessary. However, the excretion of tapentadol may be delayed in some patients of this age group. If this applies to you, your doctor may recommend a different dosage regimen.

Use in patients with liver and kidney disease (insufficiency)
Patients with severe liver problems should not take these tablets. If you have moderate problems, your doctor will recommend a different dosage regimen. In case of mild liver problems, a dosage adjustment is not required.
Patients with severe kidney problems should not take these tablets. In case of mild or moderate kidney problems, a dosage adjustment is not required.

Use in children and adolescents
Tapentadol is not suitable for children and adolescents below the age of 18 years.

How and when should you take Tapentadol?
Tapentadol is for oral use. Swallow the tablets with sufficient liquid. You may take the tablets on an empty stomach or with meals.

How long should you take Tapentadol?
Do not take the tablets for longer than your doctor has told you.

If you take more Tapentadol than you should
After taking very high doses, the following may be experienced:
- pin-point pupils, vomiting, drop in blood pressure, fast heartbeat, collapse, disturbed consciousness or coma (deep unconsciousness), epileptic fits, dangerously slow or shallow breathing or stopping breathing which may lead to death.

If this happens a doctor should be called immediately!

If you forget to take Tapentadol
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
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 after-effects when treatment is stopped, however, on uncommon occasions, people who have been taking the tablets for some time may feel unwell if they abruptly stop taking them.

Symptoms may be:
- restlessness, watery eyes, runny nose, yawning, sweating, chills, muscle pain and dilated pupils,
- irritability, anxiety, backache, joint pain, weakness, abdominal cramps, difficulty in sleeping, nausea, loss of appetite, vomiting, diarrhea, and increases in blood pressure, breathing or heart rate.

If you experience any of these complaints after stopping treatment, please consult your doctor.
You should not suddenly 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. Symptoms may be wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching, especially those covering your whole body.
Another serious side effect is a condition where you breathe more slowly or weakly than expected. 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): nausea, vomiting, dizziness, drowsiness, headache.

Common (may affect up to 1 in 10 people): decreased appetite, anxiety, confusion, hallucination, sleep problem, abnormal dreams, trembling, flushing, constipation, diarrhoea, indigestion, dry mouth, itching, increased sweating, rash, muscle cramps, feeling of weakness, fatigue, feeling of body temperature change.

Uncommon (may affect up to 1 in 100 people): depressed mood, disorientation, excitability (agitation), nervousness, restlessness, euphoric mood, disturbance in attention, memory impairment, near fainting, sedation, difficulty in controlling movements, difficulty in speaking, numbness, abnormal sensations of the skin (e.g. tingling, prickling), muscle twitches, abnormal vision, faster heart beat, palpitations, decreased blood pressure, dangerously slow or shallow breathing (respiratory depression), less oxygen in the blood, shortness of breath, abdominal discomfort, hives, sensation of heaviness, delay in passing urine, frequent urination, drug withdrawal syndrome (see "If you stop taking Tapentadol"), accumulation of water in the tissue (oedema), feeling abnormal, feeling drunk, irritability, feeling of relaxation, drug dependence.

Rare (may affect up to 1 in 1,000 people): allergic reaction to medicines (including swelling beneath the skin, hives, and in severe cases difficulty breathing, a fall in blood pressure, collapse, or shock), thinking abnormal, epileptic fit, depressed level of consciousness, coordination abnormal, slower heartbeat, impaired gastric emptying.

Not known (frequency cannot be estimated from the available data): 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. You can also report side effects directly via the MHRA Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TAPENTADOL

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

This medicine does not require any special temperature storage conditions. Keep the blisters in the outer carton to protect from light.

Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

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 contains
- The active substance is tapentadol.
  Each Tapentadol 50 mg film-coated tablet contains 58.24 mg Tapentadol hydrochloride equivalent to 50 mg Tapentadol.
  Each Tapentadol 75 mg film-coated tablet contains 87.36 mg Tapentadol hydrochloride equivalent to 75 mg Tapentadol.
  Each Tapentadol 100 mg film-coated tablet contains 116.48 mg Tapentadol hydrochloride equivalent to 100 mg Tapentadol.
- The other ingredients are: Microcrystalline cellulose E460, Lactose monohydrate, Croscarmellose sodium E468, Povidone E1201, Magnesium stearate E470b, Polyvinyl alcohol E1203, Titanium dioxide E171, Macrogol 3350 E1521, Talc E553b, Yellow iron oxide E172 (75 mg tablets), Red iron oxide E172 (100 mg tablets).

What Tapentadol looks like and contents of the pack
Tapentadol 50 mg appears as white, round, convex, film-coated tablets, debossed with "Medochemie logo" on one side and plain on the other side, with diameter 7.0 mm.
Tapentadol 75 mg appears as yellow, round, convex, film-coated tablets plain on both sides, with diameter 8.0 mm.
Tapentadol 100 mg appears as dark pink, round, convex, film-coated tablets, debossed "MC" on one side and plain on the other side, with diameter 9.0 mm.

Packs with 5, 10, 14, 20, 24, 28, 30, 40, 50, 54, 56, 60, 90, 100 film-coated tablets in transparent PVC/PE/PVDC-aluminium blisters.

Not all pack sizes may be marketed.

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This leaflet was last revised in October 2025.

P1793

CONSILIENT CODE : P1793

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Artwork Specification	Fonts	Colours	Designed by
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