



**Package leaflet: Information for the user**

**Tapentadol Celix 50 mg Prolonged-release Tablets**  
**Tapentadol Celix 100 mg Prolonged-release Tablets**  
**Tapentadol Celix 150 mg Prolonged-release Tablets**  
**Tapentadol Celix 200 mg Prolonged-release Tablets**  
**Tapentadol Celix 250 mg Prolonged-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 Celix Prolonged-release Tablets are and what they are used for
2. What you need to know before you take Tapentadol Celix Prolonged-release Tablets
3. How to take Tapentadol Celix Prolonged-release Tablets
4. Possible side effects
5. How to store Tapentadol Celix Prolonged-release Tablets
6. Contents of the pack and other information

**1. What Tapentadol Celix Prolonged-release Tablets are and what they are used for**

Tapentadol - the active substance in Tapentadol Celix Prolonged-release Tablets is a strong painkiller which belongs to the class of opioids. Tapentadol Celix Prolonged-release Tablets are used for the treatment of:

- severe chronic pain in adults that can only be adequately managed with an opioid painkiller.
- severe chronic pain in children above 6 years and adolescents that can only be adequately managed with an opioid painkiller.

**2. What you need to know before you take Tapentadol Celix Prolonged-release Tablets**

**Do not take Tapentadol Celix Prolonged-release Tablets**

- 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 Celix Prolonged-release Tablets')

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Tapentadol Celix Prolonged-release Tablets if you:

- have slow or shallow breathing,
- suffer from increased pressure in the brain or disturbed consciousness up to coma,
- have had a head injury or brain tumours,
- suffer from a liver or kidney disease (see 'How to take Tapentadol Celix Prolonged-release Tablets'),
- suffer from a pancreatic or biliary tract disease including pancreatitis,
- 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.

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 Celix Prolonged-release Tablets 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 Celix Prolonged-release Tablets 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 Celix Prolonged-release Tablets, 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 Celix Prolonged-release Tablets).

**Do not use Tapentadol Celix Prolonged-release Tablets for acute post-operative pain because of the increased risk of dependency and developing serious breathing problems.**

**If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are taking Tapentadol Celix Prolonged-release Tablets. Your doctor may adjust your dose.**

*Children and adolescents*

Children and adolescents with obesity should be monitored closely and the recommended maximum dose should not be exceeded.

Do not give this medicine to children below the age of 6 years.

*Sleep-related breathing disorders*

Tapentadol Celix Prolonged-release Tablets can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxaemia (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 Celix Prolonged-release Tablets**

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 Celix Prolonged-release Tablets at the same time. Your doctor will tell you whether Tapentadol Celix Prolonged-release Tablets is suitable for you.

Concomitant use of Tapentadol Celix Prolonged-release Tablets and sedative medicines such as benzodiazepines or related drugs (certain sleeping pills or tranquilizers (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 Celix Prolonged-release Tablets 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 Celix Prolonged-release Tablets 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.

Taking Tapentadol Celix Prolonged-release Tablets 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 Celix Prolonged-release Tablets will not work as well if given together with one of these medicines. Tell your doctor in case you are currently treated with one of these medicines.

Taking Tapentadol Celix Prolonged-release Tablets together with strong inhibitors or inducers (e.g. rifampicin, phenobarbital or 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 medicine is started or stopped. Please keep your doctor informed about all medicines you are taking.

Tapentadol Celix Prolonged-release Tablets 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 Celix Prolonged-release Tablets 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 Celix Prolonged-release Tablets with food, drink and alcohol**

Do not drink alcohol whilst taking Tapentadol Celix Prolonged-release Tablets, because some side effects such as drowsiness may be increased. Food does not influence the effect of this medicine.

**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 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 Celix Prolonged-release Tablets may cause drowsiness, dizziness and blurred vision and may impair your reactions. This may especially happen when you start taking Tapentadol Celix Prolonged-release Tablets, when your doctor changes your dosage or when you drink alcohol or take tranquilizers. 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.

**3. How to take Tapentadol Celix Prolonged-release Tablets**

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Tapentadol Celix Prolonged-release Tablets, 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 Celix Prolonged-release Tablets" below).

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.

**Adults**

The usual starting dose is 50 mg every 12 hours.

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.

Total daily doses of Tapentadol Celix Prolonged-release Tablets greater than 500 mg tapentadol are not recommended.



## Elderly patients

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.

## 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

The dose of Tapentadol Celix Prolonged-release Tablets for children and adolescents aged 6 years to less than 18 years is dependent on age and body weight.

The correct dose will be determined by your doctor. A total dose of 500 mg per day, i.e. 250 mg given every 12 hours should not be exceeded.

Children and adolescents with kidney or liver problems should not take these tablets.

Tapentadol Celix Prolonged-release Tablets are not suitable for children below the age of 6 years.

## How and when should you take Tapentadol Celix Prolonged-release Tablets

Tapentadol Celix Prolonged-release Tablets are for oral use. Always swallow the tablets whole, with sufficient liquid. Don't chew it, break it or crush it – this could lead to overdosing, because the drug will be released into your body too quickly. The score line is **not intended** for breaking the tablet. You may take the tablets on an empty stomach or with meals.

The empty shell of the tablet may not be digested completely and thus be seen in a stool. This should not worry you, since the 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 Celix Prolonged-release Tablets

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

## If you take more Tapentadol Celix Prolonged-release Tablets 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 Celix Prolonged-release Tablets

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 Celix Prolonged-release Tablets

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, diarrhoea, 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. No additional side effects were observed in children and adolescents compared to adults.

### 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, constipation, dizziness, drowsiness, headache.

**Common** (may affect up to 1 in 10 people): decreased appetite, anxiety, depressed mood, sleep problem, nervousness, restlessness, disturbance in attention, trembling, muscle twitches, flushing, shortness of breath, vomiting, diarrhoea, indigestion, itching, increased sweating, rash, feeling of weakness, fatigue, feeling of body temperature change, mucosal dryness, accumulation of water in the tissue (oedema).

**Uncommon** (may affect up to 1 in 100 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), weight loss, disorientation, confusion, excitability (agitation), perception disturbances, abnormal dreams, euphoric mood, depressed level of consciousness, memory impairment, mental impairment, fainting, sedation, balance disorder, difficulty in speaking, numbness, abnormal sensations of the skin (e.g. tingling, prickling), abnormal vision, faster heartbeat (slow heartbeat, palpitations, decreased blood pressure, abdominal discomfort, hives, delay in passing urine, frequent urination, sexual dysfunction, drug withdrawal syndrome (see 'If you stop taking Tapentadol Celix Prolonged-release Tablets'), feeling abnormal, irritability.

**Rare** (may affect up to 1 in 1,000 people): drug dependence, thinking abnormal, epileptic fits, near fainting, coordination abnormal, dangerously slow or shallow breathing (respiratory depression), impaired gastric emptying, feeling drunk, feeling of relaxation.

**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 Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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 Celix Prolonged-release Tablets

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

This medicine does not require any special storage conditions.

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 Celix Prolonged-release Tablets contain

- The active substance is tapentadol.

**Tapentadol Celix 50 mg Prolonged-release Tablets**  
Each prolonged-release tablet contains 76.570 mg of tapentadol phosphate equivalent to 50 mg tapentadol (free base of tapentadol).

**Tapentadol Celix 100 mg Prolonged-release Tablets**  
Each prolonged-release tablet contains 153.139 mg of tapentadol phosphate equivalent to 100 mg tapentadol (free base of tapentadol).

**Tapentadol Celix 150 mg Prolonged-release Tablets**  
Each prolonged-release tablet contains 229.709 mg of tapentadol phosphate equivalent to 150 mg tapentadol (free base of tapentadol).

**Tapentadol Celix 200 mg Prolonged-release Tablets**  
Each prolonged-release tablet contains 306.279 mg of tapentadol phosphate equivalent to 200 mg tapentadol (free base of tapentadol).

**Tapentadol Celix 250 mg Prolonged-release Tablets**  
Each prolonged-release tablet contains 382.848 mg of tapentadol phosphate equivalent to 250 mg tapentadol (free base of tapentadol).

- The other ingredients are:

**Tablet core:** microcrystalline cellulose; hypromellose; silica, colloidal anhydrous; magnesium stearate.

#### Tablet coating:

**Tapentadol Celix 50 mg Prolonged-release Tablets:** hypromellose; glycerol; talc; microcrystalline cellulose; titanium dioxide (E171)

**Tapentadol Celix 100 mg Prolonged-release Tablets:** hypromellose; glycerol; talc; microcrystalline cellulose; titanium dioxide (E171); iron oxide yellow (E172); iron oxide red (E172); iron oxide black (E172)

**Tapentadol Celix 150 mg Prolonged-release Tablets:** hypromellose; glycerol; talc; microcrystalline cellulose; titanium dioxide (E171); iron oxide red (E172); iron oxide black (E172)

**Tapentadol Celix 200 mg Prolonged-release Tablets:** hypromellose; glycerol; talc; microcrystalline cellulose; titanium dioxide (E171); iron oxide yellow (E172); iron oxide red (E172); iron oxide black (E172)

**Tapentadol Celix 250 mg Prolonged-release Tablets:** hypromellose; glycerol; talc; microcrystalline cellulose; titanium dioxide (E171); iron oxide red (E172); iron oxide black (E172)

### What Tapentadol Celix Prolonged-release Tablets look like and contents of the pack

**Tapentadol Celix 50 mg Prolonged-release Tablets** are white, oblong, biconvex film-coated tablets (6.2 mm x 13.2 mm) with score lines on both sides.

**Tapentadol Celix 100 mg Prolonged-release Tablets** are light yellow, oblong, biconvex film-coated tablets (6.7 mm x 14.2 mm) with score lines on both sides.

**Tapentadol Celix 150 mg Prolonged-release Tablets** are light pink, oblong, biconvex film-coated tablets (7.2 mm x 15.2 mm) with score lines on both sides.

**Tapentadol Celix 200 mg Prolonged-release Tablets** are yellow, oblong, biconvex film-coated tablets (7.7 mm x 16.2 mm) with score lines on both sides.

**Tapentadol Celix 250 mg Prolonged-release Tablets** are reddish brown, oblong, biconvex film-coated tablets (8.7 mm x 18.2 mm) with score lines on both sides.

Tapentadol Celix Prolonged-release Tablets are available in child resistant aluminium-PVC/PE/PVDC perforated unit dose blisters.

Packs with 20x1, 24x1, 28x1, 30x1, 50x1, 54x1, 56x1, 60x1, 100x1 prolonged-release tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Celix Pharma Ltd.  
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### Manufacturer

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**If you are blind or partially sighted and require this leaflet in a different format, call 0800 669 6825 or contact [medinfo@celixpharma.com](mailto:medinfo@celixpharma.com)**

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Company Name	Product Description	Celix / OLS	CCR No.
	Tapentadol_50_100_150_200_250 mg Prolonged-release Tablets	Celix	XXX
	Version No.	Artwork Code	30 October 2025
Reviewed / Approved by	3	CEL20250056P	Colors
	Component	Dimension	Printing Colors (Pantone/CMYK)
	PIL	200 W x 600 H mm	Technical Colors (Non-printable colors)
	Market	Font Size (Minimum)	Black
	UK	9pt	
Pharmacode	Font Type		
Sign / Date	932	Arial	