



**Package leaflet: Information for the user**

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

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

Tapentadol - the active substance in Vecicom Prolonged-release Tablets - is a strong painkiller which belongs to a group of medicines called opioids. Vecicom Prolonged-release Tablets are used in adults to treat severe long-term pain that can only be adequately managed with an opioid painkiller.

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

**Do not take Vecicom Prolonged-release Tablets**

- if you are allergic (hypersensitive) 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 Vecicom Prolonged-release Tablets').

**Warnings and precautions**

**Talk to your doctor or pharmacist before taking Vecicom Prolonged-release Tablets 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 tumours.
- suffer from liver or kidney problems (see 'How to take Vecicom Prolonged-release Tablets').
- suffer from 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 Vecicom Prolonged-release Tablets may lead to addiction. In this case, you should only take these tablets for short periods of time and under strict medical supervision.

*Sleep-related breathing disorders*

Vecicom Prolonged-release Tablets are an opioid painkiller. Opioids can cause sleep-related breathing disorders, such as shallow/pauses in breathing during sleep (sleep apnoea) and low level of oxygen in the blood during sleep (sleep related hypoxaemia).

The risk of sleep apnoea depends on the dose of opioids. If you experience this, your doctor may decrease your dose.

**Other medicines and Vecicom Prolonged-release Tablets**

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.**

- Your doctor will tell you which medicines are safe to take with Vecicom Prolonged-release Tablets.
- 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 Vecicom Prolonged-release Tablets at the same time. Your doctor will tell you whether Vecicom Prolonged-release Tablets is suitable for you.
  - Using Tapentadol at the same time as using 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 a cough medicine), antipsychotics, H1-antihistamines, alcohol, increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma, and may be life-threatening. Therefore, using the above medicines whilst using this medicine should only be considered when other treatment options are not possible.
  - If your doctor does prescribe Vecicom Prolonged-release Tablets together with sedative medicines, the dose and duration of treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and carefully follow the prescribed dose. Contact your doctor if you experience any of the symptoms stated above. It could be helpful to ask friends or relatives to be aware of the signs and 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 Vecicom 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.
  - Vecicom Prolonged-release Tablets 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 Vecicom Prolonged-release Tablets with rifampicin, phenobarbital or St John's Wort, products that affect the enzymes required to remove Vecicom Prolonged-release Tablets from the body, may affect how well Vecicom Prolonged-release Tablets work or may cause side effects. The effects may occur especially when the other medicine is started or stopped.
- Vecicom Prolonged-release Tablets should not be taken together with monoamine oxidase inhibitors (MAOIs) used to treat 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.**

**Vecicom Prolonged-release Tablets with food, drink and alcohol**

Do not drink alcohol whilst you are taking Vecicom Prolonged-release Tablets, because some side effects such as drowsiness may be increased. You can take Vecicom Prolonged-release Tablets 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 Vecicom Prolonged-release 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.
- if you become pregnant during treatment with Vecicom Prolonged-release Tablets, 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 Vecicom Prolonged-release Tablets, then do not drive, use tools or machinery. Any such effects are more likely to occur when you start taking Vecicom Prolonged-release Tablets, when the dose of Vecicom Prolonged-release Tablets is changed, or when you drink alcohol or take tranquilizers. Please ask your doctor before driving a car or using machinery.

**3. How to take Vecicom 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.

Your doctor will change the dose and time between doses of Vecicom Prolonged-release Tablets 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. Total daily doses of Vecicom Prolonged-release Tablets greater than 500 mg tapentadol are not recommended. Your doctor may prescribe a different, more appropriate dose or time between doses 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 Vecicom Prolonged-release Tablets**

Vecicom Prolonged-release Tablets are for oral use. Swallow the tablet with a glass of water. You may take the tablet either on an empty stomach or with food. The score line is **not intended** for breaking the tablet. Swallow whole. Do not break, crush, or chew the tablet, as it may result in overdose due to the quick release of tapentadol in your body.

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

**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 Vecicom Prolonged-release Tablets 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**

Vecicom Prolonged-release Tablets are not recommended for children and adolescents below the age of 18 years.

**How long should you take Vecicom Prolonged-release Tablets**

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

**If you take more Vecicom Prolonged-release Tablets than you should**

Taking too much Vecicom Prolonged-release Tablets 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 Vecicom Prolonged-release Tablets may cause the following:

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

**If you forget to take Vecicom 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 Vecicom 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 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 Vecicom Prolonged-release Tablets, 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 problems, 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 heartbeat, 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 Vecicom Prolonged-release Tablets').
- 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 of suicidal thoughts or behaviour.

## 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 Vecicom 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.

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 Vecicom Prolonged-release Tablets contain

- The active substance is tapentadol.

#### Vecicom 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).

#### Vecicom 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).

#### Vecicom 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).

#### Vecicom 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).

#### Vecicom 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:

#### Vecicom 50 mg Prolonged-release Tablets:

hypromellose; glycerol; talc; microcrystalline cellulose; titanium dioxide (E171)

#### Vecicom 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)

#### Vecicom 150 mg Prolonged-release Tablets:

hypromellose; glycerol; talc; microcrystalline cellulose; titanium dioxide (E171); iron oxide red (E172); iron oxide black (E172)

#### Vecicom 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)

#### Vecicom 250 mg Prolonged-release Tablets:

hypromellose; glycerol; talc; microcrystalline cellulose; titanium dioxide (E171); iron oxide red (E172); iron oxide black (E172)

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

Vecicom 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.

Vecicom 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.

Vecicom 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.

Vecicom 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.

Vecicom 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.

Vecicom 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

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## Manufacturer

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