

**Tramadol Hydrochloride  
50mg Effervescent Tablets  
Leaflet**

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**PATIENT INFORMATION LEAFLET**

**Tramadol Hydrochloride 50mg Effervescent Tablets**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your 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:**

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| <b>1</b> What Tramadol Tablet is and what it is used for        | <b>4</b> Possible side effects                      |
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**1 What Tramadol Tablets are and what they are used for**

Tramadol Hydrochloride is a pain reliever belonging to a group of medicines called opioids.

Opioids work by imitating the action of naturally occurring pain-reducing chemicals in the body called endorphins. They do this by combining with the opioid receptors in the brain and spinal cord. This blocks the transmission of pain signals sent by the nerves to the brain. Therefore, even though the cause of the pain may remain, less pain is actually felt.

Tramadol is used to treat moderate to severe pain. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

**2 What you need to know before you take Tramadol Tablets**

**Do not take Tramadol if:**

- You are allergic (hypersensitive) to Tramadol, opioids or any of the other ingredients of this medicine (see section 6 "Contents of the pack and other information")
- You have had enough alcohol to make you drunk
- You have taken other medicines such as sleeping medicines (hypnotics), pain-relievers (analgesics), other opioids or psychotropic drugs (any drug capable of affecting the mind, emotions and behaviour) (see "Other medicines and Tramadol" section)
- You are taking or have taken in the last two weeks, medicines used to treat depression called MonoAmine Oxidase Inhibitors (MAOIs) (see "Other medicines and Tramadol" section)
- You have epilepsy and it is not adequately controlled by treatment
- It is for use in the treatment of drug withdrawal symptoms (see "Warnings and precautions" section)
- You suffer from phenylketonuria (an inherited disorder where the body is unable to break down a substance called phenylalanine (see "Tramadol Effervescent Tablets contains lactose and sodium and aspartame" section)

**Tolerance, dependence, and addiction** This medicine contains tramadol 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 Tramadol 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 tramadol 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 Tramadol, 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 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 Tramadol).

**Warnings and precautions**

**Talk to your doctor before taking Tramadol:**

- if you suffer from depression and you are taking antidepressants as some of them interact with tramadol (see 'Other medicines and Tramadol')
- As using Tramadol may lead to developing withdrawal symptoms (see section 3 "If you stop taking Tramadol..."). Because of this, you should be reviewed regularly as to how long you need to continue your treatment
- If you are using Tramadol long-term, as you may become tolerant to Tramadol (where Tramadol becomes less effective in your treatment) or you may develop a mental and/or physical reliance (dependence) on Tramadol. If you have a tendency for drug abuse (misuse) or dependence, your treatment should be for short periods and under strict medical supervision
- If you are reliant (dependent) on opioids, as Tramadol is **not** a suitable substitute as it cannot help with morphine withdrawal symptoms
- If you suffer from:
  - A head injury, reduced consciousness (if you feel that you are going to faint) or a rise in pressure inside the skull that can result from or cause brain injury or brain disease (increased intracranial pressure)
  - A sensitivity to opiates
  - Shock (pale face, cold/clammy skin, fast/shallow breathing, rapid/weak pulse, yawning, sighing and in extreme cases unconsciousness)
  - Disorders of the respiratory centre (control of breathing) or respiratory function (ability to breathe)
  - Severe impairment of liver and/or kidney function
- If you have a history of epilepsy or are prone to seizures, as the risk of fits (convulsions) may be increased if your dose of Tramadol exceeds the maximum daily dose limit of 400mg or if you are taking Tramadol together with medicines which lower the body's seizure threshold (see "Other medicines and Tramadol")
- If you are taking CNS (Central Nervous System) depressants, medicines used to treat anxiety and sleep disorders (see "Other medicines and Tramadol") as there is a possibility of developing respiratory depression (where your breathing becomes slower or weaker than usual)
- As use of Tramadol should be avoided if you are due to have a general anaesthetic using nitrous oxide or enflurane as it may enhance intraoperative recall (becoming conscious during a surgical procedure performed under general anaesthetic and subsequently have a recall of these events)

**Sleep-related breathing disorders**

Tramadol contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnea (shallow/pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen in the blood). The risk of experiencing central sleep apnea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnea. There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 "Possible side effects").

Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect people in different ways. In some people, they may not get enough pain relief but other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Talk to your doctor if you experience any of the following symptoms while taking tramadol:

Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

**Other medicines and Tramadol:** Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines. Medicines which **may interact with or be affected by** Tramadol:

- if you are taking other pain relievers such as morphine and codeine (also as cough medicine), and alcohol while you are taking Tramadol. You may feel drowsier or feel that you might faint. If this happens tell your doctor.
- Concomitant use of Tramadol and tranquilizers or sleeping pills (e.g. benzodiazepines) or gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma or may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor prescribes Tramadol together with sedating medicines the dose and the duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedating 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 medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take Tramadol at the same time. Your doctor will tell you whether Tramadol is suitable for you.
- MonoAmine Oxidase Inhibitors (MAOIs), medicines used to treat depression such as moclobemide. Tell your doctor if you have taken one on the past 2 weeks
- CNS depressants, medicines used to treat anxiety and sleep disorders such as valium
- Carbamazepine, a medicine used to treat and prevent fits (seizures) (anticonvulsants)
- Selective Serotonin Re-uptake Inhibitors (SSRI), medicines used to treat depression such as citalopram
- Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), medicines used to treat mood and nerve disorders such as venlafaxine
- If you are taking certain antidepressants Tramadol may interact with these medicines and you may experience serotonin syndrome (see section 4 "Possible side effects").
- Antipsychotics, medicines used to treat mood disorders such as lithium
- Medicines which lower the body's seizure threshold e.g. bupropion, mirtazapine, tetrahydrocannabinol
- Buprenorphine, nalbuphine, pentazocine, opioid analgesic medicines used to treat sever pain
- Coumarin derivatives e.g. warfarin, a medicine used to thin the blood (anticoagulant). The effect of these medicines on blood clotting may be affected and bleeding may occur.
- Ketoconazole, a medicine used to treat fungal infections (antifungal)
- Erythromycin, a medicine used to treat bacterial infections (antibiotic)
- Ondansetron, a medicine used to prevent feeling and being sick [nausea and vomiting] (5HT-3 receptor antagonist)

**Tramadol with food and drink and alcohol**

During treatment with Tramadol, it is recommended not to drink alcohol. Food does not influence the effect of Tramadol

**Children and adolescents**

Use in children with breathing problems: Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

**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 for advice before taking this medicine.

**Pregnancy:**

- Tramadol should not be used during pregnancy.
- Babies born to mothers who took Tramadol long-term during pregnancy may develop withdrawal symptoms.

**Breast-feeding:**

- Tramadol is excreted into breast milk. For this reason, you should not take Tramadol more than once during breast-feeding, or alternatively, if you take Tramadol more than once, you should stop breast-feeding.
- However, if you take a single dose of Tramadol it is not usually necessary to stop breast-feeding.
- Based on human experience tramadol is suggested not to influence female or male fertility

**Driving and using machines**

Tramadol may cause drowsiness, dizziness and blurred vision and therefore may impair your reactions. This is more likely to occur if you drink alcohol or are taking CNS depressants or psychotropic drugs (any drug capable of affecting the mind, emotions and behaviour) (see "Other medicines and Tramadol"). If any of these symptoms are experiences, it may be necessary to avoid driving or operating machinery or pursuing any activity in which full attention is required.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or

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- in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

**Tramadol Effervescent Tablet contains lactose and sodium and aspartame**

- If you have been told by your doctor that you have an intolerance to some sugars (**lactose**) contact your doctor before taking this medicine.
- If you have been told by your doctor to stay on **low sodium diet**, contact your doctor before taking this medicine.
- If you suffer from **phenylketonuria**, an inherited disorder where the body is unable to break down a substance called phenylalanine contact your doctor before taking this medicine as it contains aspartame, as source of phenylalanine

**3 How to take Tramadol Tablets**

**Always take Tramadol exactly as your doctor 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 Tramadol, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2).

- The tablets are to be taken by dissolving in a glass of water and drinking all the liquid.

The dose of Tramadol should be adjusted according to the intensity of your pain and your individual pain sensitivity. The lowest possible dose should be taken.

In general the lowest pain-relieving dose should be taken. Do not take more than 400 mg tramadol hydrochloride daily, except if your doctor has instructed you to do so.

**Adults and children aged 12 years and over:**

**Short-term (acute) treatment of pain:**

- The starting dose is usually 50mg or 100mg. For severe pain a starting dose of 100mg is usually necessary
- This can be followed by doses of 50mg or 100mg, **not** more frequently than every 4 hours
- The duration of treatment will depend on your clinical needs
- Your doctor may prescribe a different, more appropriate dosage of Tramadol if necessary.

**Treatment of pain for long-term (chronic) conditions:**

- The usual starting dose is 50mg
- The need for continued treatment should be assessed at regular intervals (if necessary with breaks in treatment) as Tramadol should not be taken for longer than is absolutely necessary

A maximum daily dose of 400mg should **not** be exceeded unless under specialist medical supervision.

**Older people:**

In older people (over 75 years of age) the rate at which Tramadol is excreted from the body may be delayed. Therefore, if necessary, the time interval between doses may need to be extended according to your requirements.

**Patients with liver or kidney disorders or on dialysis:**

- In patients with kidney and/or liver disorders, the rate at which Tramadol is excreted from the body may be delayed. Therefore, if necessary, the time interval between doses may need to be extended according to your requirements
- In patients with severe liver impairment, the time interval between doses should be extended to 12 hours
- Tramadol is **not** recommended for patients with severe kidney impairment

**Use in children under 12 years of age:**

- Tramadol is **not** recommended for use in children under 12 years of age.

**How long should you take Tramadol?**

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment.

This will outline how to gradually reduce the dose and stop taking the medicine.

**If you take more Tramadol than you should:**

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you. If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed.

**Symptoms of overdose include:**

Constriction of the pupil of the eye (miosis), being sick (vomiting), a sudden and marked drop in blood pressure (cardiovascular collapse), sedation and consciousness disorders up to coma, fits (seizures) and respiratory depression (breathing becomes slower or weaker than usual) up to respiratory arrest (stop breathing).

- a fast hear beat
- fits
- collapse

**If you forget to take Tramadol**

**If you forget to take the tablets, pain is likely to return.** Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do **not** take a double dose to make up for a forgotten dose.

**If you stop taking Tramadol Effervescent Tablets**

It is important that you keep taking Tramadol for as long as your doctor has told you to.

You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms).

If you interrupt or prematurely stop treatment with Tramadol, your pain will return. If you decide you wish to stop taking this medicine because of unpleasant side effects, please consult your doctor. One side effect of this medicine is drug dependence. Drug dependence occurs when a person's body becomes used to a drug and begins to need it to continue functioning normally. Dependence withdrawal symptoms may occur when treatment is stopped.

Dependence, misuse and withdrawal effects are known with the use of Tramadol. Withdrawal effects include: agitation, anxiety, nervousness, difficulty in sleeping (insomnia), unusual uncontrolled muscle movement (hyperkinesia), shakiness (tremor) and stomach disorders.

- restlessness
- irritability
- feeling your heart beat (palpitations)
- increased blood pressure
- feeling being sick
- diarrhoea
- shivering or sweating

Other possible symptoms associated with stopping the use of Tramadol include: panic attacks, severe anxiety, seeing or hearing things that are not real (hallucinations), tingling or numbness in the hands or feet (paraesthesia), ringing in the ears (tinnitus) and unusual Central Nervous System (CNS) symptoms such as confusion, mental health disorders (delusions), a feeling of loss of identity/feeling detached from yourself (depersonalisation), feeling dissociated from your environment (derealisation) and unfounded or excessive fears about others (paranoia).

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

**4 Possible side effects**

Like all medicines, Tramadol may cause side effects, although not everybody gets them.

**Seek medical advice immediately if you develop the following symptoms:**

- Allergic reactions: swelling of the face, throat or tongue, fever, difficulty in breathing, dizziness
- Difficulty breathing or dizziness, wheezing, (dyspnoea, bronchospasm, anaphylaxis)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioneurotic oedema)

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

- Dizziness
- Feeling sick (nausea)

**Common side effects (may affect up to 1 in 10 people)**

- Headache
- Sleepiness or drowsiness (somnolence)

- Being sick (vomiting)
- Constipation
- Dry mouth
- Sweating
- Tiredness, weakness or lack energy (fatigue)

**Uncommon side effects (may affect up to 1 in 100 people)**

- Feeling your heartbeat (palpitations)
- Faster heartbeat (tachycardia)
- Low blood pressure when changing position (postural hypotension)
- A sudden and marked drop in blood pressure (cardiovascular collapse)
- These adverse effects may particularly occur in patients in an upright position or under physical strain.
- Dry heaving (retching).
- A feeling of pressure in the stomach or bloating
- Diarrhoea
- Severe itching (pruritis)
- Skin rashes
- Skin rashes with the formation of wheals (urticaria)

**Rare side effects (may affect up to 1 in 1000 people)**

- Slower heartbeat (bradycardia)
- Increase in blood pressure
- Tiredness, drowsiness (particularly following intravenous use)
- Changes in appetite
- abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders.
- Shakiness (tremor)
- Respiratory depression (where your breathing becomes slower or weaker than usual) (see section 2, "Warnings and precautions")
- Seizures, convulsions [fits] (epileptiform) (see section 2, "Warnings and precautions)
- Involuntary muscle contractions
- Unusual co-ordination
- Fainting (syncope)
- Seeing or hearing things that not real (hallucinations)
- Confusion
- Sleep disturbances
- Anxiety
- Nightmares
- Psychological complaints may appear after treatment with Tramadol. Their intensity and nature may vary (according to the patient's personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually suppression, occasionally increase) and decreased cognitive and sensory perception ( being less aware and less able to make decisions, which may lead to errors in judgement).
- Dependence on medicine (see section 2, "Warnings and precautions" and section 3 "If you stop taking Tramadol...")
- Blurred Vision, excessive dilation of the pupils (mydriasis), constriction of the pupil (miosis).
- Difficulty in breathing (dyspnoea)
- Muscle weakness
- Difficulty in passing urine, painful urination (dysuria) or urinary retention
- Reddening of the face (flushing)
- Blood disorders
- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden circulation failure) have occurred in very rare cases.
- Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- slow breathing, shortness of breath (dyspnoea)
- Epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.

**Very rare: may affect up to 1 in 10,000 people**

- hepatic enzyme increased

**Not known: frequency cannot be estimated from available data**

- Serotonin syndrome that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 "What you need to know before you take Tramadol Capsules").
- Increase in liver enzymes (detected through blood test)
- Low blood sugar levels (hypoglycaemia)
- Excessive sweating (diaphoresis)
- Hiccups
- Dependence and addiction (see section "How do I know if I am addicted")

**Drug Withdrawal**

When you stop taking Tramadol, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating

How do I know if I am addicted? If you notice any of the following signs whilst taking Tramadol, it could be a sign that you have become addicted.

– You need to take the medicine for longer than advised by your prescriber

– You feel you need to use more than the recommended dose

– You are using the medicine for reasons other than prescribed

– When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

**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 [atwww.mhra.gov.uk/yellowcard](http://atwww.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 Tramadol Tablets**

- 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.
- 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/tablet tube after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Keep the container tightly closed.
- 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 to protect the environment.

**6 Contents of the pack and other information**

**What Tramadol Tablets contains:** Each effervescent tablet contains 50mg of Tramadol Hydrochloride.

**The other ingredients are:** citric acid, sodium hydrogen carbonate, lactose monohydrate, sodium sulfate, sodium carbonate, povidone, sodium cyclamate, aspartame, macrogol, orange flavouring, simethicone emulsion, water, isopropanol.

**What Tramadol Tablets looks like and contents of the pack:**

Tramadol Hydrochloride 50mg Effervescent Tablets are white or off-white, round, biphane, effervescent tablets, of approximate diameter of 17.8-18.3mm with bevel-edges on both sides, and have an orange flavour.

Tramadol effervescent tablets are available in a tablet tube with a stopper containing silica gel as desiccant in packs of 10, 20, 30 or 100 tablets per pack. Not all pack sizes will be marketed.

**Product Licence Number:**

PL 36722/0119

**Marketing Authorisation Holder:**

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