

Package leaflet: Information for the user  
**Trapadex 37.5mg/325mg, film-coated tablets**  
 Tramadol hydrochloride/Paracetamol

**This medicine contains Tramadol hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

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

**1. What Trapadex is and what it is used for**

Trapadex is used to treat moderate to severe pain when your doctor recommends that a combination of tramadol hydrochloride and paracetamol is needed.

**2. What you need to know before you take Trapadex**

**Do not take Trapadex:**

- if you are hypersensitive or have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) to tramadol, paracetamol or any of the other ingredients (see section 6) in Trapadex
- in cases of acute alcohol poisoning
- if you are taking sleeping pills, pain relievers or medicines that affect mood and emotions
- if you are also taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the last 14 days before treatment with Trapadex. MAOIs are used in the treatment of depression or Parkinson's disease.
- if you have a severe liver disorder
- if you have epilepsy that is not adequately controlled by your current medicine.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Trapadex if you:

- take other medicines containing paracetamol or tramadol
- have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice
- have kidney problems
- have severe difficulties in breathing, for example asthma or severe lung problems
- have epilepsy or have already experienced fits or seizures
- have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
- are dependent on any medicine (for example morphine)
- take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine
- if you are going to have an anaesthetic (tell your doctor or dentist that you are taking Trapadex).
- if you suffer from depression and you are taking antidepressants as some of them may interact with trapadex (see 'Other medicines and Trapadex')
- If you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

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').

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.

**Sleep-related breathing disorders**

Trapadex 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.

**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 Trapadex 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 Trapadex 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 Trapadex, 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 Trapadex).

If any of the above-mentioned points applied to you in the past or applies to you while you are taking Trapadex, please make sure your doctor knows. He/she can then decide whether you should continue to use this medicine.

**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.

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

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

Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.

Do not take Trapadex with MAOIs (see section 'Do not take Trapadex').

Trapadex is not recommended with the following medicines, as it may affect how well they work:

- carbamazepine (a medicine used to treat epilepsy or some types of pain)
  - buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers).
- Please inform your doctor or pharmacist if you are taking:
- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

**The risk of side effects increases:**

- if you are taking triptans (used for migraine) or selective serotonin re-uptake inhibitors (SSRIs, used for depression). Check with your doctor if you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea.
- if you are taking other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant), medicines used to lower blood pressure, or medicines to treat allergies. Check with your doctor if you feel drowsy or feel faint.  
Concomitant use of Trapadex and sedative medicines such as benzodiazepines or related drugs 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 prescribes Trapadex together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk having a fit may increase if you take Trapadex at the same time. Your doctor will tell you whether Trapadex is suitable for you.
- if you are taking certain antidepressants. Trapadex may interact with these medicines and you may experience serotonin syndrome (see section 4 'Possible side effects').
- if you are taking warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur (see section 4).
- if you are taking Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

**The effectiveness of Trapadex may be altered if you also take the following medicines:**

- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick)
- cholestyramine (medicine used to reduce cholesterol in the blood)
- ketoconazole or erythromycin (medicines used against infections).

**Trapadex with food and alcohol**

Do not drink alcohol while you are taking Trapadex, as you may feel drowsier.

**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 Trapadex while you are pregnant or breast-feeding.

Check with your doctor if you become pregnant during treatment with Trapadex and before taking any further tablets.

**Breast-feeding**

Tramadol is excreted into breast milk. For this reason, you should not take Trapadex more than once during breast-feeding, or alternatively, if you take Trapadex more than once, you should stop breast-feeding.

Based on human experience tramadol is suggested not to influence female or male fertility. No data on the influence of the combination of tramadol and paracetamol on fertility are available.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

If you feel drowsy while taking Trapadex, do not drive, use tools or use machinery. The 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 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.

### 3. How to take Trapadex

Always take this medicine 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 Trapadex, 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 dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In general the lowest pain-relieving dose should be taken.

Swallow the tablets whole with sufficient liquid. Do not break or chew the tablets.

Take Trapadex for as short a time as possible and no longer than your doctor has told you.

#### Adults and adolescents over 12 years:

The recommended starting dose unless otherwise prescribed by your doctor is 2 tablets for adults and adolescents over 12 years. If required, further doses may be taken, as instructed by your doctor.

The shortest time between doses must be at least 6 hours.

Do not take more than 8 tablets per day.

#### Children under 12 years of age:

- not recommended.

#### Older people:

In elderly patients (above 75 years) the excretion of tramadol may be delayed.

If this applies to you, your doctor may recommend prolonging the dosage interval.

#### Severe liver or kidney disease (insufficiency)/dialysis patients:

Patients with severe liver and/or kidney insufficiency should not take Trapadex. If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

#### Method of administration:

The tablets are for oral use.

Swallow the tablets whole with sufficient liquid.

Do not break or chew the tablets.

If you think that the effect of Trapadex is too strong (you feel very drowsy or have difficulty breathing) or too weak (you do not have enough pain relief), contact your doctor.

#### If you take more Trapadex than you should

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

#### If you forget to take Trapadex

If you forget to take the tablets, pain is likely to return.

Do not take a double dose to make up for forgotten individual doses; simply continue taking the tablets as before.

#### If you stop taking Trapadex

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).

People may:

- feel agitated, anxious, nervous or shaky
- be over active
- have difficulty sleeping
- have stomach or bowel disorders.

Very few people may also get:

- panic attacks
- hallucinations, unusual perceptions such as itching, tingling and numbness
- ringing in the ears

If you experience any of these complaints after stopping this medicine, please contact your doctor. Other side effect information is listed in section 4

### 4. Possible side effects

Like all medicines, Trapadex can cause side effects, however not everybody gets them.

#### Some side effects could be serious. Contact your doctor immediately if any of the following occur:

- rarely cases of skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting. If this happens to you, stop treatment. Do not take the medicine again.
- prolonged or unexpected bleeding, from the use of Trapadex with medicines used to thin the blood (e.g. warfarin, phenprocoumon).

Additionally, if any of the following side effects get serious, contact your doctor or pharmacist:

#### Very common: may affect more than 1 in 10 people

- nausea
- dizziness, drowsiness

#### Common: may affect up to 1 in 10 people

- vomiting (being sick), digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth
- itching, sweating (hyperhidrosis)
- headache, shaking
- confusional state, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).

#### Uncommon: may affect up to 1 in 100 people

- increase in pulse or blood pressure, heart rate or heart rhythm disorders
- presence of albumin in urine, difficulties or pain on passing urine
- skin reactions (for example rashes, hives)
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ears, involuntary muscle twitching
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapses
- difficulty swallowing, blood in the stools
- shivering, hot flushes, pain in the chest
- difficulty breathing.
- increase in liver enzyme values

#### Rare: may affect up to 1 in 1,000 people

- fits, uncoordinated movements, transient loss of consciousness (syncope)
- drug dependence
- delirium
- blurred vision, constriction of pupil (miosis)
- speech disorders
- excessive dilation of the pupils (mydriasis)

#### Not known: frequency cannot be estimated from the available data

- decrease in blood sugar level (hypoglycaemia)
- frequency not known: hiccups
- 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 Trapadex’).

In addition, the following side effects have been reported by people using medicines that contain only tramadol or only paracetamol:

- feeling faint when getting up from a lying or sitting position, slow heart rate, fainting
- changes in appetite
- muscle weakness, slower or weaker breathing
- mood changes, changes in activity, changes in perception
- worsening of existing asthma
- Paracetamol intake alone or when taken together with the antibiotic flucloxacillin may induce a blood and fluid abnormality (high anion gap metabolic acidosis) when there is an increase in blood plasma acidity
- “A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2)”
- nose bleed or bleeding gums, which may result from a low blood platelet count.
- very rare cases of serious skin reactions have been reported with paracetamol.
- rare cases of respiratory depression have been reported with tramadol.

#### 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 Trapadex

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

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 use this medicine after the expiry date which is printed on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. Contents of the pack and other information

#### What Trapadex contains

The active substances are tramadol hydrochloride and paracetamol.

One tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol. The other ingredients are:

Tablet core: Pregelatinised starch, maize starch, sodium starch glycolate, microcrystalline cellulose, magnesium stearate


Film-coating: Hypromellose (E464), Titanium dioxide (E171), Triacetin, Iron oxide yellow (E172)

#### What Trapadex looks like and contents of the pack

Light yellow, oblong, biconvex, film-coated tablet, plain on both sides.

Trapadex comes in cartons of 60 tablets and 20 tablets.

#### Marketing Authorisation Holder and Manufacturer:

 **NOUMED LIFE SCIENCES LIMITED**  
Noumed House, Shoppenhangers Road  
Maidenhead, Berkshire, SL6 2RB, United Kingdom.



This leaflet was last revised in December 2024.

#### Other sources of information:

**To listen to or request a copy of this leaflet in braille, large print or audio please call, 020 33998960 (UK only)**

**Please be ready to give the following information:**

**Product name: Trapadex 37.5mg/325mg, film-coated tablets**

**Reference number: PL 44041/0053**

<b>Signature of Author:</b>				<b>Font Type &amp; Size</b>	<b>Heading</b>	
<b>Signature of RA:</b>					12 pt	
					<b>Body</b>	
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				<b>Title: Art Work Approval Form</b>		
Product	Trapadex 37.5mg/325mg, film-coated tablets			Specification:		
Customer	<b>NOUMED LIFE SCIENCES LIMITED, UK</b>					
Reason for Issue				Colours:	<b>Black</b>	
PL No.	44041/0053	Pharmacode No.		Dimensions:	<b>176 x 540mm</b>	
Item Code	LTRAP01/04	Layout No.:		No. of Folds (only for PIL)		