Tramacet 37.5 mg/325 mg film coated tablets

3218
22.02.23[7]

(tramadol hydrochloride/paracetamol)

PATIENT INFORMATION LEAFLET

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).

Your medicine is available using the above name but will be referred to as Tramacet throughout this leaflet.

What is in this leaflet:

1. WHAT TRAMACET IS AND WHAT IT IS USED FOR

Tramacet 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 TRAMACET

Do not take Tramacet
- if you are allergic to tramadol hydrochloride, paracetamol or any of the other ingredients of this medicine (listed in section 6)
- 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 Tramacet. 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 before taking Tramacet
- if you take other medicines containing paracetamol or tramadol
- if you have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice
- if you have kidney problems
- if you have severe difficulties in breathing, for example asthma or severe lung problems
- if you have epilepsy or have already experienced fits or seizures
- if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see "Other medicines and TRAMACET");
- if you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
- if you are dependent on any medicine (for example morphine)
- if you 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 Tramacet).

Sleep-related breathing disorders
Tramacet 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").
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.
If any of the above-mentioned points applied to you in the past or applies to you while you are taking Tramacet, 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 TRAMACET:
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 Tramacet
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.
Do not take Tramacet with MAOIs (see section 'Do not take Tramacet').
Tramacet is not recommended to be taken with the following:
- 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 (high anion gap metabolic acidosis which occurs when there is an increase in blood plasma acidity) that must have urgent treatment and which may occur particularly in case of severe kidney or liver impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used, especially if you take the maximum daily dose of paracetamol for longer time. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

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 Tramacet 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 Tramacet 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 Tramacet at the same time. Your doctor will tell you whether Tramacet is suitable for you.
- if you are taking certain antidepressants. TRAMACET 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).

The effectiveness of Tramacet may be altered if you also take:
- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick)
- cholestyramine (medicine used to reduce cholesterol in the blood)

Tramacet with food and alcohol
Do not drink alcohol while you are taking Tramacet, as you may feel drowsier.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not take TRAMACET while you are pregnant or breast-feeding.
Check with your doctor if you become pregnant during treatment with TRAMACET and before taking any further tablets.

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

Tramacet contains lactose
Lactose is an ingredient in these tablets.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. HOW TO TAKE TRAMACET

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
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.
Take Tramacet 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 Tramacet. 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 Tramacet 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 Tramacet 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 Tramacet
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 Tramacet
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, this medicine 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 Tramacet 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
- 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 breathing
- difficulty swallowing, blood in the stools
- skin reactions (for example rashes, hives)
- increase in liver enzyme values
- presence of albumin in urine, difficulties or pain on passing urine
- shivering, hot flushes, pain in the chest

Rare: may affect up to 1 in 1,000 people
- fits, uncoordinated movements, transient loss of consciousness (syncope)
- drug dependence
- delirium
- vision blurred, constriction of the pupil (miosis)
- speech disorders
- excessive dilation of the pupils (mydriasis)

Unknown: frequency unknown:
- decrease in blood sugar level (hypoglycaemia)

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
- nose bleeds 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.
- 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 TRAMACET”).

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 Yellow Card Scheme Website: 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 TRAMACET
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is printed on the carton and blister. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- If the tablets become discoloured or show signs of any deterioration, you should seek the advice of your pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask you pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Tramacet contains
- The active substances are tramadol hydrochloride and paracetamol.
- Each film coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.

The other ingredients are:
- **Tablet core**: powdered cellulose, pregelatinised starch, sodium starch glycolate (type A), maize starch, magnesium stearate.
- **Film-coating:** hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol 6000, yellow iron oxide (E172), propylene glycol, talc.

What Tramacet looks like and contents of the pack
Tramacet film-coated tablets are pale yellow film-coated tablets, marked with the manufacturer’s logo ♎ on one side and marked T5 on the other side.

Tramacet film-coated tablets are packed in blister strips and comes in cartons of 60 tablets.
Manufacturer and product licence holder
Tramacet is manufactured by Grunenthal GmbH, Zieglerstrasse 6, Aachen D-52078, Germany.
Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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Leaflet revision and issue date (Ref). 22.02.23[7]

Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

Tramadol hydrochloride / Paracetamol 37.5 mg/325 mg film coated tablets

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PATIENT INFORMATION LEAFLET

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- Keep this leaflet. You may need to read it again.
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- 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.
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Your medicine is available using the above name but will be referred to as Tramadol/Paracetamol throughout this leaflet.

What is in this leaflet:

1. WHAT TRAMADOL/PARACETAMOL IS AND WHAT IT IS USED FOR
Tramadol/Paracetamol 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 TRAMADOL/PARACETAMOL
Do not take Tramadol/Paracetamol
- if you are allergic to tramadol hydrochloride, paracetamol or any of the other ingredients of this medicine (listed in section 6)
- 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 Tramadol/Paracetamol. 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 before taking Tramadol/Paracetamol
- if you take other medicines containing paracetamol or tramadol
- if you have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice
- if you have kidney problems
- if you have severe difficulties in breathing, for example asthma or severe lung problems
- if you have epilepsy or have already experienced fits or seizures
- if you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see "Other medicines and Tramadol/Paracetamol");
- if you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
- if you are dependent on any medicine (for example morphine)
- if you 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 Tramadol/Paracetamol).

Sleep-related breathing disorders
Tramadol/Paracetamol 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").
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.
If any of the above-mentioned points applied to you in the past or applies to you while you are taking Tramadol/Paracetamol, 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 Tramadol/Paracetamol:
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/Paracetamol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.
Do not take Tramadol/Paracetamol with MAOIs (see section 'Do not take Tramadol/Paracetamol').
Tramadol/Paracetamol is not recommended to be taken with the following:
- 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 (high anion gap metabolic acidosis which occurs when there is an increase in blood plasma acidity) that must have urgent treatment and which may occur particularly in case of severe kidney or liver impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used, especially if you take the maximum daily dose of paracetamol for longer time. High anion gap metabolic acidosis is a serious disease that must have urgent treatment.

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 Tramadol/Paracetamol 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 Tramadol/Paracetamol 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 Tramadol/Paracetamol at the same time. Your doctor will tell you whether Tramadol/Paracetamol is suitable for you.
- if you are taking certain antidepressants. TRAMACET 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).

The effectiveness of Tramadol/Paracetamol may be altered if you also take:
- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick)
- cholestyramine (medicine used to reduce cholesterol in the blood)

Tramadol/Paracetamol with food and alcohol
Do not drink alcohol while you are taking Tramadol/Paracetamol, as you may feel drowsier.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not take Tramadol/Paracetamol while you are pregnant or breast-feeding.
Check with your doctor if you become pregnant during treatment with Tramadol/Paracetamol and before taking any further tablets.

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

Tramadol/Paracetamol contains lactose
Lactose is an ingredient in these tablets.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. HOW TO TAKE TRAMADOL/PARACETAMOL
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
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.
Take Tramadol/Paracetamol 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 Tramadol/Paracetamol. 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 Tramadol/Paracetamol 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 Tramadol/Paracetamol 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 Tramadol/Paracetamol
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 Tramadol/Paracetamol
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, this medicine 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 Tramadol/Paracetamol 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
- 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 breathing
- difficulty swallowing, blood in the stools
- skin reactions (for example rashes, hives)
- increase in liver enzyme values
- presence of albumin in urine, difficulties or pain on passing urine
- shivering, hot flushes, pain in the chest

Rare: may affect up to 1 in 1,000 people
- fits, uncoordinated movements, transient loss of consciousness (syncope)
- drug dependence
- delirium
- vision blurred, constriction of the pupil (miosis)
- speech disorders
- excessive dilation of the pupils (mydriasis)

Unknown: frequency unknown:
- decrease in blood sugar level (hypoglycaemia)

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
- nose bleeds 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.
- 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 Tramadol/Paracetamol”).

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 Yellow Card Scheme Website: 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 TRAMADOL/PARACETAMOL
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is printed on the carton and blister. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- If the tablets become discoloured or show signs of any deterioration, you should seek the advice of your pharmacist who will advise you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask you pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Tramadol/Paracetamol contains
- The active substances are tramadol hydrochloride and paracetamol.
- Each film coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.

The other ingredients are:
- **Tablet core**: powdered cellulose, pregelatinised starch, sodium starch glycolate (type A), maize starch, magnesium stearate.
- **Film-coating:** hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol 6000, yellow iron oxide (E172), propylene glycol, talc.

What Tramadol/Paracetamol looks like and contents of the pack
Tramadol/Paracetamol film-coated tablets are pale yellow film-coated tablets, marked with the manufacturer’s logo ♎ on one side and marked T5 on the other side.

Tramadol/Paracetamol film-coated tablets are packed in blister strips and comes in cartons of 60 tablets.

Manufacturer and product licence holder
Tramadol/Paracetamol is manufactured by Grunenthal GmbH, Zieglerstrasse 6, Aachen D-52078, Germany.
Procured from within the EU by product licence holder Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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