Package leaflet: Information for the user

Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets
(tramadol hydrochloride/paracetamol)

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

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 Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets is and what it is used for

This medicine has been prescribed for you for the treatment of moderate to severe pain. It contains the tramadol hydrochloride which belongs to a class of medicines called opioids, which are ‘pain relievers’. This medicine also contains paracetamol, another type of pain reliever. 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets

Do not take Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets

- 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 hydrochloride + Paracetamol Brown & Burk 37.5 mg + 325 mg film coated tablet. 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 Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets
- 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 have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick)
- 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets)
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see 'Other medicines and Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets').

<u>Tolerance, dependence, and addiction</u>

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 hydrochloride/paracetamol 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 hydrochloride/paracetamol 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 hydrochloride/paracetamol, 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 hydrochloride/paracetamol).
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.

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').

Sleep-related breathing disorders
Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets contains an active substance that belongs to the group of opioids. Tramadol hydrochloride / Paracetamol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxemia (low level of oxygen in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

The risk of experiencing central sleep apnoea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnoea.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Tramadol hydrochloride / 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.

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 hydrochloride + Paracetamol

Brown & Burk 37.5 mg + 325 mg film coated tablet, 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.

Other medicines and Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain)

Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.
Do not take Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets with MAOIs (see section 'Do not take Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets').

Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets 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).

<u>Other medicines and paracetamol</u>

Please inform your doctor or pharmacist if you are taking:

-flucloxacillin (antiobitic), 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 and 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets 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 Hydrochloride 37.5 mg and Paracetamol 325 mg film coated Tablets at the same time. Your doctor will tell you whether Tramadol Hydrochloride 37.5 mg and Paracetamol 325 mg film coated Tablets is suitable for you.

- if you are taking certain antidepressants. Tramadol Hydrochloride 37.5 mg and Paracetamol 325 mg film coated Tablets 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 Hydrochloride 37.5 mg and Paracetamol 325 mg film coated Tablets 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets with food, drink and alcohol.

Do not drink alcohol while you are taking Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets, as you may feel drowsier.

Pregnancy, breast-feeding and fertility

Do not take Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets if you are pregnant or think you might be pregnant or planning to have a baby unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Check with your doctor if you become pregnant during treatment with Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets and before taking any further tablets.

<u>Breast-feeding</u>

Do not take Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets while you are breastfeeding as Tramadol hydrochloride / Paracetamol passes into breast milk and will affect your baby.

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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets, 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film coated tablets 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using tramadol hydrochloride/paracetamol, 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).

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.

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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets 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.

Elderly patients:

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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets. 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets

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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets 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
- 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
- presence of albumin in urine, difficulties or pain on passing urine

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 cannot be estimated from the available data
- decrease in blood sugar level (hypoglycaemia)
- dependence and addiction (see section "How do I know if I am addicted?")
- 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets').

<u>Drug Withdrawal</u>

When you stop taking Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets, 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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets, 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.

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..

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 hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets.

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 stated on the pack after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 pack and other information

What Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets contains

The active substances are tramadol hydrochloride and paracetamol.
One (1) tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.
The other ingredients are:

- **Tablet core:** Maize starch, Powdered cellulose, Sodium starch Glycolate (Type A), Starch, Pregelatinised, Magnesium Stearate.

- **Film-coating:** Opadry light yellow YS-1-6382G containing Hypromellose 6cP, Hypromellose 3cP, Titanium dioxide (E171), Macrogol 400, Iron oxide yellow (E 172), Polysorbate 80.

What Tramadol hydrochloride / Paracetamol Brown & Burk 37.5 mg / 325 mg film-coated tablets looks like and contents of the pack

Light yellow, oblong shaped, biconvex, film coated tablets debossed with “I 03” on one side and plain on the other side.

Supplied in blister packs of 2, 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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