

**Applicant:** Ranbaxy Pharmaceuticals (Pty) Ltd  
**Product Name:** PATRAM  
**Dosage form and strength:** Film-coated tablets, Tramadol Hydrochloride 37,5 mg and Paracetamol 325 mg per film-coated tablet

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## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS** **S5**

**PROPRIETARY NAME and dosage form**

**PATRAM** Film-coated tablets

**Tramadol hydrochloride 37.5 mg and paracetamol 325 mg**


**Sugar free**

**Read all of this leaflet carefully before you start taking PATRAM Tablets**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PATRAM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **What is in this leaflet**

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

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## 1. What PATRAM is and what it is used for


PATRAM is indicated for the management of moderate to moderately-severe pain in adults.

PATRAM is not recommended for minor pain that may be treated adequately through lesser means.

## 2. What you need to know before you take PATRAM

### Do not not take PATRAM

- If you have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) after taking tramadol or paracetamol or any of the other ingredients in PATRAM (listed in section 6).
- If you experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions, see also section 4) stop using PATRAM immediately and contact your doctor.
- if you take other medicines containing paracetamol or tramadol;
- In acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)

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- If you are also taking MAO inhibitors (certain medicines used for treatment of depression or Parkinson's disease) or have taken them in the last 14 days before treatment with PATRAM.
- If you suffer from a moderate to severe liver disorder.
- If you have epilepsy that is not adequately controlled on your current medicine
- As part of treatment of withdrawal from drugs
- If you had serious head injuries or a brain disease causing pressure on your brain


### Warnings and precautions

#### Take special care with PATRAM:

Do not take more than your recommended dose;

**PATRAM contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately**

Dosages in excess of those recommended may cause severe liver damage and other problems (see possible side effects)


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**Tell your doctor or healthcare professional:**

- If you have ever had an allergic reaction (characterised by significant skin rash, itching, hives, difficulty breathing, and/or swollen face) while taking codeine or other opioids.
- If you have liver problems or liver disease or if you notice your eyes and skin turning yellow. This may suggest jaundice or problems with your bile ducts.
- 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 are taking any other medicine, because taking some medicines together with PATRAM may increase your risk of fits (seizures);
- If you have recently suffered from a head injury, shock or severe headaches associated with vomiting.
- If you are dependent on any medicines including those used to relieve pain, for example morphine or codeine.
- If you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocin, you should not take PATRAM.
- If you have a history of mental health disorder because taking PATRAM may increase your risk of dependence or abuse

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- If you are going to have an anaesthetic. Tell your doctor or dentist that you are taking PATRAM tablets.
- Do not give PATRAM to a child under 12 years of age;
- Do not give PATRAM to a child under 18 years of age that has just had an operation to remove their tonsils or adenoids.


**Other medicines with PATRAM:**

Always tell your healthcare professional if you taking any other medicine. (This includes complementary or traditional medicines).

You must not take PATRAM together with monoamine oxidase inhibitors (“MAOIs”) or within 14 days of discontinuation of it. You must also not take PATRAM together with other tramadol or paracetamol containing products.

PATRAM is not recommended to be taken with the following:

- Carbamazepine (a medicine commonly used to treat epilepsy or some types of pain such as severe pain attacks in the face called trigeminal neuralgia).
- Buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.
- Triptans (for migraine) or selective serotonin re-uptake inhibitors, “SSRIs” (for depression).

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- Tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine).
- Antidepressants, anaesthetics, neuroleptics (medicines that affect the state of mind).
- The risk of having a fit may increase. Your doctor will tell you whether PATRAM is suitable for you.
- Warfarin or other medicines for blood thinning. The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

#### **PATRAM with food and drink**

PATRAM may be taken with or without food or drink.


Do not drink alcohol during treatment with PATRAM as the effects of PATRAM and alcohol may intensify each other.

#### **Pregnancy and Breastfeeding and Fertility:**

Do not take PATRAM if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking PATRAM.

#### **Driving and using machines**

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It is not always possible to predict to what extent PATRAM may interfere with your daily activities.

You should ensure that you do not engage in the above activities until you are aware of the measure to which PATRAM affects you.

PATRAM may make you feel drowsy and this may affect your ability to drive, or use tools and machines, safely.

**PATRAM contains:**

Pregelatinized starch (Starch 1500), maize starch, sodium starch glycolate (Type A); colloidal silicon dioxide (aerosil 200); magnesium stearate.

Opadry White# (Y-1-7000) consisting of: hypromellose; titanium dioxide; polyethylene glycol

**3. How to take PATRAM TABLETS**


Do not share medicines prescribed for you with any other person.

Always take PATRAM exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for adults and children over 16 years of age is 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day. **DO NOT EXCEED THE RECOMMENDED DOSE.**

Your doctor will tell you for how long your treatment with PATRAM will last. If you have the impression that the effect of PATRAM is too strong or too weak, tell your doctor or pharmacist

*Patients with impaired kidney or liver function:*

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Do not take PATRAM if you have moderate to severe liver problems.

Tell your doctor if you have a kidney disorder (a creatinine clearance < 30 mL/min). Do not take more than 2 tablets every 12 hours.

PATRAM is not recommended for children under 16 years of age.

### **How and when should you take PATRAM**

The tablets should be swallowed whole with water and may be taken with or without food.

### **If you take more PATRAM than you should**

**In the event of overdose or suspected overdose and even if no symptoms of overdose are noticeable, you must be taken to the nearest doctor, hospital or Poison Centre immediately.**


Take this leaflet or some tablets with you so your doctor will know what you have taken.

### **If you forget to take PATRAM**

The pain is likely to return. Do not take a double dose to compensate; just wait for the next dose, and take a normal dose as prescribed by your doctor.

### **If you stop taking PATRAM**

Withdrawal symptoms may occur if PATRAM is discontinued abruptly. You may experience anxiety, nervous excitement, difficulty sleeping, excessive abnormal movements, tremor and gastrointestinal symptoms.

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Other symptoms that have very rarely been seen if tramadol hydrochloride; as contained in PATRAM is discontinued abruptly include: panic attacks, severe anxiety, hallucinations, tingling or prickling sensation and ringing in the ears

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

#### 4. Possible side-effects

PATRAM Tablets can have side effects.

Not all side effects reported for PATRAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this PATRAM, please consult your doctor, pharmacist or other healthcare professional for advice.

#### Very serious side effects:


If any of the following happens, stop taking PATRAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A skin rash (indicating an allergic reaction), sudden swelling of the face and neck, difficulty breathing or drop of blood pressure and fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to PATRAM. You may need urgent medical attention or hospitalisation.

#### Serious side effects

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following: The following side effects occur frequently:

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- Yellow skin and eyes (hepatitis)
- Irregular heartbeat that is much rapid and more pronounced than usual, increased blood pressure, pain in the chest
- Elevated liver enzymes, resulting in abdominal pain, dark urine, pale stools, weakness, fatigue.
- Feeling faint when getting up from lying down or sitting position, trouble performing routine tasks
- Difficulty swallowing, blood in stools
- Addiction
- Blurred vision

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- Confusional state, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits).
- Dizziness, excessive sleepiness, fatigue, feeling weak
- Headache, trembling.
- Nausea, vomiting, constipation, dry mouth, diarrhoea, stomach pain, indigestion, stomach gas.
- Loss of appetite;
- Itching, rash, swelling of the tongue.
- Loss of coordination, fits, abnormal muscle tension


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*Less frequent side effects*

- Itching, increased sweating,
- Shivering, hot flushes.
- Depression, seeing, hearing, smelling, tasting or imagining things, nightmares.
- Involuntary muscular contractions, feeling pins and needles (tingling or prickling sensation), loss of memory.
- Ringing in the ear.
- Rapid, strong, or irregular heartbeat, very fast heartbeat, dysrhythmia.
- Weight decrease
- Chills.
- Chest pain.
- Problems with urination.
- Difficulty breathing.
- Increase in blood pressure
- Low blood sugar.
- Drug dependence.
- Mental confusion and emotional disruption.
- Convulsions, fainting, speech disorders.
- Slurred speech, stumbling, convulsions, syncope, speech disorders.
- Vision blurred, constriction of the pupil (miosis).
- Excessive dilation of the pupils (mydriasis)
- Metabolic acidosis (nausea, vomiting, fatigue, confusion, rapid breathing)

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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.


If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### Reporting of side effects

If you get side effects, talk to your doctor; pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Suspected adverse reactions can also be reported directly to the HCR via email: [pharmacovigilance.africasme@sunpharma.com](mailto:pharmacovigilance.africasme@sunpharma.com) or tel: +27(0) 643 2000

By reporting side effects, you can help provide more information on the safety of PATRAM.

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## 5. How to store PATRAM

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light and moisture.

Do not remove the blister strips from the cartons until required for use.

Do not use the PATRAM Tablets after the expiry date which is printed on the carton and the edge of the blister.

The expiry date refers to the last day of that month.

## 6. Contents of the pack and other information

### What PATRAM contains

The active substance is tramadol and paracetamol

The other ingredients are pregelatinized starch (Starch 1500) ; maize starch; sodium starch glycolate (Type A); colloidal silicon dioxide (Aerosil 200); magnesium stearate; opadry white# (Y-1-7000) consisting of: hypromellose; titanium dioxide; polyethylene glycol

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

White to off-white, round biconvex film-coated tablets plain on both the surfaces.


PVC/PVDC-Aluminum blister strips of 100 tables. The blister are packed in a carton as 10 x 10

### Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext. 1

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