

## **TRD-CONTIN 100 (CONTROLLED RELEASE TABLETS OF TRAMADOL HYDROCHLORIDE, 100 MG)**

### **PACKAGE LEAFLET: INFORMATION FOR THE USER**

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**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, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider or pharmacist.

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

1. What TRD-Contin 100 is and what it is used for?
2. What you need to know before you take TRD-Contin 100?
3. How to take TRD-Contin 100?
4. Possible side effects?
5. How to store?
6. Contents of the pack and other information

#### **1. What TRD-Contin 100 tablets is and what it is used for?**

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TRD-Contin 100 is used to relieve moderate to severe pain. It belongs to the group of medicines called analgesics (pain relievers). TRD-Contin 100 tablets are designed to release the active medicine gradually over several hours.

TRD-Contin 100 is available only on a doctor's prescription.

TRD-Contin 100 is for use in adults and children over 12 years of age.

#### **2. What you need to know before you take TRD-Contin 100 tablets?**

##### **Do not take TRD-Contin 100 if you:**

**You have an allergy to any of the ingredients (see Product description section below)**

- you have an allergy to any other medicines known as opioid analgesics, e.g. morphine or codeine.
- you have taken large amounts of alcohol or other substances which can affect your level of consciousness. Some examples of these substances include sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)
- you are taking medicine for depression containing a "monoamine oxidase inhibitor" also known as MAOI, or have taken any within the past two weeks.
- you have uncontrolled epilepsy or if your epilepsy is not well controlled by treatment.
- you are younger than 12 years old or if you are between 12 – 18 years of age and are recovering from an operation to remove your tonsils and/or adenoids.
- you are having treatment for withdrawal from narcotics.

## **Warnings and Precautions**

Talk to your doctor or pharmacist before taking TRD-Contin 100 if:

- You think that you are addicted to other pain relievers (opioids);
- You suffer from consciousness disorders (if you feel that you are going to faint);
- You are in a state of shock (cold sweat may be a sign of this);
- You suffer from increased pressure in the brain (possibly after a head injury or brain disease);
- You suffer from a liver or kidney disease;
- You have difficulty in breathing;
- You have a tendency towards epilepsy or fits because the risk of a fit may increase.

Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg). Please note that TRD-Contin 100 Tablets may lead to physical and psychological addiction. When TRD-Contin 100 Tablets are taken for a long time, its effect may decrease, so that higher doses have to be taken (tolerance development). In patients with a tendency to abuse medicines or who are dependent on medicines, treatment with TRD-Contin 100 tablets should only be carried out for short periods and under strict medical supervision. Please also inform your doctor if one of these problems occurs during treatment with TRD-Contin 100 Tablets or if they applied in the past.

### **Taking Other medicines with TRD-Contin 100 tablets.**

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. TRD-Contin 100 Tablets should not be taken together with MAO inhibitors (certain medicines for the treatment of depression).

The pain-relieving effect of TRD-Contin 100 Tablets may be reduced and the length of time it acts may be shortened, if you also take medicines containing:

- Carbamazepine (for epileptic fits)
- Buprenorphine, nalbuphine, or pentazocine (pain killers)
- Ondansetron (prevents nausea)

Your doctor will tell you whether you should take TRD-Contin 100 Tablets and what dose.

The risk of side effects increases:

- if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics, the risk of having a fit may increase if you take TRD-Contin 100 Tablets at the same time. Your doctor will tell you whether TRD-Contin 100 Tablets are suitable for you.
- if you are taking certain antidepressants. TRD-Contin 100 Tablets may interact with these medicines, and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension and body temperature above 38°C.
- if you take coumarin anticoagulants (medicines for blood thinning), such as warfarin, together with TRD-Contin 100 Tablets. The effect of these medicines on blood clotting may be affected and bleeding may occur.
- if you take tranquillizers, sleeping pills, other pain relievers such as morphine, codeine (also as cough medicine), or alcohol while you are taking TRD-Contin 100 Tablets. You may feel drowsier or feel that you might faint. If this happens tell your doctor.

**Taking TRD-Contin 100 Tablets with food and alcohol:**

Do not drink alcohol during treatment with TRD-Contin 100 Tablets as its effect may be intensified. Food does not influence the effect of TRD-Contin 100 Tablets.

**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.

There is very little information regarding the safety of tramadol in human pregnancy. Therefore, you should not use TRD-Contin 100 Tablets if you are pregnant. Chronic use during pregnancy may lead to withdrawal symptoms in new-borns.

Generally, the use of TRD-Contin 100 Tablets is not recommended during breast-feeding. Small amounts of tramadol are excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. Please ask your doctor for advice.

**Driving and using machines**

TRD-Contin 100 Tablets can cause drowsiness, dizziness, and blurred vision and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicle, do not use electric tools or operate 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:
  - o the medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - o 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 TRD-Contin 100 Tablets?**

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Always use this medicine exactly as your doctor or pharmacist 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. Unless otherwise prescribed by your doctor, the recommended dose is:

#### **Adults:**

One to two TRD-Contin 100 mg tablets twice daily (corresponding to 200 - 400 mg tramadol hydrochloride). The total daily dose should not exceed 400 mg of tramadol hydrochloride, except in special clinical circumstances.

#### **Children**

Safety and efficacy of TRD-Contin tablets in children has not been established. Therefore, use of TRD-Contin in the paediatric population is not recommended.

#### **Elderly patients**

In general, dose selection for an elderly patient should be cautious, usually starting at the lower end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or other drug therapy. In patients over 75 years of age, daily doses in excess of 300 mg are not recommended.

#### **Renal insufficiency**

In all patients with creatinine clearance less than 30 mL/min, a prolonged dosage interval should be taken into consideration, with a maximum daily dose of 200 mg.

Since only 7% of an administered dose is removed by haemodialysis of 4-hour duration, dialysis patients can receive their regular dose on the day of dialysis. The recommended dose for adult patients with cirrhosis is 50 mg every 12 hours.

Administration of tramadol is not related to food intake. TRD-Contin 100 Continus tablets should not be chewed or crushed. For dosage flexibility, TRD-Contin 100 Continus tablets may be broken into two equal halves along the score line indicated on each tablet.

#### **If you take more TRD-Contin 100 tablets than recommended**

If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed. After taking very high doses, pin-point pupils, vomiting, fall in blood pressure, fast heartbeat, collapse, disturbed consciousness up to coma (deep unconsciousness), epileptic fits, and difficulty in breathing up to cessation of breathing may occur. In such cases a doctor should be called immediately!

#### **If you forget to take TRD-Contin 100 tablets**

If you forgot 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 tablets as before.

#### **If you stop taking TRD-Contin 100 tablets**

If you interrupt or finish treatment with TRD-Contin 100 Tablets too soon, pain is likely to return. If you wish to stop treatment on account of unpleasant effects, please tell your doctor. Generally, there will be no after – effects when treatment with TRD-Contin 100 Tablets is stopped. However, on rare occasions, people who have been taking TRD-Contin 100 Tablets for some time may feel unwell if they abruptly stop taking them. They may feel agitated,

anxious, nervous or shaky. They may be confused, hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may get panic attacks, hallucinations, delusions, paranoia or feeling a loss of identity. They may experience unusual perceptions such as itching, tingling and numbness, and “ringing” in the ears (tinnitus). Further unusual CNS symptoms, i.e. confusion, delusions, change of perception of their own personality (depersonalisation), and change in perception of reality (derealisation) and delusion of persecution (paranoia) have been seen very rarely. If you experience any of these complaints after stopping TRD-Contin 100 Tablets, please consult your doctor.

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

#### **4. Possible side effects?**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Usually, the frequency of side effects is classified as follows:

- very common (may affect more than 1 in 10 people),
- common (may affect up to 1 in 10 people),
- uncommon (may affect up to 1 in 100 people),
- rare (may affect up to 1 in 1,000 people)
- very rare (may affect up to 1 user in 10,000)
- not known (frequency cannot be estimated from the available data).

You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing or hives together with difficulties in breathing.

The most common side effects during treatment with TRD-Contin 100 Tablets are nausea and dizziness, which occur in more than in 1 in 10 patients.

#### Heart and blood circulation disorders

Uncommon: effects on the heart and blood circulation (pounding of the heart, fast heartbeat, feeling faint or collapse). These adverse effects may particularly occur in patients in an upright position or under physical strain.

Rare: slow heartbeat, increase in blood pressure.

#### Metabolism and nutrition disorders

Not known: decrease in blood sugar level.

#### Nervous system disorders

Very common: dizziness.

Common: headaches, drowsiness.

*Rare:* changes in appetite, abnormal sensations (e.g. itching, tingling, numbness), trembling, slow breathing, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope).

If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down. Epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.

Not known: speech disorders

#### Psychiatric disorders

Rare: hallucinations, confusion, sleep disorders, anxiety and nightmares.

Psychological complaints may appear after treatment with TRD-Contin 100 Tablets. Their intensity and nature may vary (according to the patient 's personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (slowing down but sometimes an increase in activity) and being less aware and less able to make decisions, which may lead to errors in judgment.

Dependence may occur.

#### Eye disorders

Rare: blurred vision

Not known: extreme pupil dilation (mydriasis).

#### Respiratory disorders

Rare: shortness of breath (dyspnoea).

Worsening of asthma has been reported, however it has not been established whether it was caused by tramadol.

#### Stomach and bowel disorders

Very common: feeling sick (nausea).

Common: being sick, constipation, dry mouth.

Uncommon: urge to vomit (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhoea.

#### Skin disorders

Common: sweating.

Uncommon: skin reactions (e.g. itching, rash).

#### Muscle disorders

Rare: weak muscles.

#### Liver and biliary disorders

Very rare: increase in liver enzyme values.

#### Urinary disorders

Rare: passing urine with difficulty or pain, passing less urine than normal

#### General disorders

Common: fatigue.

#### Immune system disorders

Rare: allergic reactions (e.g. difficulty breathing, wheezing, swelling of the skin) and shock (sudden circulatory failure) come in very rare cases.

If TRD-Contin 100 Tablets are taken over a long period of time dependence may occur, although the risk is very low. When treatment is stopped abruptly signs of withdrawal may appear.

## **5. How to store TRD-Contin 100 Tablets?**

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

Store at or below 30° C, in a dry place, protected from light.

Do not use this medicine after the expiry date which is stated on the carton and on the strip of medicine.

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

## **6. Other information**

### **What TRD-Contin 100 Tablets contains?**

- Each film-coated tablet contains:  
Tramadol Hydrochloride BP 100mg  
(in a controlled release system)  
Colour: Titanium Dioxide
- The other ingredients are Cetostearyl Alcohol, Lactose, Ethyl Cellulose, Talc, Magnesium Stearate, Opadry white 31F58914, Purified water.

### **What TRD-Contin 100 tablets looks like and contents of the pack?**

White, biconvex, scored, film-coated caplets of a controlled-release formulation engraved with 'MM' logo on one of the facets.

**Presentation:** Box of 50 Tablets (5x10's blister strips)

### **Manufactured by:**

Modi-Mundipharma Pvt. Ltd.

Modipuram – 250 110

U.P., India

**Registration No.:** Rwanda FDA-HMP-MA-1946

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