PATIENT INFORMATION LEAFLET

TAMOLTRA

SCHEDULING STATUS

S5

PROPRIETARY NAME AND DOSAGE FORM

TAMOLTRA film coated tablets

Please read all of this leaflet carefully before you start taking **TAMOLTRA**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **TAMOLTRA** 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.

1. WHAT TAMOLTRA CONTAINS

- The active substances are tramadol hydrochloride 37,5 mg and paracetamol 325 mg.
  - The other ingredients are magnesium stearate, microcrystalline cellulose, Opadry yellow (hypromellose, polyethylene glycol, polysorbate 80, titanium dioxide and yellow iron oxide), pregelatinised starch, sodium starch glycolate.

  Sugar free.

2. WHAT TAMOLTRA IS USED FOR

TAMOLTRA is used for the treatment of moderate to moderately severe pain in adults.

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3. BEFORE YOU TAKE TAMOLTRA

Do not take **TAMOLTRA**

- If you have any hypersensitivity to tramadol, paracetamol or other opioids such as codeine or any ingredient of **TAMOLTRA** (see **WHAT TAMOLTRA CONTAINS**)
- If you have a severe liver disorder
- If you have been drinking alcohol
- If you have been using any medicines for sleep disorders, anxiety, severe pain or other medicines that affect your nervous system
- If you are receiving a monoamine oxidase inhibitor (MAOIs) for the treatment of depression or have been using one within the last 14 days
- If you have a lung disorder
- If you experienced a head injury recently

Take special care with TAMOLTRA

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

- Dosages in excess of those recommended may cause severe liver damage
- If you are taking any other medications containing tramadol, paracetamol, anaesthetic substances, phenothiazines (used for mental disorders), tranquilizers and sedative hypnotics

- If you are taking any other medications containing tramadol, paracetamol, anaesthetic substances, phenothiazines (used for mental disorders), tranquilizers and sedative hypnotics
- If you have a history of addiction or dependence, especially to medicines of the same class as tramadol (opioids)
- If you are taking any other medicines for depression
- If you have seizures and/or convulsions
- If you use alcohol excessively
- In the event of reduced consciousness for unknown reasons, respiratory disorders and patients suffering from emotional disturbances, **TAMOLTRA** should be taken with extreme caution
- If you have kidney or liver problems.

Taking TAMOLTRA with food and drink

Do not take **TAMOLTRA** with any alcohol containing beverages.

Pregnancy and breastfeeding

Do not take **TAMOLTRA** while you are breastfeeding, as small amounts of tramadol may pass into the breast milk. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking this medicine.

Driving and using machines

Your ability to drive or operate machinery may be affected by **TAMOLTRA**. This may be

worsened by other medicines affecting your nervous system or alcohol. Do not drive or operate machines because **TAMOLTRA** could interfere with your ability to do so safely.

Taking other medicines with TAMOLTRA

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

Please consult your healthcare provider for advice if you are taking any of the following medication:

Combinations containing any of the following medications may interact with **TAMOLTRA** tablets:

- Carbamazepine (used for the management of epilepsy or seizures)
- Fluoxetine or paroxetine (used to treat depression), quinidine (used to stabilize your heart rhythm) and amitriptyline (used to treat depression)
- Cimetidine (used to treat stomach ulcers or heartburn)
- Monoamine Oxidase Inhibitors (used to treat depression) or 14 days after stopping treatment
- Digoxin (used to treat heart disorders)
- Warfarin (used to “thin” the blood)
- Diflunisal (a pain killer)
- Lithium, tricyclic antidepressants and SSRIs, medicines used in depression
- Triptans (medicines for migraine)
- Metoclopramide (used for nausea)
- Cholestyramine (used to “lower” cholesterol).

Do not use **TAMOLTRA** with other medication that contains tramadol and paracetamol.

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4. HOW TO TAKE TAMOLTRA

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

Always take **TAMOLTRA** exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure on how to use your medicine.

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose is:

For use in adults and children over the age of 16 years.

Take 1 to 2 tablets every 4 to 6 hours as instructed.

Do not take more than 8 tablets in 24 hours.

Your doctor will adjust your dose if you have a kidney disorder.

If you have the impression that the effect of **TAMOLTRA** is too strong or too weak, talk to your doctor or pharmacist.

If you take more TAMOLTRA than you should

In the event of overdosage, consult your doctor or pharmacist.

If neither is available, seek help at the nearest hospital or poison control centre. Immediate treatment is essential.

Please refer to the information on paracetamol overdosage under **Take special care with TAMOLTRA**.

If you forget to take a dose of TAMOLTRA

If you miss a dose of **TAMOLTRA**, take it as soon as you remember.

However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not take a double dose to make up for the forgotten individual dose(s).

Effects when treatment with TAMOLTRA is stopped

If **TAMOLTRA** is abruptly discontinued, withdrawal symptoms may occur, such as panic attacks, severe anxiety, hallucinations, paraesthesia (abnormal physical sensation), tinnitus (ringing in the ears), and unusual central nervous system symptoms. These symptoms may be relieved by tapering **TAMOLTRA** instead of abruptly stopping treatment.

5. POSSIBLE SIDE EFFECTS

TAMOLTRA can have side effects.

Not all side effects reported for **TAMOLTRA** are included in this leaflet. Should your general health worsen, or of you experience any untoward effects while taking **TAMOLTRA**, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

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

- unexpected or prolonged bleeding when using **TAMOLTRA** with medicines used to thin the blood (e.g. warfarin)
- increase in pulse or blood pressure, heart rate or heart rhythm disorders
- shivering, hot flushes, pain in the chest
- difficulty breathing
- feeling faint when getting up from a lying or sitting position, slow heart rate, fainting
- worsening of existing asthma.

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

Tell your doctor if you notice any of the following:

- nausea
- dizziness, drowsiness
- vomiting (being sick), digestion problems (constipation, flatulence, diarrhoea, stomach pain), dry mouth
- sweating
- headache, shaking
- confusion, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits)
- difficulty or pain when urinating

- 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
- fits, uncoordinated movements
- addiction – becoming dependant on **TAMOLTRA**
- blurred vision
- 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
- nose bleeds or bleeding gums, which may result from low platelet count.

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

6. STORAGE AND DISPOSAL OF TAMOLTRA

Store at or below 30 °C in a cool, dry place.

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Store all medicine out of reach of children.

Store in the original container.

Keep the blisters in the carton until required for use.

Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).