APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

TAMOLTRA film coated tablet

Tramadol hydrochloride 37,5 and Paracetamol 325 mg

TAMOLTRA FORTE film coated tablet

Tramadol hydrochloride 75 mg and Paracetamol 650 mg

Sugar free

Read all of this leaflet carefully before you start taking/using TAMOLTRA or TAMOLTRA FORTE

- keep this leaflet. You may need to read it again.
- if you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider
- TAMOLTRA or TAMOLTRA FORTE 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

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1. What TAMOLTRA or TAMOLTRA FORTE is and what it is used for

TAMOLTRA and TAMOLTRA FORTE contain tramadol hydrochloride and paracetamol.

Tramadol hydrochloride is a painkiller belonging to the class of the opioids that acts on the central nervous system. It is used for the management of moderate to moderately severe pain.

Paracetamol, the other active substance, has centrally acting analgesic effects.

TAMOLTRA and TAMOLTRA FORTE are used for the treatment of moderate to moderately severe pain in adults.

TAMOLTRA and TAMOLTRA FORTE are not recommended for minor pain that may be treated adequately through lesser means. Your doctor will decide whether you qualify for treatment with TAMOLTRA or TAMOLTRA FORTE.

2. What you need to know before you take TAMOLTRA or TAMOLTRA FORTE

Do not take TAMOLTRA or TAMOLTRA FORTE:

- if you are hypersensitive (allergic) to tramadol, paracetamol or other opioids such as codeine or to any of the ingredients of TAMOLTRA OR TAMOLTRA FORTE (listed in section 6)

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- if you have a severe liver disorder
- if you have been drinking alcohol
- if you are taking sleeping pills, pain relievers or medicines that affect mood and emotions
- if you are also taking medicines such as tranylcypromine and moclobemide or have taken them in the last 14 days before treatment with TAMOLTRA or TAMOLTRA FORTE. These medicines are used to treat depression and belong to a group called monoamine oxidase inhibitors (MAOIs)
- TAMOLTRA or TAMOLTRA FORTE must not be used for narcotic (an addictive substance) withdrawal treatment
- you should not take TAMOLTRA or TAMOLTRA FORTE if you suffer from severe breathing problems
- you should not take TAMOLTRA or TAMOLTRA FORTE if you are suffering from increased intracranial pressure or central nervous system depression (due to head injury), which are characterised by decreased rate of breathing, decreased heart rate, and loss of consciousness
- if you have epilepsy, which is not adequately controlled by your current medicine.

Warnings and precautions

Take special care with TAMOLTRA or TAMOLTRA FORTE:

TAMOLTRA and TAMOLTRA FORTE contain 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
- if you take other medicine containing paracetamol or tramadol, anaesthetic substances, phenothiazines (used for mental disorders), tranquilizers and sedative hypnotics
- If you are taking any other medicines for depression
- if you have severe kidney problems
- if you have liver problems or disease, as your eyes and skin may turn yellow, which may suggest jaundice
- if you have severe difficulty in breathing, for example asthma or severe lung problems
- if you have a history of addiction or dependence, especially to medicines of the same class as tramadol (opioids).

  The possibility of addiction or dependence increases if you have a personal or family history of substance abuse or if you have been diagnosed with a mental health disorder
- if you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine

- in the event of reduced consciousness for unknown reasons, respiratory disorders and patients suffering from emotional disturbances, shock, breathing problems or alcohol abuse, TAMOLTRA and TAMOLTRA FORTE should be taken with extreme caution
- if you have epilepsy or have experienced fits or seizures
- if you develop any skin reactions whilst taking TAMOLTRA or TAMOLTRA FORTE (flu-like symptoms appearing first, followed by a painful rash that spreads and blisters), stop taking TAMOLTRA or TAMOLTRA FORTE and immediately report to your doctor
- tramadol exerts its effect by converting (metabolising) into its active component. If you convert (metabolise) tramadol to this active component more rapidly and completely than other patients, you are known as an ultra-rapid metaboliser. This means you are more likely to have serious side effects, such as breathing difficulties, with slow or shallow breathing. If you experience these types of side effects, stop taking TAMOLTRA and TAMOLTRA FORTE and consult with your doctor immediately
- while taking TAMOLTRA and TAMOLTRA FORTE you may experience low levels of sodium in your blood (hyponatraemia). Symptoms may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you experience any of these symptoms while taking TAMOLTRA and TAMOLTRA FORTE, consult your doctor immediately

- if you are going to have an anaesthetic (tell your doctor or dentist that you are taking this medicine)
- TAMOLTRA and TAMOLTRA FORTE should not be taken with alcohol containing beverages.

Addiction:

If you take TAMOLTRA or TAMLOTRA FORTE for extended periods, you may become dependent on (addicted to) the tramadol it contains. You may crave TAMOLTRA or TAMOLTRA FORTE even in the absence of pain and you may have to use higher doses to get the same effect. If you have been diagnosed with addiction to opioid medicines or drugs (e.g., heroin, morphine, codeine), you should not take TAMOLTRA or TAMOLTRA FORTE. Please inform your doctor.

Withdrawal symptoms:

If you abruptly stop treatment with TAMOLTRA or TAMOLTRA FORTE, especially if you have been taking it for an extended period, you may experience withdrawal effects. You may suffer from panic attacks, severe anxiety (feeling nervous or worried), hallucinations (hearing or seeing things that are not there), paraesthesia (burning or prickling sensation that is usually felt in the hands, arms, legs, or feet) and tinnitus (ringing or buzzing in the ears).

Your doctor will gradually decrease your dose of TAMOLTRA or TAMOLTRA FORTE to prevent these side effects from occurring

Serotonin syndrome

If you take TAMOLTRA or TAMOLTRA FORTE with other medicines that influence serotonin levels in the body, you may develop serotonin syndrome (see Taking other medicines with TAMOLTRA or TAMOLTRA FORTE for a list of medicines that you should not combine with TAMOLTRA or TAMOLTRA FORTE). If you develop loose stools, fever, agitation, sweating, confusion, shivering, a rapid heart rate, excitation, or alteration in consciousness, stop taking TAMOLTRA or TAMOLTRA FORTE and immediately report to your doctor.

Sleep-related breathing disorders

TAMOLTRA and TAMOLTRA FORTE contain an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnoea (shallow/pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen in the blood). 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.

Children

TAMOLTRA and TAMOLTRA FORTE are only for use in children 16 years of age and older.

Other medicines and TAMOLTRA or TAMOLTRA FORTE

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

TAMOLTRA and TAMOLTRA FORTE should not be administered with the following:

- a group of antidepressants called Monoamine Oxidase (MAO) inhibitors, such as moclobemide and tranylcypromine, or for 14 days after stopping treatment (see Do not take TAMOLTRA or TAMOLTRA FORTE). When taken together with TAMOLTRA and TAMOLTRA FORTE it can cause diarrhoea, tachycardia (irregular heartbeat), hyperhidrosis (excessive sweating), trembling, confusional state and even coma.

TAMOLTRA and TAMOLTRA FORTE is not recommended to be taken with the following:

- alcohol
- carbamazepine (used to treat seizures). When taken together with TAMOLTRA and TAMOLTRA FORTE it can cause reduced efficacy and shorter duration due to decreased concentration of tramadol
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The effects of these medicines may be decreased.

Caution is advised when the following medicines are given with TAMOLTRA or TAMOLTRA FORTE:

- tramadol can induce convulsions and increase the potential for certain

antidepressants (such as citalopram, escitalopram, paroxetine, duloxetine, venlafaxine and amitriptyline, antipsychotics) and seizure threshold-lowering medicinal products (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions

- concomitant therapeutic use of tramadol and citalopram, escitalopram, paroxetine, duloxetine, venlafaxine and amitriptyline, moclobemide and tranylcypromine and mirtazapine may cause serotonin toxicity. Symptoms include 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 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, as well as sedative medicines such as benzodiazepines (alprazolam, diazepam, lorazepam) or related medicines with TAMOLTRA and TAMOLTRA FORTE, as there is an increased risk of drowsiness, difficulties in breathing (respiratory depression), coma which may be life-threatening.
- if you are taking warfarin (for blood thinning). The effectiveness of this medicine may be altered, and bleeding may occur
- cimetidine (used to treat stomach ulcers or heartburn)
- if you are taking digoxin used to treat heart problems
- if you are taking diflunisal used for pain.

- metoclopramide or ondansetron (used for nausea)
- if you are taking ondansetron used to treat vomiting.

TAMOLTRA or TAMOLTRA FORTE with food, drink and alcohol

Do not drink alcohol during treatment with TAMOLTRA and TAMOLTRA FORTE as the effects of TAMOLTRA and TAMOLTRA FORTE and alcohol may intensify each other. See section 3.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

TAMOLTRA and TAMOLTRA FORTE must not be taken during pregnancy.

TAMOLTRA and TAMOLTRA FORTE must not be taken during breastfeeding, as small amounts of tramadol may pass into the breast milk.

Driving and using machines

Your ability to drive or operate machinery may be affected by TAMOLTRA or TAMOLTRA FORTE, as it may cause drowsiness or dizziness. This may be worsened by other medicines affecting your nervous system or alcohol. Do not drive or operate machines

because TAMOLTRA or TAMOLTRA FORTE could interfere with your ability to do so safely.

It is not always possible to predict to what extent TAMOLTRA or TAMOLTRA FORTE may interfere with the daily activities of a patient.

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TAMOLTRA or TAMOLTRA FORTE affects them.

3. How to take TAMOLTRA or TAMOLTRA FORTE

Do not share medicines prescribed for you with any other person. Always use TAMOLTRA or TAMOLTRA FORTE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

DO NOT EXCEED THE RECOMMENDED DOSE.

- swallow the tablets whole with sufficient liquid
- do not break or chew the tablets
- you may take TAMOLTRA or TAMOLTRA FORTE at any time of the day with or without food.

Adults:

TAMOLTRA: The usual dose is 1 or 2 tablets every 4 to 6 hours, unless otherwise prescribed by your doctor. If required, further doses may be taken, as instructed by your doctor.

Do not take more than 8 tablets per day.

TAMOLTRA FORTE: The usual dose is 1 tablet every 4 to 6 hours, unless otherwise prescribed by your doctor. If required, further doses may be taken, as instructed by your doctor.

Do not take more than 4 tablets per day.

Patients with kidney or liver disease

Do not take TAMOLTRA or TAMOLTRA FORTE if you have 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.

Children:

TAMOLTRA tablets are not indicated for use in children under the age of 16 years as safety and efficacy have not been established.

TAMOLTRA FORTE tablets are not indicated for use in children under the age of 18 years as safety and efficacy have not been established.

Your doctor will tell you how long your treatment with TAMOLTRA or TAMOLTRA FORTE will last.

If you have the impression that the effect of TAMOLTRA or TAMOLTRA FORTE is too strong or too weak, tell your doctor or pharmacist.

If you take more TAMOLTRA or TAMOLTRA FORTE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed, serious liver damage from too much paracetamol. Your kidneys can also become damaged in the absence of liver damage.
A delay in starting treatment may mean that the antidote is given too late to be effective.
Please refer to the information on paracetamol overdosage under “Take special care with TAMOLTRA or TAMOLTRA FORTE”.

Symptoms of overdose may include:

- tramadol overdose: breathing difficulties, seizures
- paracetamol overdose: an unhealthy pale appearance, nausea, vomiting, severe weight loss (anorexia), stomach pain, liver damage, kidney failure, metabolic acidosis (too much acid in the body fluids), irregular heartbeat.

If you forget to take TAMOLTRA or TAMOLTRA FORTE

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TAMOLTRA or TAMOLTRA FORTE

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

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

4. Possible side effects

TAMOLTRA or TAMOLTRA FORTE can have side effects.

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

If any of the following happens, stop using TAMOLTRA or TAMOLTRA FORTE 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 or TAMOLTRA FORTE. You may need urgent medical attention or hospitalisation.

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

- increased bleeding time - unexpected or prolonged bleeding when using TAMOLTRA or TAMOLTRA FORTE with medicines used to thin the blood (e.g. warfarin)
- irregular heartbeat that is much more rapid and more pronounced than usual, increase in blood pressure, rapid, strong, or irregular heartbeat, very fast heartbeat, dysrhythmia
- elevated liver enzymes, resulting in abdominal pain, dark urine, pale stools, weakness, fatigue
- chills, chest pain, hot flushes
- if your liver is inflamed - symptoms may include stomach pain or yellowing of the skin and whites of the eyes (hepatitis)
- difficulty breathing, slower or weaker breathing
- feeling faint when getting up from a lying or sitting position, slow heart rate
- worsening of existing asthma
- hallucinations (seeing or hearing things that are not there), depression, memory lapses, suicidal thoughts, amnesia, delirium, addiction (becoming dependent on TAMOLTRA or TAMOLTRA FORTE), unusual thoughts
- inability to completely empty the bladder, kidney failure
- serious skin disorders including Stevens-Johnson Syndrome/ toxic epidermal

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necrolysis (TEN) with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, skin sores and peeling of the skin, which could be fatal.

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), anorexia
- dizziness, excessive sleepiness, headache, trembling
- nausea, vomiting, constipation, dry mouth, diarrhoea, stomach pain, indigestion, stomach gas
- skin rash, sweating.

Less frequent side effects:

- low number of red blood cells (anaemia)
- impotence, nightmares
- the loss of full control of bodily movements, fits, uncoordinated movements (stumbling), muscle weakness, muscle tension, migraine, aggravated migraine, tingling, numbness or feeling of pins and needles in the limbs, involuntary muscle twitching, speech disorders, slurred speech, spinning sensation and loss of balance, inability to act or think normally
- vision blurred, constriction of the pupil (miosis), excessive dilation of the pupils

(mydriasis), abnormal vision

- ringing in the ear
- shortness of breath
- difficulty swallowing, coughing or choking when eating or drinking, bringing food back up, sometimes through the nose, inability to chew properly, blood in the stools, tongue swelling
- if your pancreas is inflamed - symptoms may include upper abdominal pain, abdominal pain that radiates to your back, tenderness when touching the abdomen, fever, rapid pulse, nausea and vomiting (acute pancreatitis)
- skin reactions (for example rashes, hives)
- problems with urination, difficulty or pain when urinating, abnormal urine test results, kidney stones
- nose bleeds or bleeding gums, which may result from low platelet count, bruising, prolonged bleeding with injury
- changes in appetite, weakness, weight loss.

The following side effects have been reported but the frequency for them to occur is not known:

- low blood sugar, low sodium levels in the blood (with symptoms that include nausea, headache, confusion and fatigue), water retention

- Serotonin syndrome (symptoms include high body temperature, sweating, shivering, clumsiness, tremors, and confusion and other mental changes, diarrhoea, vomiting, overactive reflexes and muscle spasms)
- hiccups
- drug withdrawal syndrome (symptoms include agitation, anxiety, nervousness, insomnia, facial movements, slow uncontrolled movements, jerking movements, abnormal gait, tremor, stomach problems, panic attacks, severe anxiety, hallucinations, pins and needles, ringing in the ears).

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 or 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.

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

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store TAMOLTRA or TAMOLTRA FORTE

Store all medicines out of reach of children.

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

TAMOLTRA FORTE: Store at or below 25 °C in a cool, dry place.

Keep the blisters in the carton until required for use.

Do not store in a bathroom

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What TAMOLTRA or TAMOLTRA FORTE contains

The active ingredients are tramadol and paracetamol.

TAMOLTRA: Each film coated tablet contains tramadol hydrochloride

37,5 mg and paracetamol 325 mg.

TAMOLTRA FORTE: Each film coated tablet contains tramadol hydrochloride 75 mg and paracetamol 650 mg.

Sugar free.

The other ingredients are:

Tablet core:

Magnesium stearate, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate (Type A).

TAMOLTRA film coating: Opadry Yellow 15B82958 composition:

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Hypromellose, polyethylene glycol 400, polysorbate 80, titanium dioxide (C.I. 77891) and yellow iron oxide (C.I. 77492).

TAMOLTRA FORTE film coating: Opadry Yellow 15B82958 composition: Hypromellose, macrogol 400 (polyethylene glycol), polysorbate 80, titanium dioxide, yellow iron oxide and iron oxide red E172.

What TAMOLTRA or TAMOLTRA FORTE looks like and contents of the pack

TAMOLTRA: Slightly yellow-brown, oval, convex film coated tablets.

TAMOLTRA FORTE: Slightly orange, oval, biconvex film coated tablets widely scored on both sides.

TAMOLTRA is available in blister packs consisting of PVC/PVDC, white film and aluminium foil, with 20, 30 or 60 tablets packed in an outer carton.

TAMOLTRA FORTE is available in blister packs consisting of PVC/PVDC, white film and aluminium foil, 10, 20, 30, 40, 50, 60, 70, 80, 90 or 100 tablets packed in an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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