PATIENT INFORMATION LEAFLET

TAMOLTRA and TAMOLTRA FORTE

SCHEDULING STATUS

S5

1. NAME OF THE MEDICINE

TAMOLTRA 37,5/325 mg film coated tablets

TAMOLTRA FORTE 75/650 mg film coated tablets

Tramadol hydrochloride and Paracetamol

Sugar free

Read all of this leaflet carefully before you start taking 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

1. What TAMOLTRA and TAMOLTRA FORTE are and what they are used for

TAMOLTRA and TAMOLTRA FORTE contains tramadol hydrochloride and paracetamol (two

analgesics). Tramadol hydrochloride belongs to a class of medicines called opioids, which are 'pain relievers'.

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

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 and TAMOLTRA FORTE (see section 6)
- if you have a severe liver disorder
- if you have been drinking alcohol
- if you are taking any medicines for sleep disorders, anxiety, severe pain or other medicines that affect nervous system
- if you are receiving a monoamine oxidase inhibitor (MAOI) for the treatment of depression or have been taking one within the last 14 days
- if you have a lung disorder
- if you have recently experienced a head injury.

Warnings and precautions

Take special care with TAMOLTRA and TAMOLTRA FORTE:

TAMOLTRA and TAMOLTRA FORTE contain 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, phenothiazines (used for mental disorders), tranquilizers and sedative hypnotics

- if you are going to have an anaesthetic (tell your doctor or dentist that you are taking this medicine)
- 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 or TAMOLTRA FORTE should be taken with extreme caution
- if you have kidney or liver problems or are suffering from shock
- if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- if you feel you need to take more of this medicine to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever
- 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
- **t**aking this medicine regularly, particularly for a long time, can lead to **addiction. Your doctor or healthcare provider will explain how long you** will be taking it for, and when it is appropriate to stop, how to do this safely

- rarely, TAMOLTRA or TAMOLTRA FORTE can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Children

Do not give TAMOLTRA or TAMOLTRA FORTE to children under the age of 18 years because it is unlikely to be safe.

Other medicines and TAMOLTRA or TAMOLTRA FORTE

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

You must not take TAMOLTRA and TAMOLTRA FORTE together with monoamine oxidase inhibitors ("MAOIs") (see section Do not take TAMOLTRA and TAMOLTRA FORTE).

Do not use TAMOLTRA or TAMOLTRA FORTE with other medicines that contains tramadol and paracetamol.
Please consult your healthcare provider for advice if you are taking any of the following medicine.
TAMOLTRA and TAMOLTRA FORTE is not recommended with the
following medicines as it may affect how well they work:

- 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)
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers) as the pain-relieving effect may be reduced.

TAMOLTRA and TAMOLTRA FORTE may increase the risk of side effects if you also take the following medicines:

- fluoxetine or paroxetine (used to treat depression), quinidine (used to stabilize your heart

rhythm) and amitriptyline (used to treat depression)

- warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered, and bleeding may occur
- digoxin (used to treat heart disorders)
- diflunisal (a pain killer)
- triptans (medicines for migraine)
- lithium, tricyclic antidepressants and SSRIs, medicines used in depression. TAMOLTRA and TAMOLTRA FORTE 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, body temperature above 38 °C
- tranquilizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant), medicines used to lower blood pressure, antidepressants or medicines to treat allergies (antihistamines) increase the risk of drowsiness and breathing difficulties (respiratory depression)
- medicines which may cause convulsions (fits), such as certain antidepressants, antipsychotics, anaesthetics, medicines that affect the state of mind, or bupropion (used to help stop smoking) as the risk of having a fit may increase.

The effectiveness of TAMOLTRA and TAMOLTRA FORTE may be altered if you also take the following medicines:

- cimetidine (used to treat stomach ulcers or heartburn)
- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick)
- cholestyramine (used to lower cholesterol in the blood)
- ketoconazole or erythromycin (medicines used against infections).

TAMOLTRA and TAMOLTRA FORTE with food and drink

Do not drink alcohol or any alcohol containing beverages while you are taking this medicine, as you may feel drowsy.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking TAMOLTRA or TAMOLTRA FORTE.

Do not take TAMOLTRA or TAMOLTRA FORTE while you are 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 and TAMOLTRA FORTE as they may make you sleepy or dizzy. 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 your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which TAMOLTRA or TAMOLTRA FORTE affects you.

3. How to take TAMOLTRA and TAMOLTRA FORTE

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

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose is:

For use in adults and children over the age of 18 years:

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

Do not take more than 8 tablets in 24 hours.

TAMOLTRA FORTE: Take 1 tablet every 4 to 6 hours as instructed.

Do not take more than 4 tablets in 24 hours.

Take the tablets with a glass of liquid, preferably water.

The tablets can be swallowed (or you can halve the TAMOLTRA FORTE) with a glass of liquid, preferably water. Do not crush or chew the tablets.

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

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

Do not stop treatment abruptly because you may experience unwanted withdrawal symptoms. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

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 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 control centre.

Symptoms of overdose may include:

- drowsiness, difficulty breathing, coma, seizures (fits), abdominal pain, nausea and vomiting.

Please refer to the information on paracetamol overdosage under section Take special care with TAMOLTRA and TAMOLTRA FORTE.

If you forget to take TAMOLTRA or TAMOLTRA FORTE

If you miss a dose of TAMOLTRA or TAMOLTRA FORTE, 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 forgotten individual doses.

If you stop taking TAMOLTRA or TAMOLTRA FORTE

If TAMOLTRA or TAMOLTRA FORTE is abruptly discontinued, withdrawal symptoms may occur, such as panic attacks, severe anxiety, hallucinations, paraesthesia (abnormal physical sensation), tinnitus (ringing in the ears), restlessness, difficulty sleeping, irritability, agitation, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking and shivering or sweating. These symptoms may be relieved by tapering TAMOLTRA or TAMOLTRA FORTE instead of abruptly stopping treatment.

4. Possible side effects

TAMOLTRA and TAMOLTRA FORTE can have side effects.

Not all side effects reported for TAMOLTRA and 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 taking 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, tongue, 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 and TAMOLTRA FORTE. 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 and TAMOLTRA FORTE 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
- worsening of existing asthma
- a rare, serious disorder of the skin and mucous membranes that start with flu-like symptoms appear followed by a painful rash that spreads and blisters (Stevens-Johnson syndrome)
- severe skin reaction that starts with fever and flu-like symptoms followed by severe skin peeling and blistering resulting in large raw painful areas (toxic epidermal necrolysis)
- serotonin syndrome characterised by agitation or restlessness, confusion, rapid heart rate and high blood pressure, loss of muscle coordination or twitching muscles, muscle rigidity
- withdrawal symptoms characterised by as panic attacks, severe anxiety, hallucinations, paraesthesia (abnormal physical sensation), tinnitus (ringing in the ears), restlessness, difficulty sleeping, irritability, agitation, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking and shivering or sweating
- addiction – becoming dependant on TAMOLTRA or TAMOLTRA FORTE
- if you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital immediately.

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:

- loss of appetite, anxiety, confusion, sleep disorders, mood changes (anxiety, nervousness, feeling of high spirits)
- dizziness, drowsiness, headache, shaking
- nausea, vomiting, digestion problems (constipation, flatulence, diarrhoea, stomach pain or discomfort, dry mouth)
- skin rash, increased sweating, dermatitis (itchy, dry skin or a rash on swollen, reddened skin)
- abnormal physical weakness or lack of energy, fatigue.

Less frequent side effects:

- anaemia (pale skin, tiredness or dizziness and shortness of breath)
- neutropenia or agranulocytosis (any signs of infection such as sore throat, fever and chills)
- thrombocytopenia (bleeding from your gums or nose, blood in your urine or stool, or easy or excessive bruising)
- weight loss
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapses, feeling disconnected or detached from one's body and thoughts (depersonalisation), mood changes, changes in activity, changes in perception
- inability in a man to achieve an erection or orgasm
- uncoordinated movements, fits, tingling, numbness or feeling of pins and needles in the limbs, ringing in the ears, involuntary migraine, muscle twitching, speech disorders, sensation of whirling and loss of balance, slurred speech
- blurred vision, constriction of the pupil (miosis), excessive dilation of the pupils (mydriasis)
- ringing or buzzing sound in the ears
- difficulty breathing (dyspnoea)
- difficulty swallowing, blood in the stools
- abnormal liver test results
- difficulty or pain on passing urine, abnormal urine test results

- high levels of creatinine.

Side effects with unknown frequency:

- decrease in blood sugar level.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8

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 and TAMOLTRA FORTE

Store all medicines out of reach of children.

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 blisters in carton until required for use.

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 and TAMOLTRA FORTE contain

The active substances are tramadol hydrochloride 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.

Film coating:

TAMOLTRA: Hypromellose, polyethylene glycol, polysorbate 80, titanium dioxide and yellow iron oxide.

TAMOLTRA FORTE: Hypromellose, macrogol (polyethylene glycol), polysorbate 80, titanium dioxide, yellow iron oxide and iron oxide red (E172).

What TAMOLTRA and TAMOLTRA FORTE look 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 of 10 tablets consisting of PVC/PVDC, white film and aluminium foil, with either 2, 3 or 6 blisters per pack.

TAMOLTRA FORTE is available in blister packs of 10 tablets consisting of PVC/PVDC, white film and aluminium foil, with either 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 blisters per pack.

Holder of Certificate of Registration

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