Applicant: Oethmaan Biosims (Pty) Ltd	**SAHPRA approval date:** 16 August 2023
Product: OZTRAK 37.5/325	**Dosage form and strength:** Each film-coated tablet contains: 37,5 mg tramadol hydrochloride and 325 mg paracetamol

APPROVED PATIENT INFORMATION LEAFLET – CLEAN COPY

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

OZTRAK 37.5/325, film-coated tablets

37,5 mg Tramadol hydrochloride and 325 mg Paracetamol

Sugar free

Read all of this leaflet carefully before you start taking OZTRAK 37.5/325.

- 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.
- OZTRAK 37.5/325 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

Initial: 16/08/2023

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1. What OZTRAK 37.5/325 is and what it is used for

OZTRAK 37.5/325 contains tramadol and paracetamol.

Tramadol 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.

2. What you need to know before you take OZTRAK 37.5/325

Do not take OZTRAK 37.5/325:

- If you are allergic to tramadol, paracetamol, any of the other ingredients mentioned in section 6.1, or other opioids such as codeine.
- If you are suffering from acute alcohol poisoning.
- 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 OZTRAK 37.5/325 which are used to treat

depression. These medicines are used to treat depression and belong to a group called monoamine oxidase inhibitors (MAOIs).

- If you have a severe liver disorder.
- OZTRAK 37.5/325 must not be used for narcotic (an addictive substance) withdrawal treatment.
- You should not take OZTRAK 37.5/325 if you suffer from severe breathing problems.
- You should not take OZTRAK 37.5/325 if you are suffering from increased intracranial pressure or central nervous system depression, which are characterised by decreased rate of breathing, decreased heart rate, and loss of consciousness.
- You should not take OZTRAK 37.5/325 if you have fits that are not controlled.

Warnings and precautions

Take special care with OZTRAK 37.5/325:

- If you take other medicines containing paracetamol or tramadol.
- If you have liver problems or disease as your eyes and skin may turn yellow, which may suggest jaundice.
- If you have kidney problems.
- If you have recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick).
- If you are dependent on any other medicines (for example morphine).
- If you have epilepsy or have experienced fits or seizures.

- 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 OZTRAK 37.5/325 and consult with your doctor immediately.
- If you abruptly stop treatment with OZTRAK 37.5/325 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 OZTRAK 37.5/325 to prevent these side effects from occurring.
- OZTRAK 37.5/325 contains paracetamol. If you are allergic to paracetamol, you may break out in a severe skin rash after you take OZTRAK 37.5/325. You should stop using OZTRAK 37.5/325 at the first appearance of a skin rash or any other sign of allergy.
- 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).
- OZTRAK 37.5/325 should not be taken with alcohol containing beverages.
- While taking OZTRAK 37.5/325 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 OZTRAK 37.5/325, consult your doctor immediately.

- If you suffer from sleep-related breathing disorders, take special care when taking OZTRAK 37.5/325.
- Talk to your doctor if you develop a craving for OZTRAK 37.5/325.

Other medicines and OZTRAK 37.5/325

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

OZTRAK 37.5/325 should not be administered with the following:

- A group of antidepressants called Monoamine Oxidase (MAO) Inhibitors (such as moclobemide and tranylcypromine). When taken together with OZTRAK 37.5/325 it can cause diarrhoea, tachycardia (irregular heartbeat), hyperhidrosis (excessive sweating), trembling, confusional state, even coma.
- Carbamazepine (used to treat seizures). When taken together with OZTRAK 37.5/325 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 OZTRAK 37.5/325:

- 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, 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 OZTRAK 37.5/325 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.
- If you are taking digoxin used to treat heart problems.
- If you are taking diflunisal used for pain.
- If you are taking ondansetron used to treat vomiting.

OZTRAK 37.5/325 with food and drink

Do not drink alcohol during treatment with OZTRAK 37.5/325 as the effects of OZTRAK 37.5/325 and alcohol may intensify each other.

Pregnancy and breastfeeding and fertility

OZTRAK 37.5/325 must not be taken during pregnancy.

OZTRAK 37.5/325 must not be taken during breastfeeding since there is no information available regarding safety during breastfeeding.

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 professional for advice before taking this medicine.

Driving and using machines

Do not drive while taking this medicine until you know how it affects you.

OZTRAK 37.5/325 can affect your ability to drive as it may make you sleepy or dizzy.

If you feel drowsy while taking OZTRAK 37.5/325, do not drive, use tools or use machinery.

OZTRAK 37.5/325 contains Sodium

OZTRAK 37.5/325 contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take OZTRAK 37.5/325

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

Always take OZTRAK 37.5/325 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with OZTRAK 37.5/325 will last. If you have the impression that the effect of OZTRAK 37.5/325 is too strong or too weak, talk to your doctor or pharmacist.

- Swallow the tablets whole with sufficient liquid.
- Do not break or chew the tablets.

Adults:

The recommended dosage 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.

If you take more OZTRAK 37.5/325 than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

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.

If you forget to take OZTRAK 37.5/325

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 OZTRAK 37.5/325

Withdrawal symptoms may occur if OZTRAK 37.5/325 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.

- **Possible side effects:**

OZTRAK 37.5/325 can have side effects.

Not all side effects reported for OZTRAK 37.5/325 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OZTRAK 37.5/325, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking OZTRAK 37.5/325 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rash or itching all over the body
- Allergic reactions along with breathing problems or closing of the throat
- Increased bleeding time

These are all very serious side effects. If you have them, you may have had a serious reaction to OZTRAK 37.5/325. 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: The following side effects occur frequently:

- A severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).

- Onset of rash at a fixed location on the body each time you take the same medicines (fixed drug eruption).
- Irregular heartbeat that is much rapid and more pronounced than usual.
- Elevated liver enzymes, resulting in abdominal pain, dark urine, pale stools, weakness, fatigue.

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
- headache, trembling
- nausea, vomiting, constipation, dry mouth, diarrhoea, stomach pain, indigestion, stomach gas

Less frequent side effects

- depression, seeing, hearing, smelling, tasting or imagining things, nightmares
- involuntary muscular contractions, tingling or prickling sensation, loss of memory
- ringing in the ear
- rapid, strong, or irregular heartbeat, very fast heartbeat, dysrhythmia

- difficulty swallowing, blood in faeces
- chills
- chest pain
- problems with urination
- difficulty breathing
- increase in blood pressure, hot flushes
- 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)

<u>Frequency unknown</u>

- An increased risk of stomach pain and inflammation of the pancreas.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via http:///www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of this medicine.

4. How to store OZTRAK 37.5/325

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Protect from light and moisture.

Store in the original package/container.

Keep the blister in the carton until required for use.

Do not store in a bathroom.

Do not use OZTRAK 37.5/325 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).

5. Contents of the pack and other information

What OZTRAK 37.5/325 contains

The active substances in each film-coated tablet are 37,5 mg tramadol hydrochloride and 325 mg paracetamol.

The other ingredients are: Magnesium stearate, maize starch, microcrystalline cellulose, pregelatinised starch, sodium starch glycolate, Opadry yellow coating containing hypromellose, iron oxide yellow, titanium dioxide and triacetin.

What OZTRAK 37.5/325 looks like and contents of the pack

Light yellow, oblong, biconvex, film-coated tablets, plain on both sides.

OZTRAK 37.5/325 is packed in a blister comprising of plain aluminium foil with VMCH coating and white opaque PVC film or in a blister comprising of plain aluminium foil with VMCH coating and white opaque PVC/PVdC film placed in a carton along with a patient information leaflet.

Pack sizes: 30 and 60 tablets.

Not all pack sizes may be marketed.

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Name, Business Address and Telephone Number of the Holder of the Certificate of Registration

Oethmaan Biosims (Pty) Ltd

207A Sherwood House

Greenacres Office Park

c/o Victory and Rustenburg Roads

Victory Park

Johannesburg

2195

Telephone number: 011 433 0602

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