PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

TRAPACETOL 37,5 mg/325 mg film-coated tablets

Tramadol hydrochloride/Paracetamol

Sugar free

Read all of this leaflet carefully before you start taking TRAPACETOL.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- TRAPACETOL 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 TRAPACETOL is and what it is used for
2. What you need to know before you take TRAPACETOL
3. How to take TRAPACETOL
4. Possible side effects
5. How to store TRAPACETOL
6. Contents of the pack and other information

1. What TRAPACETOL is and what it is used for

TRAPACETOL is a combination of two analgesics, tramadol and paracetamol, which act together to relieve your pain.

TRAPACETOL is intended for use in the treatment of moderate to moderately-severe pain in adults. TRAPACETOL is not recommended for minor pain that may be treated adequately through lesser means.

2. What you need to know before you take TRAPACETOL

Do not take TRAPACETOL

- if you are allergic to tramadol hydrochloride, paracetamol or any of the other ingredients of TRAPACETOL (listed in section 6);
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are also taking monoaminde oxidase inhibitors (MAOIs) (certain medicines used for treatment of depression or Parkinson's disease) or have taken them in the last 14 days before treatment with TRAPACETOL;
- if you suffer from a severe liver disorder;
- if you have severe difficulties in breathing for example asthma or severe lung problems;
- if you have recently suffered from a head injury, shock or severe headaches associated with vomiting;
- if you are pregnant or breastfeeding your baby.
- if you have epilepsy that is not adequately controlled on your current medicine.

Warnings and precautions

Take special care with TRAPACETOL:

- if you take other medicines containing paracetamol or tramadol;
- if you have liver problems or liver disease or if you notice the whites of your eyes and your skin turning yellow. This may suggest jaundice or problems with your bile ducts.
- if you have epilepsy or have already experienced fits or seizures;
- if you are dependent on any medicines, including those used to relieve pain, for example morphine;
- if you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine;
- if you are going to have an anaesthetic. Tell your doctor or dentist that you are taking TRAPACETOL.

If any of the above-mentioned points applied to you in the past or applies to you while you are taking TRAPACETOL, please make sure your doctor knows. He/she can then decide whether you should continue to use TRAPACETOL.

Other medicines and TRAPACETOL:

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Important: TRAPACETOL contains paracetamol and tramadol. Tell your doctor if you are taking any other medicine containing paracetamol or tramadol, so that you do not exceed the maximum daily doses.

You **must not** take TRAPACETOL together with monoamine oxidase inhibitors (MAOIs) (see section Do not take TRAPACETOL).

TRAPACETOL is not recommended to be taken with the following:

- carbamazepine (used to treat epilepsy or some types of pain such as severe pain attacks in the face called trigeminal neuralgia);
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.

The risk of side effects increases:

- if you are taking triptans (used for migraine) or selective serotonin re-uptake inhibitors, “SSRIs” (used for depression). If you experience confusion, restlessness, fever, sweating, uncoordinated movement of your limbs or eyes, uncontrollable jerking of muscles or diarrhoea you should call your doctor.
- if you are taking tranquillisers, sleeping pills, 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. You may feel drowsy or faint. If this happens, tell your doctor.
- 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 TRAPACETOL at the same time. Your doctor will tell you whether TRAPACETOL is suitable for you.

- if you are taking certain antidepressants. TRAPACETOL 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 are taking warfarin (used for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

The effectiveness of TRAPACETOL may be altered if you also take

- metoclopramide and domperidone (medicines for treatment of nausea and vomiting);
- cholestyramine (used to reduce cholesterol in the blood).

Your doctor will tell you which medicines are safe to take with TRAPACETOL.

TRAPACETOL with food and drink

TRAPACETOL may make you feel drowsy. Alcohol may make you feel more drowsy, so it is best not to drink alcohol while you are taking TRAPACETOL.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your healthcare professional for advice before taking TRAPACETOL.
Do not take TRAPACETOL if you are pregnant.

Small amounts of tramadol may pass into the breast milk. Therefore you should not take TRAPACETOL during breastfeeding.

Based on human experience it seems that tramadol does not influence female or male fertility. No data on the influence of the combination of tramadol and paracetamol on fertility are available.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

TRAPACETOL may make you feel drowsy and this may affect your ability to drive a vehicle or use tools and machines safely.

3. How to take TRAPACETOL

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

Always take TRAPACETOL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

To be used in adults and children over 16 years of age.

DO NOT EXCEED THE RECOMMENDED DOSE.

Adults:

For the management of pain, the recommended dose of TRAPACETOL is 1 or 2 tablets every 4 to 6 hours as needed for pain, relief up to a maximum of 8 tablets per day.

Method of administration:

The tablets are for oral use.

If you take more TRAPACETOL than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TRAPACETOL

If you forget 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 the tablets as before.

If you stop taking TRAPACETOL

Generally there will be no after-effects when treatment with TRAPACETOL is stopped. However, on rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly (see section 4). If you have been taking TRAPACETOL for some time, you should talk to your doctor if you want to stop because your body may have become used to it.
If you have any further questions on the use of TRAPACETOL, ask your doctor or pharmacist.

4. Possible side effects

TRAPACETOL can have side effects.

Not all side effects reported for TRAPACETOL are included in this leaflet. Should you not experience any pain relief, or your general health worsens or if you experience any untoward effects while taking TRAPACETOL, please consult your healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips and 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 reaction to TRAPACETOL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea
- dizziness, drowsiness
- vomiting, digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth
- itching, sweating (hyperhidrosis)
- headache, shaking
- feeling confused, sleep disorders, mood changes (anxiety, nervousness, a feeling of high spirits).

Less frequent side effects:

- increase in pulse or blood pressure, heart rate or heart rhythm disorders
- difficulty or pain on passing water
- skin reactions (for example rashes, hives)
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ear, 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, difficulties in carrying out coordinated movements
- addiction, delirium
- blurred vision, constriction of the pupils (miosis) or excessive dilatation of the pupils (mydriasis)
- speech disorder
- transient loss of consciousness (syncope).

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 experience side effects, talk to doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TRAPACETOL.

5. How to store TRAPACETOL

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C, protected against moisture. (1)

Store in original packaging and keep blisters in the outer carton until required for use. (1)

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).

6. Contents of the pack and other information

What TRAPACETOL contains

The active substances are tramadol hydrochloride and paracetamol.

Each film-coated tablet contains 37,5 mg tramadol hydrochloride and 325 mg paracetamol.

TRAPACETOL is sugar free.

The other ingredients are hypromellose 3cP (HPMC 2910), hypromellose 6cP (HPMC 2910), iron oxide yellow, macrogol (PEG 400), magnesium stearate, microcrystalline cellulose, polysorbate 80, pregelatinised starch, purified water, sodium starch glycolate (Type A) and titanium dioxide.

What TRAPACETOL looks like and contents of the pack.

TRAPACETOL: A yellow coloured, elongated, film-coated tablet with “325” debossed on one side and “37.5” debossed on other side.

Pack sizes of 20, 30 or 60 film-coated tablets packed in blister strips of aluminium foil and white opaque PVC-PVdC film packed in an outer unit carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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0157

This leaflet was last revised in

24 January 2022

Registration number

51/2.9/0438