

Trabest 37.5mg/325mg Film Coated Tablets

Tramadol/Paracetamol (37.5mg/325mg)

What is in the leaflet

1. What Trabest Tablet is used for
2. How Trabest Tablet works
3. Before you take Trabest Tablet
4. How to take Trabest Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Trabest Tablet
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of revision

What Trabest Tablet is used for

This medicine is intended for the management of moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

This medicine should only be taken by adults and adolescents over 16 years of age.

How Trabest Tablet works

Trabest is a combination of two analgesics, Tramadol and Paracetamol, which act together to relieve your pain.

Before you take Trabest Tablet

- When you must not take it

- If you are allergic or have had an allergic reaction (such as skin rash, swelling of the face, wheezing or difficulty breathing) to paracetamol, tramadol or any of the other ingredients of this medicine (listed in section 6).
- In cases of acute alcohol poisoning.
- If you are taking sleeping pills, pain relievers or medicines that affect mood and emotions.
- If you are also taking medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the last 14 days, before starting treatment with Trabest. MAOIs are used in the treatment of depression or Parkinson's disease.
- If you have a severe liver disorder.
- If you have epilepsy that is not adequately controlled by your current medicine.

- Before you start to take it

Follow all instructions given to you by your doctor carefully, even if they differ from the information contained in this leaflet.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Your doctor will tell you which medicines are safe to take with Trabest.

Do not exceed the maximum daily doses of paracetamol or tramadol from this or other medicines.

Do not take Trabest with monoamine oxidase inhibitors ('MAOIs') (see section 'Do not take Trabest').

Trabest is not recommended with the following medicines, as it may affect how they work:

- carbamazepine (a medicine used to treat epilepsy or some types of pain).
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.

Trabest may increase the risks of side effects if you also take the following medicines:

- triptans (used for migraine) or selective serotonin re-uptake inhibitors (SSRIs, used for depression). Check with your doctor if you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea. tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also used as cough medicine), baclofen (a muscle relaxant), medicines used to lower blood pressure, antidepressants or medicines used to treat allergies. Check with your doctor if you may feel drowsy or feel faint.
- antidepressants, anaesthetics, neuroleptics (medicines that affect

the state of mind), or bupropion (used to help stop smoking). The risk of having a fit may increase. Your doctor will tell you whether Trabest is suitable for you.

- warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur (see section 4).

The effectiveness of Trabest may be altered if you also take the following medicines:

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

How to take Trabest Tablet

- How much to take

Adults and adolescents over 16 years

The recommended dose is to start with 2 tablets, unless otherwise prescribed by your doctor. If required, further doses may be taken, as instructed by your doctor.

The shortest time between doses must be at least 6 hours.

Do not take more than 8 tablets per day.

Your doctor may increase the time between doses if:

- you are older than 75 years
- you have kidney problems
- you have liver problems

Children under 16 years of age

The use of this medicine in children below the age of 16 years is not recommended.

If you feel that the effect of Trabest is too strong (you feel very drowsy or have difficulty breathing) or too weak (you may not have enough pain relief), contact your doctor.

Trabest 37.5mg/325mg Film Coated Tablets

Tramadol/Paracetamol (37.5mg/325mg)

- When to take it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- How long to take it

Take Trabest for as short a time as possible and no longer than your doctor has told you.

If you stop taking Trabest

Generally, there will be no after-effects when treatment with Trabest is stopped.

However, rarely, people who have been using a medicine containing tramadol may become dependent on it, making it hard to stop taking it. If you have been taking Trabest for some time and want to stop, contact your doctor because your body may have become used to Trabest.

People may:

- feel agitated, anxious, nervous or shaky
- be over active
- have difficulty sleeping
- have stomach or bowel disorders

Very few people may also get:

- Panic attacks
- hallucinations, usually perceptions such as itching, tingling, and numbness
- ringing in the ears

If you experience any of these complaints after stopping Trabest, please contact your doctor. Other side effect information is listed in section 4.

If you have any further questions on the use of this medicine, ask your doctor and pharmacist.

- If you forget to take it

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 take too much (overdose)

Contact your doctor or pharmacist immediately even if you feel well. There is a risk of delayed, serious liver damage.

While you are using it

- Things you must do

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

- Things you must not do

Trabest with food, drink and alcohol

Do not drink alcohol while you are taking Trabest as you may feel drowsy.

Driving and using machines

Do not drive, use tools or operate machinery if you feel drowsy while taking Trabest.

- Things to be careful of

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Trabest if you are pregnant. Check with your doctor if you become pregnant during treatment with Trabest and before taking any further tablets.

Do not take Trabest while you are breast-feeding, as small amounts of tramadol may pass into the breast-milk.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious. Contact your doctor immediately if any of the following occur:

- Signs of an allergic reaction such as skin rash, sudden swelling of the face and neck, difficulties breathing, drop of blood pressure, fainting. If this happens to you, stop treatment. Do not take the medicine again.

- Prolonged or unexpected bleeding, from the use of Trabest together with medicines used to thin the blood (e.g. warfarin, phenprocoumon).

Additionally, if any of the following side effects become serious, contact your doctor or pharmacist:

Very common side effects (affecting more than 1 in 10 people treated)

- nausea
- dizziness, drowsiness.

Common side effects (affecting less than 1 in 10, but more than 1 in 100 people treated)

- vomiting (being sick)
- digestion problems (constipation, flatulence, diarrhoea)
- stomach pain
- dry mouth
- itching
- sweating
- headache
- shaking
- confusion
- sleep disorders
- mood changes (anxiety, nervousness, feeling of high spirits).

Uncommon side effects (affecting less than 1 in 100, but more than 1 in 1,000 people treated)

- increase in pulse or blood pressure
- heart rate or heart rhythm disorders
- pain or difficulty on passing water
- skin reactions (for example rashes, hives)
- 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
- chest pain
- difficulty breathing.

Trabest 37.5mg/325mg Film Coated Tablets

Tramadol/Paracetamol (37.5mg/325mg)

Rare side effects (affecting less than 1 in 1,000, but more than 1 in 10,000 people treated)

- fits
- difficulties in carrying out coordinated movements
- addiction
- blurred vision.

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
- nose bleeds or bleeding gums, which may result from low blood platelet count.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

If you notice any side effects not listed in this leaflet, please tell your doctor.

You may report any side effects or diverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Trabest Tablet

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister, after "EXP". The expiry date refers to the last day of that month.

Store this medicine below 30°C.

- Disposal

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

- Ingredients

- Active ingredient(s):

Tramadol hydrochloride and paracetamol. One (1) film-coated tablet contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.

- Inactive ingredients:

Tablet core:

Pregelatinised maize starch
Hydroxy propyl cellulose (E436)
Sodium starch glycolate (type A)
Colloidal anhydrous silica
Microcrystalline cellulose (Avicel PH101 and Avicel PH102)
Magnesium stearate (E470b)

Film-coating:

Opadry yellow (03F52262)

- MAL number

MAL19041001AZ

Manufacturer

Lupin Limited
Plot No. M-2 and M-2-A,
SEZ Phase -II, Misc
Zone Apparel Park
Pithampur Dist Dhar
454775 MP

Product Registration Holder

Generic Health SDN BHD,
Upper Penthouse,
Wisma RKT, No. 2,
Jalan Raja Abdullah,
Off Jalan Sultan Ismail,
50300 Kuala Lumpur.

Date of revision

20/06/2021

Serial Number

NPRA(R2/1)210602/687