Tramadol hydrochloride/Paracetamol 37.5 mg/325 mg

film-coated tablets

Tramadol Hydrochloride/Paracetamol

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

Keep this leaflet. You may need to read it again.

Do not take more than the recommended dosage. See also section 4.

This medicine has been prescribed for you and is not pass on to others. It may harm them, even those who are under the age of 18.

If you get any side effects, talk to your doctor or pharmacist or nurse. This medicine may cause side effects that may affect your ability to drive or use machines.

WHAT IS IN THIS LEAFLET
1. What Tramadol/Paracetamol is and what it is used for
2. What you need to know before you take Tramadol/Paracetamol
3. How to take Tramadol/Paracetamol
4. Possible side effects
5. How to store Tramadol/Paracetamol
6. Contents of the pack and other information

1. WHAT TrAMADOL/PARACE TAmOL IS ANd WHAT IT IS USEd FoR

Tramadol/Paracetamol is a combination of two analgesics (pain killers) tramadol and paracetamol that act together to relieve your pain.

It is used in the treatment of moderate to severe pain when your doctor has decided that a combination of tramadol and paracetamol is needed.

2. WHAT yoU Need To kNoW beFore yoU TAke USE TrAmAdol/P ArAceTAmol

Tramadol/Paracetamol is not recommended for use in children under 12 years.

3. HoW To TAke TrAmAdol/PArAceTAmol

The tablets should be taken for as short a time as possible.

The tablets must be swallowed whole with some liquid. The tablets should not be chewed or crushed.

The tablets should be taken at regular intervals (dosage interval).

The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity. In severe liver or kidney disease (insufficiency) the dosage should be reduced.

If in your case the insufficiency is mild or moderate, your doctor may recommend prolonging the dosage interval.

If you think that the effect of Tramadol/Paracetamol is too strong (i.e. you feel very drowsy or have difficulty in breathing), tell your doctor or pharmacist.

If your symptoms do not get any better, see your doctor.

4.  Possible side effects

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

• opioid analgesics such as codeine, morphine, oxycodone or fentanyl

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor before you take Tramadol/Paracetamol.

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If you have kidney problems or anuria (lack of urine output) Tramadol/Paracetamol may be reduced or stopped.

If you are planning a pregnancy or are breast-feeding, consult your doctor before you take Tramadol/Paracetamol.

Do not drive, operate machinery or perform other activities for which you need to be alert until you know how Tramadol/Paracetamol affects you.

If you have liver diseases (insufficiency), your doctor may reduce your dose.

Talk to your doctor or pharmacist before taking Tramadol/Paracetamol.

If you are taking, have recently taken or might take any other medicines that may interact with Tramadol/Paracetamol, check with your doctor or pharmacist.

If you have taken MAOIs in the last 14 days before treatment with Tramadol/Paracetamol, you must use the treatment of depression on Parkinson’s disease. See section 2.4.4.

Tramadol/Paracetamol may increase the risk of side effects if you take the following medicines:

• alcohol

• any other medicines to treat allergies. Check with your doctor if you feel drowsy or feel faint.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even those who are under the age of 18.

5. How to store Tramadol/Paracetamol

Keep the tablets out of reach of children.

Keep the tablets in the blister pack until they have expired. The expiry date is shown on the pack.

6. Contents of the pack and other information

This medicine contains paracetamol and tramadol. Tell your doctor if you are

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If you take Tramadol/Paracetamol... then you should

Immediate medical advice should be sought in the event of overdose, even if you feel well, because of the risk of delayed, serious liver damage. If you miss Tramadol/Paracetamol, you should not take it. You might be at risk of developing fatal breathing difficulties, heart attack, or other adverse reactions.

If you forget to take Tramadol/Paracetamol

Do not take a double dose or several doses at the same time. If you take too much Tramadol/Paracetamol (overdose) overdose or Paracetamol on purpose, or if you take it by mistake, take immediate medical advice. You might be at risk of developing fatal breathing difficulties, heart attack, or other adverse reactions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tramadol/Paracetamol can cause side effects, although not everybody gets them.

The very common side effects (may affect more than 1 in 10 people):

• itching
• flushing
• dizziness

These are usually mild and not troublesome.

The common side effects (may affect from 1 in 10 up to 1 in 100 people):

• feeling sick or vomiting
• feeling sleepy or drowsy
• feeling irritable or nervous
• trouble sleeping
• feeling faint when getting up from a lying or sitting position
• sneezing
• swelling of the face, the hands, the mouth, and the legs
• urination problem

If you have any further queries on the use of this product, ask your doctor or pharmacist.

If you have been using Tramadol/Paracetamol for some time, you should talk to your doctor or pharmacist if you want to stop taking it. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have tremors in the arms and legs, difficulty swallowing, hot flushes, shivering, blood in the stools, difficulty sleeping and have stomach or bowel disorders. Very few people may also get panic attacks, difficulty sleeping, or involuntary muscle twitching.

In exceptional cases blood tests may reveal certain abnormalities, for instance, low counts of blood cells or blood platelets. Very rare cases of serious skin reactions have been reported for paracetamol containing medicines. Use of Tramadol/Paracetamol together with medicines used to thin the blood (e.g. phenoprocoumon, warfarin) may increase the bleeding risk. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

5. HOW TO STORE TRAMADOL/PARACETAMOL

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 packaging after EXP. The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

This leaflet was last revised in May 2015