Tramadol hydrochloride/Paracetamol 37.5 mg/325 mg film-coated tablets

Package leaflet: Information for the user

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

1. What Tramadol/Paracetamol IS And WHAT It IS Used For

Tramadol/Paracetamol is intended for use in the treatment of moderate to severe pain when your doctor recommends a combination of tramadol and paracetamol in needed.

2. WHAT YoU NeEd To kNoW beFore YoU TAke TrAmAdol/PArAceTAmol

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

3. HoW To TAke TrAmAdol/PArAceTAmol

Do not take Tramadol/Paracetamol if you:

• are allergic to tramadol, tramadol or any of the other ingredients of this medicine (see section 6) • have liver problems or alcoholic liver disease or you have noticed your eyes and skin turning yellow, which may suggest jaundice or problems with your liver • have difficulty breathing, for example, asthma or lung problems or if you have difficulty breathing, for example, asthma or lung problems • have liver problems or alcoholic liver disease or you have noticed your eyes and skin turning yellow, which may suggest jaundice or problems with your liver • have liver problems or alcoholic liver disease or you have noticed your eyes and skin turning yellow, which may suggest jaundice or problems with your liver

4.  PoSSibLe sIdE eFFects

If you think that the effect of Tramadol/Paracetamol is too strong (i.e. you feel very drowsy or have difficulty with breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor or pharmacist.

5. HoW To sTOre TrAmAdol/PArAceTAmol

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

6. Contents of the pack and other information

The tablets should be kept in a dry place and in the original packaging.

7.  sECuRITy

This medicine contains paracetamol and tramadol. Tell your doctor if you are breast-feeding or planning to breast-feed.

Breast-feeding

Tramadol hydrochloride/Paracetamol contains tramadol hydrochloride and paracetamol. Tell your doctor if you are breast-feeding or planning to breast-feed.

8.  sTOp TAking TrAmAdol/PArAceTAmol

If you suffer from severe liver problems

9.  sTOp TAking TrAmAdol/PArAceTAmol

Do not take Tramadol/Paracetamol

If you think that the effect of Tramadol/Paracetamol is too strong (i.e. you feel very drowsy or have difficulty with breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor or pharmacist.

Important: This medicine contains paracetamol and tramadol. Tell your doctor if you are breast-feeding or planning to breast-feed.

Breast-feeding

Tramadol/Paracetamol contains tramadol hydrochloride and paracetamol. Tell your doctor if you are breast-feeding or planning to breast-feed.

10.  sTOp TAking TrAmAdol/PArAceTAmol

If you suffer from severe liver problems

11.  sTOp TAking TrAmAdol/PArAceTAmol

Do not take Tramadol/Paracetamol

If you think that the effect of Tramadol/Paracetamol is too strong (i.e. you feel very drowsy or have difficulty with breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor or pharmacist.
P In some rare cases a skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting. If this happens to you, stop treatment and see a doctor immediately. You must not take the medicine again.

Q If you stop taking Tramadol/Paracetamol

R You should not throw away medicines you no longer use. These measures will help protect the environment.

S This medicine does not require any special storage conditions.

T See the pack size of the tablets you have, as this may not be the pack size you are using.

U The expiry date refers to the last day of that month. 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.

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

W This leaflet was last revised in 07/2016.

X Consilient Health Ltd., 5th floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland.

Y Not all pack sizes may be marketed.

Z Boxes of 2 film-coated tablets (blister with 2 tablets) or 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100 film-coated tablets (blister with 10 tablets) are available.

**8. POSSIBLE SIDE EFFECTS**

Use this medicine, this medicine can cause side effects, although not everybody gets them.

**The very common side effects (may affect more than 10% of people):**

- nausea
- dizziness
- breathlessness
- These symptoms are usually mild and not troublesome.

**Common side effects (may affect up to 1 in 10 people):**

- tingling
- headache
- drowsiness
- These symptoms are usually mild and not troublesome.

**Uncommon side effects (may affect up to 1 in 100 people):**

- high blood pressure, heart rhythm and rate disorders
- difficulty in passing or passing of urine, feeling in the arm
- skin reactions (e.g. rash, itch)
- depression
- hallucinations
- drug abuse

**Very rare side effects (may affect up to 1 in 1,000 people):**

- sleep disorders, fits, difficulties in carrying out coordinated movements
- rash, unusual tingling feeling (“pins and needles”), involuntary muscle twitching
- digestion problems (constipation, flatulence, diarrhoea)
- nightmares
- hallucinations (hearing, seeing or sensing things that are not really there)

**Rare side effects (may affect up to 1 in 10,000 people):**

- abdominal pain.

**Unknown side effects (frequency cannot be estimated from the available data):**

**Side effects of using tramadol hydrochloride alone:**

On rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment. They may feel asthmatic, nervous or cold in their head. They may be hypotensive, have difficulty sleeping and have back or breast disorders. Very few people may get panic attacks. Individuals with a particularly parasympathetic nervous system, who can easily become stressed, may notice a change in sex (towards women). If you notice any of these effects, or any other unusual symptoms, please talk to your doctor or pharmacist as soon as possible.

In exceptional cases blood tests may reveal certain abnormalities, for instance, low counts of blood platelets, which may result in nose bleeds or bleeding gums.

In such cases, because a medicine of the type of tramadol may make you become dependent on it, making it extremely dangerous.

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