PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

TRAMADOL 50mg is an oral Capsule
Composition:
Each Hard Gelatin Capsule contains:
TRAMADOL HCL BP…….50mg

Read all of this leaflet carefully before you starts using this medicine.
• Keep this leaflet. You may need to read it again
• If you have any further questions, ask your doctor or pharmacist
• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
• If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet

1. WHAT TRAMADOL 50mg CAPSULE IS AND WHAT IT IS USED FOR?

TRAMADOL belongs to a group of medicines called opioids. It is used for the management (treatment and prevention) of moderate to severe pain.

2. BEFORE YOU TAKE TRAMADOL 50mg CAPSULE

Contraindication

Do not take TRAMADOL if you are allergic to TRAMADOL or in cases of acute intoxication with alcohol, hypnotics, centrally acting analgesics, opioids or psychotropic drugs.

Special warnings and precautions for use

At therapeutic doses, tramadol has the potential to cause withdrawal symptoms.

In patients with a tendency to drug abuse or dependence, treatment should be for short periods and under strict medical supervision.

Tramadol is not suitable as a substitute in opioid-dependent patients. Although it is an opioid agonist, tramadol cannot suppress morphine withdrawal symptoms.

Convulsions have been reported at therapeutic doses and the risk may be increased at doses exceeding the usual upper daily dose limit. Patients with a history of epilepsy or those susceptible to seizures should only be treated with tramadol if there are compelling reasons. The risk of convulsions may increase in patients taking tramadol and concomitant medication that can lower the seizure threshold.

Tramadol should be used with caution in patients with head injury, increased intracranial pressure, severe impairment of hepatic and renal function and in patients prone to convulsive disorders or in shock.

Care should be taken when treating patients with respiratory depression, or if concomitant CNS depressant drugs are being administered, as the possibility of respiratory depression cannot be excluded in these situations. At therapeutic doses, respiratory depression has infrequently been reported.

Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, even medicines bought without a prescription.

Interaction with other medicinal products and food:

Tramadol should not be combined with MAO inhibitors.

Patients treated with monoamine oxidase inhibitors within 14 days prior to administration of the opioid pethidine have experienced life-threatening interactions affecting the central nervous system as well as the respiratory and circulatory centres. The possibility of similar interactions occurring between monoamine oxidase inhibitors and tramadol cannot be ruled out.

Concomitant administration of tramadol with other centrally acting drugs including alcohol may potentiate CNS depressant effect.

The combination with mixed agonist/antagonists (e.g. buprenorphine, nalbuphine, pentazocine) and tramadol is not advisable, because the analgesic effect of a pure agonist may be theoretically reduced in such circumstances.

Tramadol can induce convulsions and increase the potential for selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, antipsychotics and other seizure threshold-lowering medicinal products (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions.

Concomitant therapeutic use of tramadol and serotonergic drugs, such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors, tricyclic antidepressants and mirtazapine may cause serotonin toxicity.

Simultaneous administration of carbamazepine markedly decreases serum concentrations of tramadol to an extent that a decrease in analgesic effectiveness and a shorter duration of action may occur.

Caution should be exercised during concomitant treatment with tramadol and coumarin derivatives (e.g. warfarin) due to reports of increased INR and ecchymoses in some patients.

Pregnancy and Lactation:
Do not take TRAMADOL if you pregnant, planning a pregnancy or breast-feeding, unless your doctor has advised you to, as it may affect the development of your baby. Ask your doctor for advice before taking any medicines

Driving and using machines
Not applicable**.**

3. HOW TO TAKE TRAMADOL 50mg CAPSULE
Always take TRAMADOL 50mg Capsule exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is:
Adults and children over 12 years: One or two Tramadol capsules (equivalent to 50 mg – 100 mg tramadol hydrochloride)

If you take more TRAMADOL 50mg Capsule than you should
If you take more TRAMADOL 50mg Capsule than you should, talk to a doctor or go to the nearest hospital.

If you forget to take TRAMADOL 50mg Capsule
• Do not take the missed dose
• Take your next dose at the usual time, and then keep taking your medicine as your doctor has told you
• Do not take a double dose to make up for a forgotten dose
If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking TRAMADOL 50mg Capsule
You should continue taking TRAMADOL for as long as your doctor has told you to, even if you start to feel better. If you stop before finishing the prescribed course of treatment your infection may still be present or may reappear.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, TRAMADOL 50mg Capsule can cause side effects, although not everybody gets them.
TRAMADOL 50mg Side effects include; Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, or headache may occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or Pharmacist.

5. HOW TO STORE TRAMADOL 50mg CAPSULE
Keep out of the sight and reach of children
Store below 30^{o}C, protect from light.
Store in the original Carton.
Do not take TRAMADOL 50mg Capsule after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your Pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

The active substance in TRAMADOL 50mg Capsule is:
Each Capsule contain:
TRAMADOL HCL BP…….50mg
The other ingredients are:
Starch
Magnesium Stearate
Purified Talc
Microcrystalline Cellulose
Lactose

What TRAMADOL 50mg Capsule looks like and contents of the pack:
TRAMADOL 50mg is a Green/ Yellow coloured size "2" hard gelatin capsules containing a white colour free flowing powder. Alu-PVC blister of 10 Capsules, such 10 blisters are packed in carton along with the pack insert.

MANUFACTURER

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