If you have any further questions, ask your doctor or pharmacist, or see section 4.

- **Driving and using machines**
  - Tramadol can make you feel drowsy, so you should drive with caution, and only under medical supervision.

- **Breast-feeding**
  - As with all medicines this should be avoided during breast-feeding, as its effect may be intensified.
  - If you are breast-feeding and you need to take Tramadol, as its effect may be intensified.
  - However, the benefit of breast-feeding should be balanced against the potential risks. If you feel that you must breast-feed, you should notify your doctor or pharmacist.

- **Other medicines and Tramadol**
  - Certain other medicines (such as MAOIs, certain antidepressants and others related drugs) increase the risk of dangerous side effects (see section 4). Possible side effects of these medicines may need to be reduced, such as warfarin; the dose of these medicines may need to be reduced, or may need to be stopped. The pain-relieving effect of Tramadol may be weakened and/or shortened if you also take MAOIs in the past 2 weeks.

Other medicines and Tramadol

- **Pregnancy**
  - The safety of tramadol during pregnancy has not been established. If you may have a baby, ask your doctor or pharmacist before taking Tramadol.

- **Use in children with breathing problems**
  - Be aware that the symptoms of tramadol toxicity may be worse with breathing problems, since the child is likely to have an increased risk of serious breathing problems, since the child is likely to have an increased risk of serotonin syndrome (see section 4), we advise you to only use it if your doctor or pharmacist determines that it is appropriate.

3. How to take Tramadol

- **Swallow the capsules whole.**
  - Do not chew the capsules.

- **Take your dose at regular intervals.**
  - Take it after meals or at bedtime.

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- **Keep taking your dose even if you feel better or if you feel worse after number of days.**

- **Do not take Tramadol in the same time as medicines belonging to the class of antidepressants**
  - If you take certain antidepressants, Tramadol may interact with these medicines and may increase the risk of serotonin syndrome (see section 4). Possible side effects of these medicines may need to be reduced, or may need to be stopped. The pain-relieving effect of Tramadol may be weakened and/or shortened if you also take MAOIs in the past 2 weeks.

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Information for the user

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Adults and adolescents aged 12 and over
The usual dose is 100 mg (1 or 2 capsules) every 4-6 hours, according to severity of pain. However, you should not take more than 400 mg (8 capsules) a day.

Children below 12 years of age
Tramadol is not recommended for use in children below age 12.

Elderly patients
In elderly patients (above 75 years) the dose should be reduced. If this applies to you, your doctor may proceed to adjust the dose in steps or to give the minimum dose.

Rare
may affect up to 1 in 10,000 people.
The frequency of side effects is classified as:

Very common:

Common:

Uncommon:

Rare:

Very rare: may affect up to 1 in 10,000 people.
The frequency of side effects is classified as:

Common: may affect up to 1 in 10 people.

Uncommon: may affect up to 1 in 100 people.

Rare: may affect up to 1 in 1,000 people.

Very rare: may affect up to 1 in 10,000 people.

Not known: frequency cannot be estimated from the available data.
The following side effects may occur:

Very common: nausea, dizziness.

Common: headache, sleepiness; vomiting (being sick), dry mouth, sweating.

Uncommon: rapid breathing or pulsation of the heart, increased heartbeats, low blood pressure (especially when getting up), that may lead to a collapse. These side effects may particularly occur in elderly patients in an upright position or under physical or mental strain. Dizziness, sweating, feeling of pressure in the chest, skin, mucous membranes, vision, pupils (miosis); difficulty in urination; agitation, hallucinations, inability to talk, retching, vomiting, increased appetite, tingling skin sensations.

Rare: sweating, muscle weakness.

in appetite, tingling skin sensations.

Generalized allergic reactions: rash, severe exfoliative dermatitis and angioedema, see below. Other: agitation, confusion, anxiety, sleep disturbances, hallucinations, changes in mood (high or low), irritability, inability to concentrate, signs of a withdrawal syndrome. When treatment is stopped, symptoms of withdrawal reactions and addiction may occur. When treatment is stopped, symptoms of withdrawal reactions may occur, such as agitation, anxiety, nervousness, sleeplessness, uncontrolled motor behaviour and tachycardia or gastrointestinal symptoms. Other symptoms that have rarely been seen with tramadol discontinuation e.g. pancytopenia, severe anemia and thrombocytopenia, changing skin sensation, hearing sounds e.g. ringing or buzzing, feeling of pressure in the chest, weight loss, increased heart rate, raised blood pressure, involuntary sweating, muscular rigidity, lack of coordination and/or coordination disturbances.

If you get any of these effects after stopping treatment with Tramadol please talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
You may report side effects you get while taking this medicine to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search 1 NFPA.