PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Tadomon® 25 mg, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg prolonged-release tablets
Tapentadol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet:

1. What Tadomon is and what it is used for

Tapentadol - the active substance in Tadomon - is a strong painkiller which belongs to the class of opioids. Tadomon is used for the treatment of severe chronic pain in adults that can only be adequately managed with an opioid painkiller.

2. What you need to know before you take Tadomon

Do not take Tadomon if you
- are allergic to tapentadol or any of the other ingredients of this medicine (listed in section 6),
- have asthma or if your breathing is dangerously slow or shallow (respiratory depression, hypercapnia),
- have paralysis of the gut,
- have acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions) (see "Other medicines and Tadomon").

Warnings and precautions
Talk to your doctor or pharmacist before taking Tadomon if you:
- have slow or shallow breathing,
- suffer from increased pressure in the brain or disturbed consciousness up to coma,
- have had a head injury or brain tumour,
- suffer from a liver or kidney disease (see "How to take Tadomon"),
- suffer from a pancreatic or biliary tract disease including pancreatitis,
- are taking medicines referred to as mixed opioid agonist/antagonists (e.g. pentazocine, nalbuphine) or partial μ-opioid agonists (e.g. buprenorphine),
- have a tendency towards epilepsy or fits or if you are taking other medicines known to increase the risk of seizures because the risk of a fit may increase.

- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- are a smoker.
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

This medicine contains tapentadol which is an opioid medicine. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Tadomon, it is important that you consult your doctor. Use (even at therapeutic doses) may lead to physical dependence, which may result in you suffering withdrawal effects and a recurrence of your problems if you suddenly stop taking this medicine treatment.

Tadomon may lead to physical and psychological addiction. If you have a tendency to abuse medicines or if you are dependent on medicines, you should only take these tablets for short periods and under strict medical supervision.

Sleep-related breathing disorders
Tadomon can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and Tadomon
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor will tell you which medicines are safe to take with Tadomon.
- The risk of side effects increases if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take Tadomon at the same time. Your doctor will tell you whether Tadomon is suitable for you.
- Concomitant use of Tadomon and sedative medicines such as benzodiazepines or related medicines (certain sleeping pills or tranquillizers (e.g. barbiturates) or pain relievers such as opioids, morphine and codeine (also as cough medicine), antipsychotics, H1-antihistamines, alcohol) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe Tadomon together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
- The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening. Please tell your doctor if you are taking gabapentin or pregabalin or any sedative medicines and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- If you are taking a type of medicine that affects serotonin levels (e.g. certain medicines to treat depression), speak to your doctor before taking Tadomon as there have been cases of "serotonin syndrome". Serotonin syndrome is a rare, but life-threatening condition. The signs include involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension and body temperature above 38°C. Your doctor can advise you on this.

- Taking Tadomon together with other medicines that belong to the group of mixed μ-opioid receptor agonists/antagonists (e.g. pentazocine, nalbuphine) or partial μ-opioid receptor agonists (e.g. buprenorphine) has not been investigated. Tadomon may not work as well if taken with one of these medicines. Tell your doctor if you are currently being treated with one of these medicines.
- Taking Tadomon with medicines (e.g. rifampicin, phenobarbital or St John's Wort) that affect the enzymes required to remove tapentadol from the body, may affect how well tapentadol works or may cause side effects. The effects may occur especially when the other medicine is started or stopped. Please keep your doctor informed about all medicines you are taking.
- Tadomon should not be taken together with monoamine oxidase inhibitors (MAOIs - certain medicines for the treatment of depression). Tell your doctor if you are taking MAO inhibitors or have taken these during the last 14 days.

Tadomon with food, drink and alcohol
Do not drink alcohol whilst taking Tadomon because some side effects such as drowsiness may be increased. Food does not influence the effect of this medicine.

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 this medicine:
- if you are pregnant, unless your doctor has instructed you to do so. If used over prolonged periods during pregnancy, tapentadol may lead to withdrawal symptoms in the newborn baby, which might be life-threatening for the newborn if not recognized and treated by a doctor.
- during childbirth because it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn,
- during breast-feeding, because the active substance may be excreted in the breast milk.

Driving and using machines
Tadomon may cause drowsiness, dizziness and blurred vision and may impair your reactions. This may especially happen when you start taking Tadomon, if your doctor changes your dose or if you are drinking alcohol or taking tranquillizers.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine."

3. How to take Tadomon

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

Your doctor will adjust the dosage according to the intensity of your pain and your individual pain sensitivity. In general, the lowest pain-relieving dose should be taken.

Adults
The usual dose is 1 tablet every 12 hours. Total daily doses of Tadomon greater than 500 mg tapentadol are not recommended. Your doctor may prescribe a different, more appropriate dose or interval of dosing, if this is necessary for you. If you feel that the effect of these tablets is too strong or too weak, talk to your doctor or pharmacist.

Elderly patients
In elderly patients (above 65 years) usually no dose adjustment is necessary. However, the excretion of tapentadol may be delayed in some patients of this age group. If this applies to you, your doctor may recommend a different dose regimen.

Kidney disease
Patients with severe kidney problems should not take this medicine. In case of mild or moderate kidney problems, a dose adjustment is not required.

Liver disease
Patients with severe liver problems should not take this medicine. If you have moderate problems, your doctor will recommend a different dose regimen. In case of mild liver problems, a dose adjustment is not required.

Children and adolescents
Tadomon is not suitable for children and adolescents below the age of 18 years.

How and when should you take Tadomon
Tadomon is for oral use.
Always swallow the tablets whole, with sufficient liquid. Don't chew, break or crush them – this could lead to an overdose because the active substance will be released into your body too quickly.
You may take the tablets on an empty stomach or with meals.
The empty shell of the tablet may not be digested completely and may be seen in your stools. Do not worry - the active substance has already been absorbed into your body and what you see is just the empty shell.

How long should you take Tadomon
Do not take this medicine for longer than your doctor has told you.

If you take more Tadomon than you should
After taking very high doses, the following may be experienced:
- pin-point pupils, vomiting, drop in blood pressure, fast heart beat, collapse, disturbed consciousness or coma (deep unconsciousness), epileptic fits, dangerously slow or shallow breathing or stopping breathing.

If this happens a doctor should be called immediately!

If you forget to take Tadomon
If you forget to take the tablets, your pain is likely to return. Do not take a double dose to make up for a forgotten dose, simply continue taking the tablets as before.

If you stop taking Tadomon
If you interrupt or stop treatment too soon, your pain is likely to return. If you wish to stop treatment, please tell your doctor first before stopping treatment.

Generally, there will be no after-effects when treatment is stopped. However, on uncommon occasions, people who have been taking the tablets for some time may feel unwell if they abruptly stop taking them.

Symptoms may be:
- restlessness, watery eyes, runny nose, yawning, sweating, chills, muscle pain and dilated pupils,
- irritability, anxiety, backache, joint pain, weakness, abdominal cramps, difficulty in sleeping, nausea, loss of appetite, vomiting, diarrhoea, and increases in blood pressure, breathing or heart rate.

If you experience any of these complaints after stopping treatment, please consult your doctor.

You should not suddenly stop taking this medicine unless your doctor tells you to. If your doctor wants you to stop taking your tablets, he/she will tell you how to do this, this may include a gradual reduction of the dose.

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

4. Possible side effects

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

Important side effects or symptoms to look out for and what to do if you are affected:
- This medicine may cause allergic reactions (uncommon). Symptoms may be wheeziness, swelling of the eyelids, face or lips, rash or itching, especially those covering your whole body. In more severe cases, difficulties in breathing, a fall in blood pressure, collapse or shock may occur.
- Another serious side effect is a condition where you breathe more slowly or weakly than expected (rare). It mostly occurs in elderly and weak patients.

If you are affected by these important side effects, contact a doctor immediately.

Other side effects that may occur:

Very common (may affect more than 1 in 10 people)
feeling sick (nausea), constipation, dizziness, drowsiness, headache.

Common (may affect up to 1 in 10 people)
decreased appetite, anxiety, depressed mood, sleep problem, nervousness, restlessness, disturbance in attention, trembling, muscle twitches, flushing, shortness of breath, vomiting, diarrhoea, indigestion, itching, increased sweating, rash, feeling of weakness, fatigue, feeling of body temperature change, mucosal dryness, accumulation of water in the tissue (oedema).

Uncommon (may affect up to 1 in 100 people)
weight loss, disorientation, confusion, excitability (agitation), perception disturbances, abnormal dreams, euphoric mood, depressed level of consciousness, memory impairment, mental impairment, fainting, sedation, balance disorder, difficulty in speaking, numbness, abnormal sensations of the skin (e.g. tingling, prickling), abnormal vision, faster heart beat, slower heart beat, palpitations, decreased blood pressure, abdominal discomfort, hives, delay in passing urine, frequent urination, sexual dysfunction, drug withdrawal syndrome (see “If you stop taking Tadomon”), feeling abnormal, irritability.

Rare (may affect up to 1 in 1,000 people)
drug dependence, thinking abnormal, epileptic fit, near fainting, coordination abnormal, , impaired gastric emptying, feeling drunk, feeling of relaxation.

Not known (frequency cannot be estimated from the available data)

delirium.

In general, the likelihood of having suicidal thoughts and behaviour is increased in patients suffering from chronic pain. In addition, certain medicines for the treatment of depression (which have an impact on the neurotransmitter system in the brain) may increase this risk, especially at the beginning of treatment. Although tapentadol also affects neurotransmitters, data from human use of tapentadol do not provide evidence for an increased risk.

Reporting of side effects
If you get any side effects, talk 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 at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Tadomon

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

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Tadomon contains
The active substance is tapentadol.
Each tablet contains 25 mg, 50 mg, 100 mg, 150 mg, 200 mg or 250 mg tapentadol (as tartrate).
The other ingredients are:
Tablet core:
Povidone, microcrystalline cellulose, Hypromellose, colloidal anhydrous silica, magnesium stearate.
Tablet coat:
Hypromellose, polydextrose, titanium dioxide (E171), maltodextrin, medium-chain triglycerides.
25 mg & 250 mg tablets also contain yellow iron oxide (E172), black iron oxide (E172) and red iron oxide (E172).
100 mg tablets also contain yellow iron oxide (E172).
150 mg & 200 mg tablets also contain yellow iron oxide (E172) and red iron oxide (E172).

What Tadomon looks like and contents of the pack
25 mg tablets: Light beige, round and biconvex film-coated tablets, with a diameter of 8.1 mm ± 0.2 mm and a thickness of 4.2 mm ± 0.3 mm.
50 mg tablets: White to off-white, round and biconvex film-coated tablets, with a diameter of 12.1 mm ± 0.2 mm and a thickness of 4.1 mm ± 0.3 mm.
100 mg tablets: Light yellow, oblong and biconvex film-coated tablets, with a length of 16.7 mm ± 0.2 mm and a thickness of 5.0 mm ± 0.3 mm.

150 mg tablets: Light pink, oblong and biconvex film-coated tablets, with a length of 18.2 mm ± 0.2 mm and a thickness of 5.6 mm ± 0.3 mm.
200 mg tablets: Light ochre, oblong and biconvex film-coated tablets, with a length of 18.2 mm ± 0.2 mm and a thickness of 5.6 mm ± 0.3 mm.
250 mg tablets: Red-brown, oblong and biconvex film-coated tablets, with a length of 21.2 mm ± 0.2 mm and a thickness of 6.0 mm ± 0.3 mm.

Tablets are packed in blisters of 7, 7x1, 10, 10x1, 14, 14x1, 20, 20x1, 24, 24x1, 28, 28x1, 30, 30x1, 40, 40x1, 50, 50x1, 54, 54x1,56, 56x1, 60, 60x1, 90, 90x1, 100 and 100x1 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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