Package leaflet: Information for the user

Tapentadol MSN 25 mg prolonged-release tablets
Tapentadol MSN 50 mg prolonged-release tablets
Tapentadol MSN 100 mg prolonged-release tablets
Tapentadol MSN 150 mg prolonged-release tablets
Tapentadol MSN 200 mg prolonged-release tablets
Tapentadol MSN 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 Tapentadol MSN is and what it is used for

Tapentadol - the active substance in Tapentadol MSN - is a strong painkiller which belongs to the class of opioids. Tapentadol MSN is used for the treatment of:
- severe chronic pain in adults that can only be adequately managed with an opioid painkiller.
- severe chronic pain in children above 6 years and adolescents that can only be adequately managed with an opioid painkiller

2. What you need to know before you take Tapentadol MSN

Do not take Tapentadol MSN:

- If you are allergic to tapentadol or any of the other ingredients of this medicine (listed in section 6)
- If you have asthma or if your breathing is dangerously slow or shallow (respiratory depression, hypercapnia)
- If you have paralysis of the gut
- If you have acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions) (see “Other medicines and Invented Name>”)

Warnings and precautions

Talk to your doctor or pharmacist before taking Tapentadol MSN 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 tumours,
- suffer from a liver or kidney disease (see "How to take Tapentadol MSN"),
- 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 mu-opioid agonists (e.g. buprenorphine).
- if you 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.

Tolerance, dependence and addiction

This medicine contains tapentadol, which is an opioid. It can cause dependence and/or addiction.

This medicine contains tapentadol which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Tapentadol MSN can also lead to dependence, abuse and addiction which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.
The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Tapentadol MSN if:
- you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- you are a smoker.
- you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Tapentadol MSN, it could be a sign that you have become dependent or addicted:
- You need to take the medicine for longer than advised by your doctor.
- You need to take more than the recommended dose.
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (see section 3, If you stop taking Tapentadol MSN).

Children and adolescents
Children and adolescents with obesity should be monitored closely and the recommended maximum dose should not be exceeded.

Do not give this medicine to children below the age of 6 years.

Sleep-related breathing disorders.
Tapentadol MSN 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 Tapentadol MSN
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Tapentadol MSN at the same time. Your doctor will tell you whether Tapentadol MSN is suitable for you.

Concomitant use of Tapentadol MSN and sedative medicines such as benzodiazepines or related drugs (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 Tapentadol MSN 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 Tapentadol MSN 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 38ºC. Your doctor may advise you on this.

Taking tapentadol together with other types of medicines referred to as mixed mu-opioid agonist/antagonists (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g., buprenorphine) has not been studied. It is possible that Tapentadol MSN will not work as well if given together with one of these medicines. Tell your doctor in case you are currently treated with one of these medicines.

Taking Tapentadol MSN together with strong inhibitors or inducers (e.g. rifampicin, phenobarbital, St John's Wort) of certain enzymes that are necessary to eliminate tapentadol from your body, may influence how well tapentadol works or may cause side effects, especially when this other medication is started or stopped. Please keep your doctor informed about all medicines you are taking.

Tapentadol MSN should not be taken together with MAO inhibitors (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.

If you use Tapentadol MSN together with the below medicines that have anticholinergic effects the risk of side effects may be increased:
- medicines to treat depression.
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics).
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics).
- muscle relaxants.
- medicines to treat Parkinson's disease.

Tapentadol MSN with food, drink and alcohol

Do not drink alcohol whilst taking Tapentadol MSN 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 these tablets:

- 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 it may be excreted in the breast milk.

Driving and using machines
Tapentadol MSN may cause drowsiness, dizziness and blurred vision and may impair your reactions. This may especially happen when you start taking Tapentadol MSN, when your doctor changes your dosage or when you drink alcohol or take tranquillizers. Please ask your doctor whether it is permitted to drive a car or use machines.

3. How to take Tapentadol MSN

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Tapentadol MSN, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also"If you stop taking Tapentadol MSN" below).

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 starting dose is 50 mg every 12 hours.
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.
Total daily doses of Tapentadol MSN greater than 500 mg tapentadol are not recommended.

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 dosage regimen.

Liver and Kidney disease (insufficiency)
Patients with severe liver problems should not take these tablets. If you have moderate problems, your doctor will recommend a different dosage regimen. In case of mild liver problems, a dosage adjustment is not required.
Patients with severe kidney problems should not take these tablets. In case of mild or moderate kidney problems, a dosage adjustment is not required.

Use in children and adolescents
The dose of Tapentadol MSN for children and adolescents aged 6 years to less than 18 years is dependent on age and body weight.

The correct dose will be determined by your doctor. A total dose of 500 mg per day, i.e. 250 mg given every 12 hours should not be exceeded.
Children and adolescents with kidney or liver problems should not take these tablets.

Tapentadol MSN is not suitable for children below the age of 6 years.

How and when should you take Tapentadol MSN?
Tapentadol MSN is for oral use.
Always swallow the tablets whole, with sufficient liquid.
Don't chew it, break it or crush it – this could lead to overdosing, because the drug 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 thus be seen in stool. This should not worry you, since the active substance of the tablet has already been absorbed in your body and what you see is just the empty shell.

How long should you take Tapentadol MSN?
Do not take the tablets for longer than your doctor has told you.

If you take more Tapentadol MSN 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 which may lead to death.

If this happens a doctor should be called immediately!

If you forget to take Tapentadol MSN
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 Tapentadol MSN
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, diarrhea, 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. No additional side effects were observed in children and adolescents compared to adults.

Important side effects or symptoms to look out for and what to do if you are affected:
This medicine may cause allergic reactions. Symptoms may be wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching, especially those covering your whole body. Another serious side effect is a condition where you breathe more slowly or weakly than expected. 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): 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): allergic reaction to medicines (including swelling beneath the skin, hives, and in severe cases difficulty breathing, a fall in blood pressure, collapse, or shock), 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 Tapentadol MSN"), feeling abnormal, irritability.

Rare (may affect up to 1 in 1,000 people): drug dependence, thinking abnormal, epileptic fit, near fainting, coordination abnormal, dangerously slow or shallow breathing (respiratory depression), 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 nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance
Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tapentadol MSN

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 medicinal product does not require any special storage conditions.
Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

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 protect the environment.

6. Contents of the pack and other information

What Tapentadol MSN contains
The **active** substance is tapentadol.
Each prolonged-release tablet contains 25 mg tapentadol (as tartrate).
Each prolonged-release tablet contains 50 mg tapentadol (as tartrate).
Each prolonged-release tablet contains 100 mg tapentadol (as tartrate).
Each prolonged-release tablet contains 150 mg tapentadol (as tartrate).
Each prolonged-release tablet contains 200 mg tapentadol (as tartrate).
Each prolonged-release tablet contains 250 mg tapentadol (as tartrate).

The other ingredients are:
Tablet core: microcrystalline cellulose, silica, colloidal anhydrous, magnesium stearate, hypromellose.
Tablet coat: polyvinyl alcohol-part, hydrolyzed (E1203), titanium dioxide (E171), macrogol (E1521), Talc (E553b), iron oxide red (E172) [only for 25 mg, 150 mg, 200 mg, 250 mg].

What Tapentadol MSN looks like and contents of the pack
Tapentadol MSN 25 mg are light pink film-coated oblong shaped biconvex prolonged-release tablets debossed with ‘T17’on one side and plain on the other side.

Tapentadol MSN 50 mg are white film-coated oblong shaped biconvex prolonged-release tablets debossed with ‘T9’on one side and plain on other side.

Tapentadol MSN 100 mg are white film-coated oblong shaped biconvex prolonged-release tablets debossed with T10’on one side and plain on other side.

Tapentadol MSN 150 mg are light pink film-coated oblong shaped biconvex prolonged-release tablets debossed with‘T11’ on one side and plain on other side.

Tapentadol MSN 200 mg are light pink film-coated oblong shaped biconvex prolonged-release tablets debossed with ‘T12’ on one side and plain on other side.

Tapentadol MSN 250 mg are light pink film-coated oblong shaped biconvex prolonged-release tablets debossed with ‘T13’on one side and plain on other side.

Tapentadol MSN prolonged-release tablets are packed in peelable child-resistant blisters containing 7, 10, 14, 20, 24, 28, 30, 40, 50, 54, 56, 60, 90, 100 or in peelable child-resistant perforated unit-dose blisters containing 10x1, 14x1, 20x1, 28x1, 30x1, 40x1 50x1, 56x1, 60x1, 90x1, 100x1 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
MSN Labs Europe Limited,
KW20A, Corradino Park,

Paola PLA 3000,
Malta

Manufacturer
Pharmadox Healthcare Limited
KW20A Kordin Industrial Park, Paola, PLA3000, Malta

MSN Labs Europe Limited
KW20A Corradino Park, Paola, PLA3000, Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany:	Tapentadol Vivanta 25 mg; 50 mg; 100 mg; 150 mg; 200 mg; 250 mg Retardtabletten
Denmark:	Tapentadol Vivanta
Spain:	Tapentadol Vivanta 25 mg; 50 mg; 100 mg; 150 mg; 200 mg; 250 mg comprimidos de liberación prolongada EFG
Ireland:	Tapentadol MSN 25 mg; 50 mg; 100 mg; 150 mg; 200 mg; 250 mg prolonged-release tablets

This leaflet was last revised in {MM/YYYY}.