Package leaflet: Information for the user

Tapentadol Neuraxpharm 50 mg prolonged-release capsules, hard
Tapentadol Neuraxpharm 100 mg prolonged-release capsules, hard
Tapentadol Neuraxpharm 150 mg prolonged-release capsules, hard
Tapentadol Neuraxpharm 200 mg prolonged-release capsules, hard
Tapentadol Neuraxpharm 250 mg prolonged-release capsules, hard

tapentadol

This medicine contains tapentadol which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.
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 Neuraxpharm is and what it is used for

The full name of your medicine is 'Tapentadol Neuraxpharm prolonged-release capsules, hard'.
It is referred to as 'Tapentadol Neuraxpharm' in this leaflet.
This medicine is used in adults.
This medicine has been prescribed for you for the treatment of severe long-term pain that can only be adequately managed with an opioid painkiller.
It contains tapentadol which belongs to a class of medicines called opioids, which are 'pain relievers'.
This medicine has been prescribed to you and should not be given to anyone else.
Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly.
Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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

Do not take this medicine:
- 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 no bowel movement as shown by severe constipation and bloating which may be accompanied by pain or discomfort in the lower stomach
- if you have poisoning with alcohol, sleeping pills, pain relievers or medicines that affect mood and emotions (see 'Other medicines and Tapentadol Neuraxpharm').

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you:
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of this medicine to get the same level of pain relief. This may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- have slow or shallow breathing
- suffer from increased pressure in the brain or are not fully conscious
- have had a head injury or brain tumors
- suffer from liver or kidney problems (see "How to take Tapentadol Neuraxpharm")
- suffer from a pancreatic disease including inflammation of the pancreas (pancreatitis) or disease of the bile duct (biliary tract disease)
- are taking medicines referred to as mixed opioid agonist/antagonists (e.g., pentazocine, nalbuphine) or partial mu-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.
- have a tendency to abuse medicines or if you are dependent on medicines, as tapentadol may lead to 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 this medicine, 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.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

<u>Sleep-related breathing disorders</u>
This medicine 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 Neuraxpharm
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 this medicine at the same time. Your doctor will tell you whether this medicine is suitable for you.
- Concomitant use of tapentadol 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, H_1-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 this medicine 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 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.
- Tapentadol may not work as well if taken with opioid-like medicines (e.g. those containing pentazocine, nalbuphine or buprenorphine). Tell your doctor if you are currently being treated with one of these medicines.
- Taking tapentadol 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 this medicine works or may cause side effects. The effects may occur especially when the other medicine is started or stopped.
- This medicine 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.

Tapentadol Neuraxpharm with alcohol
Do not drink alcohol whilst you are taking this medicine, because some side effects such as drowsiness may be increased.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
Do not take this medicine if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.
If you use this medicine during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
Do not take this medicine while you are breastfeeding as tapentadol passes into breast milk and will affect your baby.

Driving and using machines

The 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 you doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.
If you feel drowsy, dizzy, have blurred vision or a slow reaction time whilst taking this medicine, then do not drive, use tools or machinery.

Any such effects are more likely to occur when you start taking this medicine, when the dose is changed, or when you are drinking alcohol or taking tranquilizers. Please ask your doctor before driving or using machines.

3. How to take Tapentadol Neuraxpharm

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will change the dose and time between doses of this medicine according to your pain level and your needs. Generally, the lowest pain-relieving dose should be taken.
Your prescriber should have discussed with you, how long the course of capsules will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Adults
Total daily doses of this medicine greater than 500 mg tapentadol are not recommended.

The usual dose is one capsule every 12 hours. Your doctor may prescribe a different, more appropriate dose or timing of dosing, if this is necessary for you. If you feel that the effect of these capsules is too strong or weak, talk to your doctor or pharmacist.

Elderly patients
In elderly patients (above 65 years) usually no dose adjustment is necessary. However, your doctor may adjust your dose or time between doses if required.

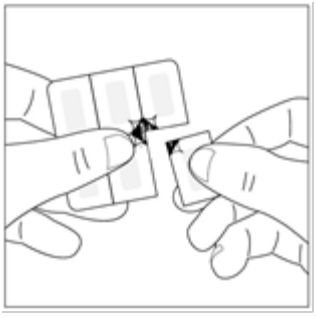
Patients with liver or kidney problems (insufficiency)
Do not take this medicine if you have severe liver or kidney problems. If you have moderate liver problems, your doctor will adjust your dose or time between doses. If you have mild liver problems or mild to moderate kidney problems, a dose adjustment is not required

Use in children and adolescents
This medicine is not recommended for children and adolescents below the age of 18 years.

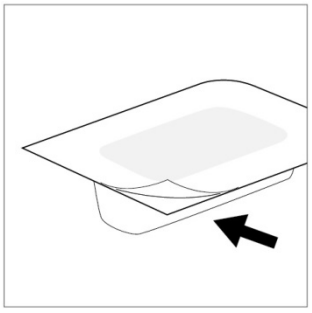
How should you take Tapentadol Neuraxpharm
This medicine is for oral use.
Swallow the capsule with a glass of water. You may take the capsule either on an empty stomach or with food.

If you have difficulty swallowing, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of cold soft food (e.g. apple sauce) and taken immediately. Do not store for future use.
Drink some fluid, e.g. water, after you have swallowed the soft food containing the capsule contents.
The capsule and the capsule contents must not be crushed or chewed, as it may result in overdose due to quick release of tapentadol in your body.

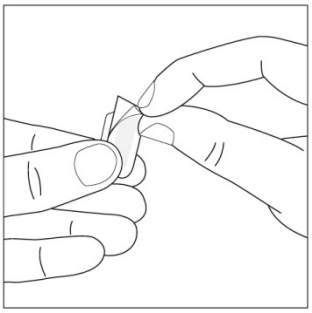
Opening instructions for the peel-off blister
This medicine may be provided in peel-off child-resistant blisters. You cannot press out the capsules through the peel-off blister and this may damage the prolonged-release capsule. Please observe the following opening instructions for the peel-off blister:
1. Tear off a single dose along the perforation line of the blister.



2. An unsealed area is now accessible which is located at the corner where the perforation lines have crossed.



3. Pull at the unsealed section to peel off the cover seal.



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

If you take more tapentadol than you should
Taking too much tapentadol may be life-threatening. Immediate medical advice should be sought in the event of an overdose, even if you feel well.
Very high doses of this medicine may cause the following:
- pin-point pupils in the eyes
- being sick (vomiting)
- drop in blood pressure
- fast heart beat
- altered consciousness, collapse or deep unconsciousness (coma)
- epileptic fits
- dangerously slow or shallow breathing or stopping breathing

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

If you stop taking this medicine
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.
If you experience any of these complaints after stopping this medicine, please contact your doctor.
Do not stop taking this medicine unless your doctor tells you to. If your doctor wants you to stop taking your capsules, 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 including swelling beneath the skin, hives, and in severe cases difficulty breathing, a fall in blood pressure, collapse, or shock (uncommon). Symptoms may be wheeziness, difficulty breathing, swelling of the eyelids, face or lips, or rash or itching, which may cover your whole body.
- 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, being sick (vomiting), diarrhoea, indigestion
- sleep problem, tiredness or exhaustion (fatigue), feeling of weakness, trembling, muscle twitches, shortness of breath
- feeling depressed, nervousness, restlessness, lack of attention
- feeling hot (flushing), increased sweating, feeling of body temperature change, dry areas like nostrils, mouth, lips, eyelids, ears, genitals and anus
- itching, rash
- water retention (oedema)

Uncommon (may affect up to 1 in 100 people)
- weight loss
- low awareness of time, place or identity (disorientation), confusion, excitable (agitated), disturbances in perception, abnormal dreams, forgetfulness, mental impairment
- feeling very happy (euphoria), less consciousness, fainting, sedation, feeling unsteady, difficulty in speaking, numbness
- abnormal sensations of the skin (e.g. tingling, prickling), skin reactions (hives)
- abnormal vision
- faster or slower heartbeat, palpitations, low blood pressure
- stomach discomfort, delay in passing urine, passing urine more often than usual
- sexual dysfunction
- drug withdrawal effects (see ‘If you stop taking this medicine”)
- feeling strange, irritable

Rare side effects (may affect up to 1 in 1,000 people)
- thinking abnormal, epileptic fits, near fainting, uncoordinated, feeling drunk or relaxed
- delayed emptying of the stomach (impaired gastric emptying)

Not known (frequency cannot be estimated from the available data)
- delirium
- dependence and addiction (see section `How do I know if I am addicted?´)

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.

<u>Drug Withdrawal</u>

When you stop taking tapentadol, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst taking tapentadol, it could be a sign that you have become addicted.
- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 Website: 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 Tapentadol Neuraxpharm

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 blister or bottle after EXP. 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 protect the environment.

6. Contents of the pack and other information

What this medicine contains

The active substance is tapentadol.

- Tapentadol Neuraxpharm 50 mg prolonged-release capsules, hard
  Each prolonged-release capsule contains 50 mg tapentadol (as phosphate).

- Tapentadol Neuraxpharm 100 mg prolonged-release capsules, hard
  Each prolonged-release capsule contains 100 mg tapentadol (as phosphate).

- Tapentadol Neuraxpharm150 mg prolonged-release capsules, hard
  Each prolonged-release capsule contains 150 mg tapentadol (as phosphate).

- Tapentadol Neuraxpharm 200 mg prolonged-release capsules, hard
  Each prolonged-release capsule contains 200 mg tapentadol (as phosphate).

- Tapentadol Neuraxpharm 250 mg prolonged-release capsules, hard

Each prolonged-release capsule contains 250 mg tapentadol (as phosphate).

The other ingredients are:
Capsules contents:
cellulose, microcrystalline; talc; ethylcellulose; povidone (K30); dibutyl sebacate.
Capsule shell:
gelatin; titanium dioxide (E171); red iron oxide (150, 200 and 250 mg strengths only) (E172); yellow iron oxide (100, 150 and 200 mg strengths only) (E172).

What this medicine looks like and contents of the pack

Tapentadol Neuraxpharm 50 mg prolonged-release capsules, hard are hard capsules with white cap and white body filled with white to off-white spherical pellets. They are approximately 18.0 mm in length.

Tapentadol Neuraxpharm 100 mg prolonged-release capsules, hard are hard capsules with ivory cap and ivory body filled with white to off-white spherical pellets. They are approximately 21.7 mm in length.

Tapentadol Neuraxpharm 150 mg prolonged-release capsules, hard are hard capsules with light orange cap and light orange body filled with white to off-white spherical pellets. They are approximately 23.3 mm in length.

Tapentadol Neuraxpharm 200 mg prolonged-release capsules, hard are hard capsules with orange cap and orange body filled with white to off-white spherical pellets. They are approximately 25.3 mm in length.

Tapentadol Neuraxpharm 250 mg prolonged-release capsules, hard are hard capsules with swedish orange cap and swedish orange body filled with white to off-white spherical pellets. They are approximately 26.1 mm in length.

Tapentadol Neuraxpharm 50 mg prolonged-release capsules are available in packs of 28 or 56 capsules. Not all pack sizes may be marketed.

Tapentadol Neuraxpharm 100 mg, 150 mg, 200 mg and 250 mg prolonged-release capsules are available in packs of 56 capsules.
The capsules are supplied in peelable child-resistant paper/PET/aluminium-PVC/PE/PVDC perforated unit dose blisters.

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