PACKAGE LEAFLET

Package leaflet: Information for the user

Tapentadol Mylan 25 mg prolonged-release tablets
Tapentadol Mylan 50 mg prolonged-release tablets
Tapentadol Mylan 100 mg prolonged-release tablets
Tapentadol Mylan 150 mg prolonged-release tablets
Tapentadol Mylan 200 mg prolonged-release tablets
Tapentadol Mylan 250 mg prolonged-release tablets

tapentadol phosphate

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 Phosphate is and what it is used for

Tapentadol - the active substance in Tapentadol Phosphate - is a strong painkiller which belongs to the class of opioids. Tapentadol Phosphate 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 Tapentadol Phosphate

Do not take Tapentadol Phosphate
- 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 Tapentadol Phosphate”).

Warnings and precautions
Talk to your doctor or pharmacist before taking Tapentadol Phosphate 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 Phosphate”),

- 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),
- 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 Tapentadol Phosphate, 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.

Rarely, increasing the dose of this medicine or by taking this medicine for a long time you may become more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

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.

Tapentadol Phosphate 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

Tapentadol Phosphate 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 Phosphate
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 Phosphate at the same time. Your doctor will tell you whether Tapentadol Phosphate is suitable for you.
- Concomitantuse of Tapentadol Phosphate and sedative medicines such as benzodiazepines or related medicines (certain sleeping pills or tranquillisers (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 Phosphate 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 Phosphate 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 ºC. Your doctor may advise you on this.
- Tapentadol Phosphate 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 Phosphate 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 Phosphate 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 Phosphate 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 Phosphate 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 Phosphate with food, drink and alcohol
Do not drink alcohol whilst taking Tapentadol Phosphate , 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 recognised and treated by a doctor.
- during breast-feeding, because it may be excreted in the breast milk.

Use of Tapentadol Phosphate is not recommended:

- during childbirth, because it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn.

Driving and using machines
Tapentadol Phosphate may cause drowsiness, dizziness and blurred vision and may impair your reactions. This may especially happen, when you start taking Tapentadol Phosphate, when your doctor changes your dose or when you drink alcohol or take tranquilisers.

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

3. How to take Tapentadol Phosphate

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

Your prescriber should have discussed with you, how long the course of prolonged-release tablets 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
The usual starting dose is 50 mg taken twice daily, approximately every 12 hours.
Total daily doses of Tapentadol Phosphate 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.

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 dose regimen. In case of mild liver problems, a dose adjustment is not required.
Patients with severe kidney problems should not take these tablets. In case of mild or moderate kidney problems, a dose adjustment is not required.

Use in children and adolescents
Tapentadol Phosphate is not suitable for children and adolescents below the age of 18 years.

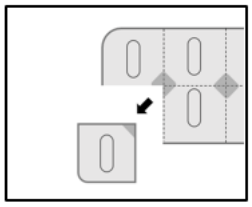
How and when should you take Tapentadol Phosphate
Tapentadol Phosphate is for oral use.
Always swallow the tablet whole with sufficient liquid. Do not break, chew or crush it, this will lead to overdosing, because the medicine will be released into your body too quickly. You may take the tablets on an empty stomach or with meals.

The score line is not intended for breaking the tablet.

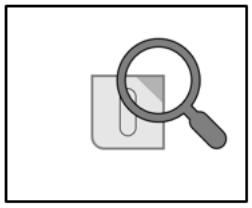
The empty shell of the tablet may not be digested completely and thus be seen in stool. This should not worry you, since the medicine (active substance) of the tablet has already been absorbed in your body and what you see is just the empty shell.

Opening instruction for the blister
This medicine is packed in a child-resistant perforated unit-dose blister. You cannot press out the tablets through the blister. Please observe the following opening instruction for the blister:

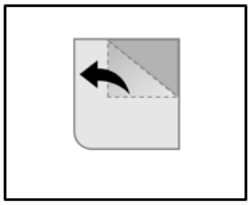
1. Tear off a single dose along the perforation line of the blister.



2. Hereby an unsealed area is accessible which is located at the position, where the perforation lines have crossed.



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



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

If you take more Tapentadol Phosphate 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 may occur.

If this happens a doctor should be called immediately.

If you forget to take Tapentadol Phosphate
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 Phosphate

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 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. 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 problems, 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 Phosphate'), 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 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 Tapentadol Phosphate prolonged-release tablets

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 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 Tapentadol Phosphate prolonged-release tablets contains

- The active substance is tapentadol phosphate.

  Tapentadol Mylan 25 mg prolonged-release tablets

Each prolonged-release tablet contains 38.285 mg tapentadol phosphate equivalent to 25 mg tapentadol

Tapentadol Mylan 50 mg prolonged-release tablets
Each prolonged-release tablet contains 76.570 mg tapentadol phosphate equivalent to 50 mg tapentadol

Tapentadol Mylan 100 mg prolonged-release tablets
Each prolonged-release tablet contains 153.139 mg tapentadol phosphate equivalent to 100 mg tapentadol

Tapentadol Mylan 150 mg prolonged-release tablets
Each prolonged-release tablet contains 229.709 mg tapentadol phosphate equivalent to 150 mg tapentadol

Tapentadol Mylan 200 mg prolonged-release tablets
Each prolonged-release tablet contains 306.279 mg tapentadol phosphate equivalent to 200 mg tapentadol

Tapentadol Mylan 250 mg prolonged-release tablets
Each prolonged-release tablet contains 382.848 mg tapentadol phosphate equivalent to 250 mg tapentadol

- The other ingredients are:
  Tablet core: microcrystalline cellulose (E460); Hypromellose (E464); silica, colloidal anhydrous (E551); magnesium stearate.
  Tablet coating: Hypromellose (E464); glycerol (E422); talc (E553b); microcrystalline cellulose (E460); titanium dioxide (E171); red iron oxide (E172) (25, 100, 150, 200 and 250 mg strengths only) yellow iron oxide (E172) (25, 100 and 200 mg strengths only); black iron oxide (E172) (25, 100, 150, 200 and 250 mg strengths only).

What Tapentadol Phosphate prolonged-release tablets looks like and contents of the pack

Tapentadol Phosphate 25 mg are light brown, oblong, biconvex prolonged-release tablets (6 mm x 12 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.

Tapentadol Phosphate 50 mg are white, oblong, biconvex prolonged-release tablets (6 mm x 13 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.

Tapentadol Phosphate 100 mg are light yellow, oblong, biconvex prolonged-release tablets (7 mm x 14 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.

Tapentadol Phosphate 150 mg are light pink, oblong, biconvex prolonged-release tablets (7 mm x 15 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.

Tapentadol Phosphate 200 mg are yellow, oblong, biconvex prolonged-release tablets (8 mm x 16 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.

Tapentadol Phosphate 250 mg are reddish brown, oblong, biconvex prolonged-release tablets 9 mm x 18 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.

Tapentadol Phosphate is available in pack sizes of:

Tapentadol Mylan 25 mg, 50mg, 100mg, 150mg, 200mg and 250mg prolonged-release tablets
20x1, 24 x1, 28 x1, 30 x1, 40 x1, 50 x1, 54 x1, 56 x1, 60 x1 or 100 x1 in child resistant perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan
Station Close
Potters Bar
Hertfordshire
EN6 1TL
United Kingdom

Manufacturer
Viatris UK Healthcare Limited
Station Close
Potters Bar
Hertfordshire
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United Kingdom

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This leaflet can be made available in large print, audio or Braille on request. Contact 0800 198 5000 to request this, quoting the following numbers: 04569/1840 or 04569/1841or 04569/1842 or 04569/1843 or 04569/1844 or 04569/1845.