Package leaflet: Information for the user

Tapentadol Aspire 25mg, 50mg, 100mg, 150mg, 200mg and 250mg prolonged-release tablets

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 this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1 What this medicine is and what it is used for

The full name of your medicine is 'Tapentadol Aspire 25mg, 50mg, 100mg, 150mg, 200mg or 250mg prolonged release tablets'. It is referred to as 'this medicine' in the rest of this leaflet.

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 in adults.

This medicine 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 this medicine

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 other psychotropic medicines (medicines that affect mood and emotions) (see 'Other medicines and tapentadol')
- for acute post-operative pain because of the increased risk of dependency and developing serious breathing problems. If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are taking this medicine. Your doctor may adjust your dose.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:
- have slow or shallow breathing
- suffer from increased pressure in the brain or disturbed consciousness, including comas
- have had a head injury or brain tumours
- suffer from liver or kidney problems (see 'How to take this medicine')
- 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 previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

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 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 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, 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).

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 an opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Sleep-related breathing disorders

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

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 this medicine.
- 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.
- Use of this medicine and sedative medicines such as benzodiazepines or related drugs (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 when taken at the same time as this medicine. 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. Please tell your doctor about all sedative medicines you are taking 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.
- The use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) taken at the same time as tapentadol, 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 this medicine 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.
- This medicine 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 this medicine 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 this medicine will not work as well if given together with one of these medicinal products. Tell your doctor in case you are currently treated with one of these medicinal products.
- Taking this medicine together with strong inhibitors or inducers (e.g. rifampicin, phenobarbital or St John's Wort) or 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.
- This medicine 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.

Please keep your doctor informed about all medicines you are taking.

If you use tapentadol 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.

Taking this medicine with food, drink and alcohol

Do not drink alcohol whilst you are taking this medicine, because some side effects such as drowsiness may be increased. You can take this medicine with or without food.

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 recognised and treated by a doctor
- if you become pregnant during treatment with this medicine. Check with your doctor
- during childbirth, as it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn
- if you are breast-feeding, as it may pass into the breast milk.

Driving and using machines

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

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected. There is further information for patients who are intending to drive in Great Britain - go to https://www.gov.uk/drug-driving-law.

3 How to take this medicine

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, 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 this medicine" below).

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.

Adults

The usual dose is 1 tablet every 12 hours.

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

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 tablets 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, the excretion of tapentadol may be delayed in some patients of this age group. If this applies to you, your doctor may adjust your dose or time between doses if required.

Patients with liver or kidney disease (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.

Children and adolescents

This medicine is not suitable for children and adolescents below the age of 18 years.

How and when should you take this medicine

This medicine is for oral use.

Swallow the tablets with a glass of water. You may take the tablets either on an empty stomach or with food. Do not chew, break or crush the tablet, as it may result in overdose due to quick release of tapentadol in your body.

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 your stool. This should not worry you, since the drug (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 this medicine

Do not take the tablets for longer than your doctor has told you.

Your prescriber should have discussed with you, how long the course of 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.

If you take more of this medicine than you should

Taking too much of this medicine 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 heartbeat
- altered consciousness, collapse or deep unconsciousness (coma)
- 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 this medicine

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 this medicine

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 contact 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, they 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. 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)
- 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
- low awareness of time, place or identity (disorientation), confusion, excitable (agitated), disturbances in perception, abnormal dreams, forgetfulness (memory impairment), mental impairment
- very happy (euphoria), less consciousness, fainting, sedation, feeling unsteady (balance disorder), 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 (may affect up to 1 in 1,000 people)
- drug dependence
- thinking abnormal, epileptic fits, near fainting, uncoordinated, feeling drunk or relaxed
- dangerously slow or shallow breathing (respiratory depression)
- delayed emptying of the stomach (impaired gastric emptying).

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

Drug Withdrawal

When you stop taking this medicine, 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 this medicine, 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.

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 does 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 this medicine

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.

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.

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** ingredient is tapentadol.

Each Tapentadol Aspire 25mg prolonged-release tablet contains 25mg tapentadol (as phosphate).

Each Tapentadol Aspire 50mg prolonged-release tablet contains 50mg tapentadol (as phosphate).

Each Tapentadol Aspire 100mg prolonged-release tablet contains 100mg tapentadol (as phosphate).

Each Tapentadol Aspire 150mg prolonged-release tablet contains 150mg tapentadol (as phosphate).

Each Tapentadol Aspire 200mg prolonged-release tablet contains 200mg tapentadol (as phosphate).

Each Tapentadol Aspire 250mg prolonged-release tablet contains 250mg tapentadol (as phosphate).

The **other** ingredients are:
- Tablet core: hypromellose, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.
- 25mg tablet coat: hypromellose, glycerol, talc, microcrystalline cellulose, titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172).
- 50mg tablet coat: hypromellose, glycerol, talc, microcrystalline cellulose, titanium dioxide (E171).
- 100mg tablet coat: hypromellose, glycerol, talc, microcrystalline cellulose, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).
- 150mg tablet coat: hypromellose, glycerol, talc, microcrystalline cellulose, titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172).
- 200mg tablet coat: hypromellose, glycerol, talc, microcrystalline cellulose, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).
- 250mg tablet coat: hypromellose, glycerol, talc, microcrystalline cellulose, titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172).

What this medicine looks like and contents of the pack
- Tapentadol Aspire 25mg prolonged-release tablets are light brown, oblong, biconvex film-coated prolonged release tablets with score lines on both sides.
- Tapentadol Aspire 50mg prolonged-release tablets are white, oblong, biconvex film-coated prolonged release tablets with score lines on both sides.
- Tapentadol Aspire 100mg prolonged-release tablets are light yellow, oblong, biconvex film-coated prolonged release tablets with score lines on both sides.
- Tapentadol Aspire 150mg prolonged-release tablets are light pink, oblong, biconvex film-coated prolonged release tablets with score lines on both sides.
- Tapentadol Aspire 200mg prolonged-release tablets are yellow, oblong, biconvex film-coated prolonged release tablets with score lines on both sides.
- Tapentadol Aspire 250mg prolonged-release tablets are reddish brown, oblong, biconvex film-coated prolonged release tablets with score lines on both sides.

The tablets are supplied in PVC-PE-PVDC-Aluminium blisters in a cardboard box containing 7, 10, 14, 20, 24, 28, 30, 40, 50, 54, 56, 60, 90 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aspire Pharma Ltd
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom

Manufacturer:

Develco Pharma GmbH
Grienmatt 27
DE-79650 Schopfheim
Germany

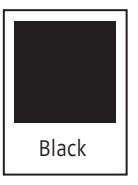
This leaflet was last revised in October 2025.

This leaflet is available in formats suitable for the blind and partially sighted.
Please contact Aspire Pharma Ltd via telephone: (+44) 01730 231148 or email: medinfo@aspirepharma.co.uk for more information.

1010583 - P4.1

ASPIRE® PHARMA

Artwork for:	Aspire Pharma Limited
Product name:	Tapentadol prolonged-release tablets
Size:	25mg/50mg/100mg/150mg/200mg/250mg
PL/PA no:	PL35533/0189-194
Type:	Leaflet
Artwork dimensions:	200mm x 600mm
Reason for request:	Text update
Version no:	P4.1
Date of revision:	22.10.25
Colours:	As swatches
Font(s):	Strada Pro
A/W software:	Indesign CC
Laetus Code:	XXX



Black