

Package leaflet: Information for the user

Tapimio 25 mg prolonged-release tablets
Tapimio 50 mg prolonged-release tablets
Tapimio 100 mg prolonged-release tablets
Tapimio 150 mg prolonged-release tablets
Tapimio 200 mg prolonged-release tablets
Tapimio 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 Tapimio is and what it is used for
2. What you need to know before you take Tapimio
3. How to take Tapimio
4. Possible side effects
5. How to store Tapimio
6. Contents of the pack and other information

1. What Tapimio is and what it is used for

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

Do not take Tapimio

- 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 Tapimio”)

Warnings and precautions

Talk to your doctor or pharmacist before taking Tapimio 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 Tapimio”),
- 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 Tapimio, 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.

Tapimio 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

Tapimio 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 Tapimio

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 Tapimio at the same time. Your doctor will tell you whether Tapimio is suitable for you.
- Concomitant use of Tapimio 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 Tapimio 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 Tapimio 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 may advise you on this.

- Taking Tapimio 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 Tapimio 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 Tapimio 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.
- Tapimio 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.

Tapimio with food, drink and alcohol

Do not drink alcohol whilst taking Tapimio, 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 Tapimio is not recommended

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

Driving and using machines

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

3. How to take Tapimio

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.

Adults

The usual starting dose is 50 mg taken twice daily, approximately every 12 hours.

Total daily doses of Tapimio 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

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

How and when should you take <Invented name>

Tapimio is for oral use.

Always swallow the tablet with sufficient liquid. Don't 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.

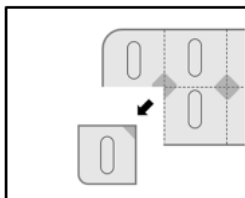
The tablet can be divided into equal doses.

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:

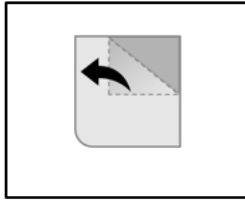
1. Tear off a single dose along the perforation line of the blister.



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 Tapimio**

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

If you take more Tapimio 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 Tapimio

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 Tapimio

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

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

Symptoms may be:

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

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

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

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

4. Possible side effects

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

Important side effects or symptoms to look out for and what to do if you are affected:

- This medicine may cause allergic reactions. 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 <Invented name>'), 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 HPRA Pharmacovigilance Website: www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tapimio

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 <Invented name> contains

- The active substance is tapentadol.

Tapimio 25 mg prolonged-release tablets

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

Tapimio 50 mg prolonged-release tablets

Each prolonged-release tablet contains tapentadol phosphate equivalent to 50 mg tapentadol.

Tapimio 100 mg prolonged-release tablets

Each prolonged-release tablet contains tapentadol phosphate equivalent to 100 mg tapentadol.

Tapimio 150 mg prolonged-release tablets

Each prolonged-release tablet contains tapentadol phosphate equivalent to 150 mg tapentadol.

Tapimio 200 mg prolonged-release tablets

Each prolonged-release tablet contains tapentadol phosphate equivalent to 200 mg tapentadol.

Tapimio 250 mg prolonged-release tablets

Each prolonged-release tablet contains 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 Tapimio looks like and contents of the pack

Tapimio 25 mg are brownish, oblong, biconvex prolonged-release tablets (6 mm x 12 mm) with score lines on both sides.

The tablet can be divided into equal doses.

Tapimio 50 mg are white, oblong, biconvex prolonged-release tablets (6 mm x 13 mm) with score lines on both sides.

The tablet can be divided into equal doses.

Tapimio 100 mg are yellowish, oblong, biconvex prolonged-release tablets (7 mm x 14 mm) with score lines on both sides.
The tablet can be divided into equal doses.

Tapimio 150 mg are bright reddish, oblong, biconvex prolonged-release tablets (7 mm x 15 mm) with score lines on both sides.
The tablet can be divided into equal doses.

Tapimio 200 mg are yellow, oblong, biconvex prolonged-release tablets (8 mm x 16 mm) with score lines on both sides.
The tablet can be divided into equal doses.

Tapimio 250 mg are reddish brown, oblong, biconvex prolonged-release tablets (9 mm x 18 mm) with score lines on both sides.
The tablet can be divided into equal doses.

Tapimio is available in pack sizes of:

Tapimio 25 mg

20x1, 30x1, 40x1, 50x1, 54x1, 60x1 or 100x1 prolonged-release tablets in child resistant perforated unit dose blisters.

Tapimio 50 mg

20x1, 24x1, 28x1, 30x1, 50x1, 54x1, 56x1, 60x1 or 100x1 prolonged-release tablets in child resistant perforated unit dose blisters.

Tapimio 100, 150, 200, 250 mg

20x1, 24x1, 30x1, 50x1, 54x1, 56x1, 60x1 or 100x1 prolonged-release tablets in child resistant perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Neuraxpharm Ireland Limited,
4045 Kingswood Road,
Citywest Business Campus,
Dublin 24,
Ireland

Manufacturer:

Develco Pharma GmbH,
Grienmatt 27,
79650 Schopfheim,
Germany

neuraxpharm Arzneimittel GmbH
Elisabeth-Selbert- Straße 23
40764 Langenfeld
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Germany	Tapentadol neuraxpharm 25 mg Retardtabletten
	Tapentadol neuraxpharm 50 mg Retardtabletten
	Tapentadol neuraxpharm 100 mg Retardtabletten
	Tapentadol neuraxpharm 150 mg Retardtabletten
	Tapentadol neuraxpharm 200 mg Retardtabletten
	Tapentadol neuraxpharm 250 mg Retardtabletten
Ireland	Tapimio 25 mg prolonged-release tablets
	Tapimio 50 mg prolonged-release tablets
	Tapimio 100 mg prolonged-release tablets
	Tapimio 150 mg prolonged-release tablets
	Tapimio 200 mg prolonged-release tablets
	Tapimio 250 mg prolonged-release tablets
Spain	Tapimio 25 mg comprimidos de liberación prolongada
	Tapimio 50 mg comprimidos de liberación prolongada
	Tapimio 100 mg comprimidos de liberación prolongada
	Tapimio 150 mg comprimidos de liberación prolongada
	Tapimio 200 mg comprimidos de liberación prolongada
	Tapimio 250 mg comprimidos de liberación prolongada
Sweden	Tapimio Depot 25 mg depottabletter
	Tapimio Depot 50 mg depottabletter
	Tapimio Depot 100 mg depottabletter
	Tapimio Depot 150 mg depottabletter
	Tapimio Depot 200 mg depottabletter
	Tapimio Depot 250 mg depottabletter

This leaflet was last revised in

03/2023