Package leaflet: Information for the user

Palexia 20 mg/ml drank

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 Palexia is and what it is used for

Tapentadol - the active substance in Palexia - is a strong painkiller which belongs to the class of opioids. Palexia is used for the treatment of moderate to severe acute pain in children and adolescents from 2 years of age and a body weight of more than 16 kg and in adults that can only be adequately managed with an opioid painkiller.

2. What you need to know before you take Palexia

Do not take Palexia
- 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 Palexia"),

Warnings and precautions

Talk to your doctor or pharmacist before taking Palexia, 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 Palexia”),
- suffer from a pancreatic or biliary tract disease, including pancreatitis.

- are taking medicines referred to as mixed opioid agonist/antagonists (e.g., pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine).
- if you have a tendency towards epilepsy or fits or if you are taking other medicines known to increase the risk of seizures because the risk of a fit may increase.
- 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 Palexia 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.

Palexia 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 Palexia for short periods and under strict medical supervision.

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

Do not give this medicine to children below the age of 2 years or a body weight of less than 16kg.

Sleep-related breathing disorders
PALEXIA 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 Palexia
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 Palexia at the same time. Your doctor will tell you whether Palexia is suitable for you.

- Concomitant use of Palexia and sedative medicines such as benzodiazepines or related drugs (certain sleeping pills or tranquillizers (e.g., barbiturates) or pain relievers such as opioids, morphine and codeine (also as cough medicine), antipsychotics, H1-antihistamines, alcohol) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
  However if your doctor does prescribe Palexia 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 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.

- 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 Palexia as there have been cases of "serotonin syndrome". Serotonin syndrome is a rare, but life threatening condition. The signs include involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension and body temperature above 38ºC. Your doctor may advise you on this.

- Taking Palexia 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 Palexia 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 Palexia 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.

- Palexia 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.

Palexia with food, drink and alcohol

Do not drink alcohol whilst taking Palexia 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 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 recognized and treated by a doctor.

Use of <TRADEMARK> is not recommended

- during childbirth, because it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn,
- during breast-feeding, because tapentadol may be excreted in the breast milk.

Driving and using machines

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

Palexia 20 mg/ml contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per maximum single dose, that is to say essentially 'sodium-free'.

Palexia 20 mg/ml contains sodium benzoate
This medicine contains 5,9 mg benzoate salt per 5 ml solution (maximum single dose) which is equivalent to 1,18 mg/ml.
Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Palexia 20 mg/ml contains propylene glycol
This medicine contains 10 mg propylene glycol per 5 ml solution (maximum single dose) which is equivalent to 2 mg/ml.

3. How to take Palexia

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

Adults

The usual dose is 50 mg tapentadol (2.5 ml oral solution), 75 mg tapentadol (3.75 ml oral solution) or 100 mg tapentadol (5 ml oral solution) tapentadol every 4 to 6 hours.

Total daily doses greater than 700 mg tapentadol on the first day of treatment and daily doses greater than 600 mg tapentadol on the following days of treatment 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 this medicine 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 dosage regimen.

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

Patients with severe kidney problems should not take this medicine. In case of mild or moderate kidney problems, a dosage adjustment is not required.

Use in children and adolescents
Palexia should only be given to children in the hospital.
Palexia should only be given to children with a body weight of more than 16 kg.

The dose of Palexia for children and adolescents aged 2 years to less than 18 years is 1.25 mg/kg every 4 hours.

Always wait 4 hours before giving the next dose. The dose may be decreased as the acute pain decreases.

The correct administration will be determined by your doctor.

Liver and Kidney disease (insufficiency)
Children and adolescents with liver or kidney problems should not take this medicine.

How and when should you take Palexia?
Palexia is for oral use.

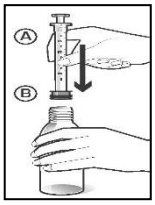
You may take the oral solution on an empty stomach or with meals.

There is a dosing pipette with an attached adaptor in the pack which should be used to take the exact amount (volume) needed from the bottle that corresponds to the prescribed dose of tapentadol.

Directions for opening the bottle and using the dosing pipette

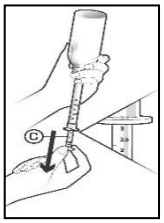
The bottle has a child resistant screw cap. To remove the cap, push it down and turn it counter clockwise (Fig. 1). Remove the cap and peel off the safety seal from the top of the bottle. If the safety seal is damaged, do not use this medicine and talk to your pharmacist.

Fig 1



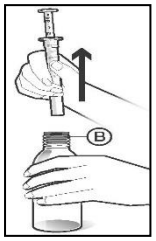
Place the bottle on a firm and flat surface. Open the plastic bag containing the dosing pipette/adaptor at the perforated end and remove the dosing pipette(A) with the attached adaptor (B). Plug the adaptor with the dosing pipette firmly into the neck of the bottle (Fig 2).

Fig 2



To fill the dosing pipette, turn the bottle upside down. Whilst holding the dosing pipette in place, gently pull the plunger (C) down to the line that matches the dose prescribed by your doctor (See section "How to take Palexia"). **Do not remove** the dosing pipette at this point! (Fig 3)

Fig 3



Turn the bottle upright and thereafter carefully remove the dosing pipette from the bottle. After you have removed the dosing pipette, carefully check that you have taken the right amount of the solution. The adaptor (B) that was previously attached to the dosing pipette should now remain in the bottle (Fig. 4).

Fig 4

Take your medicine by placing the dosing pipette into your mouth and gently pressing the plunger. Press the plunger fully to ensure all solution is used. If you prefer, you can dilute the medicine in a glass of water or a non-alcoholic drink before you take it; in this case drink the whole glass to ensure that you have taken the correct dose of medicine (Fig.5)

Fig 5

Leave the adaptor in the bottle, tightly close the bottle and store it in an upright position. Rinse the dosing pipette with water after each use and allow it to dry. When you take your medicine the next time, place the dosing pipette into the adaptor in the neck of the bottle and follow the instructions above.

How long should you take Palexia?
Do not take this medicine for longer than your doctor has told you.

If you take more Palexia than you should
After taking very high doses, the following may be experienced:
- pin-point pupils, vomiting, drop in blood pressure, fast heartbeat, 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 Palexia
If you forget to take this medicine, your pain is likely to return. Do not take a double dose to make up for a forgotten dose, simply continue taking this medicine as before.

If you stop taking Palexia
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 this medicine for some time may feel unwell if they abruptly stop taking it.
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 this medicine 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 are very sleepy and 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, vomiting, dizziness, drowsiness, headache.

Common (may affect up to 1 in 10 people)**:** decreased appetite, anxiety, confusion, hallucination, sleep problem, abnormal dreams, trembling, flushing, constipation, diarrhoea, indigestion, dry mouth, itching, increased sweating, rash, muscle cramps, feeling of weakness, fatigue, feeling of body temperature change.

Uncommon (may affect up to 1 in 100 people)**:** depressed mood, disorientation, excitability (agitation), nervousness, restlessness, euphoric mood, disturbance in attention, memory impairment, near fainting, sedation, difficulty in controlling movements, difficulty in speaking, numbness, abnormal sensations of the skin (e.g. tingling, prickling), muscle twitches, abnormal vision, faster heartbeat, palpitations, decreased blood pressure, dangerously slow or shallow breathing (respiratory depression), less oxygen in the blood, shortness of breath, abdominal discomfort, hives, sensation of heaviness, delay in passing urine, frequent urination, drug withdrawal syndrome (see "If you stop taking Palexia"), accumulation of water in the tissue (oedema), feeling abnormal, feeling drunk, irritability, feeling of relaxation.

Rare (may affect up to 1 in 1,000 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), thinking abnormal, epileptic fit, depressed level of consciousness, coordination abnormal, slower heartbeat, impaired gastric emptying.

Unknown: 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.

No Additional side effects were observed in children and adolescents.

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Palexia

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 bottle after <EXP>. The expiry date refers to the last day of that month.

Unopened: This medicinal product does not require any special storage conditions.

After first opening of the bottle, the solution should not be used for longer than 6 weeks.
Store in an upright position after first opening.

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 Palexia contains

The **active** substance is tapentadol.
1 ml of Palexia 20 mg/ml oral solution contains 20 mg tapentadol (as hydrochloride)

The **other** ingredients are:
Sodium benzoate (E211)
Citric acid monohydrate

Sucralose (E955)
Raspberry flavour, containing propylene glycol (E1520)
Sodium hydroxide (for pH adjustment)
Purified water

What Palexia looks like and contents of the pack

Palexia is a clear, colourless oral solution.

Palexia 20 mg/ml oral solution is supplied in plastic bottles containing 100 millilitres or 200 millilitres of solution, including a 5 ml dosing pipette with 0.1 ml intervals and an adapter attached to the dosing pipette. Additionally, the right scale shows the single doses for adults.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van vergunning voor het in de handel brengen
Grünenthal B.V.
De Corridor 21K
3621 ZA Breukelen
Voor inlichtingen en vragen: 030-6046370 of info.nl@grunenthal.com

Fabrikant
Grünenthal GmbH
Zieglerstrasse 6
52078 Aken
Duitsland

In het register ingeschreven onder:

Palexia 20 mg/ml drank: RVG 120266

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern-Ireland) under the following names:

Austria, Belgium, Croatia, Cyprus, Czech Republic, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, United Kingdom (Northern-Ireland): PALEXIA

This leaflet was last revised in juli 2024.