Package leaflet: Information for the user
PALEXIA 4 mg/ml oral solution

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

The full name of your medicine is 'PALEXIA 4 mg/ml oral solution'. It is referred to as 'PALEXIA' in the rest of this leaflet.

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 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 no bowel movement as shown by severe constipation and bloating which may be accompanied by pain or discomfort in the lower stomach
- if you have poisoning with alcohol, sleeping pills, pain relievers or medicines that affect mood and emotions (see 'Other medicines and 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 are not fully conscious.

- have had a head injury or brain tumours.

- suffer from liver or kidney problems (see "How to take PALEXIA").
- suffer from a pancreatic disease including inflammation of the pancreas (pancreatitis) or disease of the bile duct (biliary tract disease).
- are taking medicines referred to as mixed opioid agonist/antagonists (e.g., pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine).
- have a tendency towards epilepsy or fits or if you are taking other medicines known to increase the risk of seizures because the risk of a fit may increase.
- have a tendency to abuse medicines or if you are dependent on medicines, as PALEXIA may lead to addiction. In this case, you should only take this medicine for short periods of time and under strict medical supervision.
- 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.

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

Do not give this medicine to children below the age of 2 years.

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. Your doctor will tell you which medicines are safe to take with PALEXIA.

- 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 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 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 38^0C. Your doctor can advise you on this.
- PALEXIA 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 PALEXIA with products (e.g. rifampicin, phenobarbital or St John's Wort) that affect the enzymes required to remove PALEXIA from the body, may affect how well PALEXIA works or may cause side effects. The effects may occur especially when the other medication is started or stopped.
- Do not take PALEXIA with monoamine oxidase inhibitors (MAOIs – certain medicines for the treatment of depression). Tell your doctor if you are taking a MAOI or have taken a MAOI during the last 14 days.

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

Taking PALEXIA with food, drink and alcohol

Do not drink alcohol whilst you are taking PALEXIA, because some side effects such as drowsiness may be increased. You can take PALEXIA 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 recognized and treated by a doctor.
- if you become pregnant during treatment with PALEXIA. Check with your doctor.

Use of PALEXIA is not recommended:

- during childbirth, as it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn
- if you are breast-feeding, as tapentadol may pass into the breast milk.

Driving and using machines

If you feel drowsy, dizzy, have blurred vision or a slow reaction time whilst taking PALEXIA, then do not drive, use tools or machinery.
Any such effects are more likely to occur when you start taking PALEXIA, when the dose of PALEXIA is changed, or when you drink alcohol or take tranquilizers.
Please ask your doctor before driving a car or using machinery.

PALEXIA 4 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 4 mg/ml contains sodium benzoate
This medicine contains 59 mg benzoate salt in each unit volume which is equivalent to 2.4 mg/ml. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

PALEXIA 4 mg/ml contains propylene glycol
This medicine contains 48 mg propylene glycol per 25 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 change the dose and time between doses of PALEXIA according to your pain level and your needs. Generally, the lowest pain-relieving dose should be taken.

Adults
The usual dose every 4 to 6 hours is either:
- 50 mg tapentadol (12.5 ml oral solution), or
- 75 mg tapentadol (18.75 ml oral solution), or
- 100 mg tapentadol (25 ml oral solution).

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 timing of dosing, if this is necessary for you.
If you feel that the effect of this medicine is too strong or weak, talk to your doctor or pharmacist.

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

Patients with liver or kidney problems (insufficiency)
Do not take PALEXIA 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

PALEXIA should only be given to children in the hospital.

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 with or without food.
Use a dosing pipette and the adaptor provided in the pack to take the exact volume of the solution from the bottle as prescribed by your doctor. The volume corresponds to the prescribed dose.

Directions for opening the bottle and using the dosing pipette

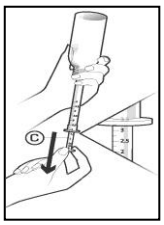
Fig 1

- The bottle has a child resistant screw cap. To remove the cap, push it down and turn it anti-clockwise (Fig. 1). After the cap is removed, 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 2

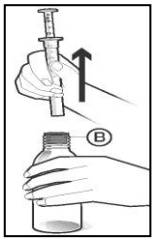
- Place the bottle on a stable flat surface. Open the plastic bag containing the dosing pipette / adaptor at the perforated end and remove the dosing pipette (A) with the attached adaptor (B). Plug the adaptor with the dosing pipette firmly into the neck of the bottle (Fig 2).

Fig 3



- 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 4



- **Turn the bottle upright** and then 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 5

- 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 dispensed. 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)

- Leave the adaptor in the bottle. Replace the cap and tightly close the bottle. Store the bottle in an upright position. After use, rinse the dosing pipette with water 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

Taking too much PALEXIA 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 PALEXIA 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.

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 withdrawal effects when treatment is stopped. However, on uncommon occasions, people who have been taking this medicine for some time may feel unwell if they suddenly stop taking it.
Symptoms may be:

- feeling restless, irritable, anxious, weak or sick (nausea), loss of appetite, being sick (vomiting), diarrhoea
- watery eyes, runny nose, increase in size of the pupils in the eyes (dilated pupils)
- difficulty in sleeping, yawning
- sweating, shivering
- muscle or joint pain, backache, abdominal cramps
- increase in blood pressure, breathing or heart rate.

If you experience any of these complaints after stopping PALEXIA, please contact your doctor.
Do not 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 including swelling beneath the skin, hives, and in severe cases difficulty breathing, a fall in blood pressure, collapse, or shock (rare). 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 are very sleepy and breathe more slowly or weakly than expected (uncommon). 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), being sick (vomiting)
- dizziness, drowsiness, headache.

Common (may affect up to 1 in 10 people)

- decreased appetite, constipation, diarrhoea, indigestion
- anxiety, confusion, hearing, seeing or sensing things that are not really there (hallucinations), sleep problem, abnormal dreams
- trembling, feeling hot (flushing), dry mouth
- itching, increased sweating, rash
- muscle cramps, feeling of weakness, tiredness or exhaustion (fatigue), feeling of body temperature change.

Uncommon (may affect up to 1 in 100 people)

- feeling depressed, very happy (euphoria), nervous, restless, or excitable (agitated), low awareness of time, place or identity (disorientation)
- lack of attention, forgetfulness, almost fainting, sedation, uncoordinated movements, muscle twitches, difficulty in speaking
- numbness, abnormal sensations of the skin (e.g. tingling, prickling)
- abnormal vision
- faster heartbeat, palpitations, decreased blood pressure, less oxygen in the blood, shortness of breath
- stomach discomfort
- skin reactions (hives)
- feeling of heaviness
- delay in passing urine, passing urine more often than usual
- drug withdrawal effects (see ‘If you stop taking PALEXIA’)
- water retention (oedema)
- feeling strange, drunk, irritable or relaxed.

Rare (may affect up to 1 in 1,000 people)

- epileptic fits
- thinking abnormal, impaired consciousness, uncoordinated movements, slower heartbeat
- delayed emptying of the stomach (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 via HPRA Pharmacovigilance Website: www.hpra.ie.
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. 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: The solution should not be used for longer than 6 weeks. Store in an upright position.

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** ingredient is tapentadol.
1 ml of PALEXIA 4 mg/ml oral solution contains 4 mg tapentadol (as hydrochloride)

The **other** ingredients are:
Sodium benzoate (E 211), Citric acid monohydrate, Sucralose (E 955), Raspberry flavour containing propylene glycol (E 1520), Purified water.

What PALEXIA looks like and contents of the pack
PALEXIA 4 mg/ml oral solution is a clear, colourless oral solution.

In Ireland, PALEXIA 4 mg/ml oral solution is available in plastic bottles containing 100 millilitres of solution, including a 5 ml dosing pipette with 0.1 ml graduation and an adapter attached to the dosing pipette.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Grünenthal Pharma Ltd., 4045 Kingswood Road, Citywest Business Park, Citywest, Co. Dublin, Ireland. Tel: +44(0)870 351 8960. E-mail: medicalinformationie@grunenthal.com

Manufacturer:
Grünenthal GmbH, Zieglerstrasse 6, 52078, Aachen, Germany.

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:

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

Other formats of this leaflet

A service is available to request a copy of this leaflet in Braille, large print or audio.
Please call: +44 173 3375 370

Please be ready to give the following information:

- **Product name:** PALEXIA 4 mg/ml oral solution
- **Reference number:** PA 2242/12/10

This leaflet was last revised in July 2024