Package leaflet: Information for the user

PALEXIA 100 mg film-coated 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 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 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.

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 these tablets for short periods and under strict medical supervision.

Sleep-related breathing disorders.

PALEXIA contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnea (shallow/pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen in the blood).
The risk of experiencing central sleep apnea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnea.

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.
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.

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 can 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 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 recognized and treated by a doctor.
- during childbirth because it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn
- during breast-feeding, because it 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 contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

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

How and when should you take PALEXIA
PALEXIA is for oral use.
Swallow the tablets with sufficient liquid. You may take the tablets on an empty stomach or with meals.

How long should you take PALEXIA
Do not take the tablets 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 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 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 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, 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.

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: HPRA PharmacovigilanceWebsite: 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 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 PALEXIA contains

The **active** substance is tapentadol.
Each tablet contains 100 mg tapentadol (as 116.48 mg tapentadol hydrochloride).

The **other** ingredients are:
Tablet core: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone K30, magnesium stearate.
Tablet coat: polyvinylalcohol, titanium dioxide (E 171), macrogol 3350, talc, yellow iron oxide (E 172), red iron oxide (E 172), black iron oxide (E 172).

What PALEXIA looks like and contents of the pack

Pale pink round shaped film-coated tablets of 9 mm diameter, marked with Grünenthal logo on one side and "H8" on the other side.

PALEXIA film-coated tablets are packed in blisters and are supplied in boxes of 5, 10, 10x1, 14, 14x1, 20, 20x1, 24, 28, 28x1, 30, 30x1, 40, 50, 50x1, 54, 56, 56x1, 60, 60x1, 90, 90x1, 100 and 100x1 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Grünenthal Pharma Ltd., 4045 Kingswood Road, Citywest Business Park, Citywest, Co. Dublin, Ireland.

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

This medicinal product is authorised in the Member States of the EEA under the following names:
Germany: Palexia Akutschmerz

Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, France, Finland, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom (NI): PALEXIA

Other formats of this leaflet
A service is available to listen to or 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 100 mg film-coated tablets
- **Reference number:** PA 2242/12/3

This leaflet was last revised in September 2021