

# Package leaflet: Information for the user

## PALEXIA 50 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
2. What you need to know before you take PALEXIA
3. How to take PALEXIA
4. Possible side effects
5. How to store PALEXIA
6. Contents of the pack and other information

### 1. What PALEXIA is and what it is used for

The full name of your medicine is 'PALEXIA 50 mg film-coated tablets'. It is referred to as 'PALEXIA' in the rest of this leaflet.

The active ingredient of PALEXIA is tapentadol.

PALEXIA belongs to the class of opioids and is used in adults to treat sudden moderate to severe pain, when your doctor recommends the use of a strong 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
- if you suffer from increased pressure in the brain or are not fully conscious
- if you have had a head injury or brain cancer
- if you have had an epileptic fit or if you are at risk of having epileptic fits
- if you suffer from liver or kidney problems (see Section 3)
- if you suffer from a pancreatic disease including inflammation of pancreas (pancreatitis) or disease of the bile duct (biliary tract disease)
- If you 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 tendency to abuse or if you are dependent on medicines, as PALEXIA may lead to addiction. In this case, you should only take these tablets for short periods of time and under strict medical supervision.

#### 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.

- Your breathing may become dangerously slow or shallow (respiratory depression) if you are taking certain sleeping pills or tranquilizers (e.g. barbiturates, benzodiazepines), or pain relievers such as morphine and codeine (also as cough medicine) in combination with PALEXIA. If this happens tell your doctor.
- Your consciousness may be decreased, you may feel drowsier or feel you might faint, if you take PALEXIA with sedatives such as benzodiazepines, antipsychotics (medicines that affect the state of mind or emotions), H1-antihistamines, opioids or alcohol. If this happens tell your doctor.
- 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 confusion, restlessness, fever, sweating, uncoordinated movement of arms, legs or eyes, uncontrollable jerking of muscles, muscle twitches and diarrhoea. 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, buprenorphine). Tell your doctor in case 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.
- PALEXIA should not be taken together with monoamine oxidase inhibitors (MAOIs - 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.

#### 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 PALEXIA:

- if you are pregnant, unless your doctor has instructed you to do so
- if you become pregnant during treatment with PALEXIA. 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

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 the dose of PALEXIA is changed, when you drink alcohol or take tranquilizers (see Section 'Other medicines and PALEXIA').

If you experience any of the above effects, please ask your doctor before driving a car or using machinery.

#### PALEXIA contains lactose.

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

### 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 is 1 tablet every 4 to 6 hours.

On the first day of treatment, the recommended maximum total daily dose of tapentadol is up to 700 mg. On the following days, the recommended maximum total daily dose is up to 600 mg.

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.

#### How and when should you take PALEXIA

PALEXIA is for oral use.

Swallow the tablets with a small glass of water. You may take the tablets either on an empty stomach or with food.

#### How long should you take PALEXIA

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

#### 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 and 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. In case of mild liver problems, a dose adjustment is not required.

If you have mild to moderate kidney problems, a dose adjustment is not required.



**Children and adolescents**

PALEXIA is not recommended for children and adolescents below the age of 18 years.

**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 heart beat
- altered consciousness, collapse or deep unconsciousness (coma)
- epileptic fits
- dangerously slow, shallow or stopping breathing.

**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 withdrawal effects when treatment is stopped. However, on uncommon occasions, people who have been taking the tablets for some time may feel unwell if they suddenly stop taking them.

After stopping PALEXIA suddenly, you may:

- feel restless, irritable, anxious, weak, feel sick (nausea), have loss of appetite, be sick (vomiting), diarrhoea
- have watery eyes or runny nose, increase in size of the pupils in the eyes (dilated pupils)
- find difficulty in sleeping, yawn
- sweat or shiver
- have muscle or joint pain, backache, abdominal cramps
- have an increase in blood pressure, increase in 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 your tablets, he/she will tell you how to do this. This may include a gradual reduction of the dose.

Other side effect information is listed in Section 4.

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, 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 (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, excitability (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 heart beat, palpitations, decreased blood pressure, less oxygen in the blood, shortness of breath

- stomach discomfort
- skin reactions/rashes (hives)
- feeling of heaviness
- delay in passing urine, urge to pass 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 strange thoughts, impaired consciousness, uncoordinated movements, slower heart beat
- delayed emptying of the stomach (impaired gastric emptying).

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 may increase this risk, especially at the beginning of treatment. There is not enough evidence from human use for an increased risk with PALEXIA.

**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, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@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** ingredient is tapentadol.

One (1) tablet contains 50 mg tapentadol (as 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.

**What PALEXIA looks like and contents of the pack**

PALEXIA 50 mg film-coated tablets are white round shaped film-coated tablets of 7 mm diameter, marked with Grünenthal logo on one side and "H6" on the other side.

PALEXIA film-coated tablets are packed in blisters.

PALEXIA is sold 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 Ltd, Regus Lakeside House, 1 Furzeground Way, Stockley Park East, Uxbridge, Middlesex UB11 1BD, United Kingdom.

**Manufacturers:**

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

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, United Kingdom: 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 50 mg film-coated tablets

• **Reference number:** PA 1189/7/1

**This leaflet was last revised in**

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