

Package leaflet: Information for the user

PALEXIA SR 50 mg, 100 mg, 150 mg, 200 mg and 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.

- What is in this leaflet:**
1. What PALEXIA SR is and what it is used for
 2. What you need to know before you take PALEXIA SR
 3. How to take PALEXIA SR
 4. Possible side effects
 5. How to store PALEXIA SR
 6. Contents of the pack and other information

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

The full name of your medicine is 'PALEXIA SR 50 mg, 100 mg, 150 mg, 200 mg or 250 mg prolonged-release tablets'. It is referred to as 'PALEXIA SR' in the rest of this leaflet.

Tapentadol - the active substance in PALEXIA SR - is a strong painkiller which belongs to the class of opioids. PALEXIA SR is used in adults for the treatment of severe long-term pain that can only be adequately managed with an opioid painkiller.

2. What you need to know before you take PALEXIA SR

- Do not take PALEXIA SR**
- 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 SR')

- Warnings and precautions**
- Talk to your doctor or pharmacist before taking PALEXIA SR 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 tumors
 - have had an epileptic fit or if you are at risk of having epileptic fits
 - suffer from liver or kidney problems (see 'How to take PALEXIA SR')
 - 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 to abuse medicines or if you are dependent on medicines, as PALEXIA SR 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 SR

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 SR.

- 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 SR. If this happens tell your doctor.
 - Your consciousness may be decreased, you may feel drowsier or feel you might faint, if you take PALEXIA SR 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 SR 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 SR 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 SR with products (e.g. rifampicin, phenobarbital or St John's Wort) that affect the enzymes required to remove PALEXIA SR from the body, may affect how well PALEXIA SR works or may cause side effects. The effects may occur especially when the other medication is started or stopped.
 - PALEXIA SR should not be taken together with monoamine oxidase inhibitors (MAOIs - 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.
- Please keep your doctor informed about all medicines you are taking.

Taking PALEXIA SR with food, drink and alcohol

Do not drink alcohol whilst you are taking PALEXIA SR, because some side effects such as drowsiness may be increased. You can take PALEXIA SR 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 SR:

- if you are pregnant, unless your doctor has instructed you to do so
- if you become pregnant during treatment with PALEXIA SR. 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 SR, then do not drive, use tools or machinery.

Any such effects are more likely to occur when you start taking PALEXIA SR, when the dose of PALEXIA SR is changed, or when you drink alcohol or take tranquilizers. Please ask your doctor before driving a car or using machinery.

PALEXIA SR 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 SR

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 SR 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 12 hours.

Daily doses of PALEXIA SR greater than 500 mg tapentadol 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 these tablets is too strong or weak, talk to your doctor or pharmacist.

How and when should you take PALEXIA SR

PALEXIA SR is for oral use.

Swallow the tablets with a glass of water. You may take the tablets either on an empty stomach or with food. Do not chew, break or crush the tablet, as it may result in overdose due to quick release of tapentadol in your body.

How long should you take PALEXIA SR

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 or kidney problems (insufficiency)

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

If you take more PALEXIA SR than you should

Taking too much PALEXIA SR 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 SR 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 or shallow breathing or stopping breathing.

If you forget to take PALEXIA SR

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 SR

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.

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 SR, 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.

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 and hives (uncommon). 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 breathe more slowly or weakly than expected (rare). 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)
- constipation
- dizziness, drowsiness, headache.

Common (may affect up to 1 in 10 people)

- decreased appetite, anxiety, being sick (vomiting), diarrhoea, indigestion
- sleep problem, tiredness or exhaustion (fatigue), feeling of weakness, trembling, muscle twitches, shortness of breath
- feeling depressed, nervousness, restlessness, lack of attention
- feeling hot (flushing), increased sweating, feeling of body temperature change, dry areas like nostrils, mouth, lips, eyelids, ears, genitals and anus
- itching, rash
- water retention (oedema).

Uncommon (may affect up to 1 in 100 people)

- weight loss
- low awareness of time, place or identity (disorientation), confusion, excitable (agitated), disturbances in perception, abnormal dreams, forgetfulness, mental impairment
- very happy (euphoria), less consciousness, fainting, sedation, feeling unsteady, difficulty in speaking, numbness
- abnormal sensations of the skin (e.g. tingling, prickling), skin reactions (hives)
- abnormal vision
- faster or slower heart beat, palpitations, low blood pressure
- stomach discomfort, delay in passing urine, passing urine more often than usual
- sexual dysfunction
- drug withdrawal effects (see ‘If you stop takingPALEXIA SR’)
- feeling strange, irritable.

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

- addiction
- thinking abnormal, epileptic fits, near fainting, uncoordinated, feeling drunk or relaxed
- 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 (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.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store PALEXIA SR

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 SR contains

The active ingredient is tapentadol.

- One (1) PALEXIA SR 50 mg prolonged-release tablet contains 50 mg tapentadol (as hydrochloride).
- One (1) PALEXIA SR 100 mg prolonged-release tablet contains 100 mg tapentadol (as hydrochloride).
- One (1) PALEXIA SR 150 mg prolonged-release tablet contains 150 mg tapentadol (as hydrochloride).

- One (1) PALEXIA SR 200 mg prolonged-release tablet contains 200 mg tapentadol (as hydrochloride).
- One (1) PALEXIA SR 250 mg prolonged-release tablet contains 250 mg tapentadol (as hydrochloride).

The other ingredients are:

- Tablet core: hypromellose, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.
- 50mg tablet coat: hypromellose, lactose monohydrate, talc, macrogol 6000, propylene glycol, titanium dioxide (E 171).
- 100 mg tablet coat: hypromellose, lactose monohydrate, talc, macrogol 6000, propylene glycol, titanium dioxide (E 171), yellow iron oxide (E 172).
- 150 mg tablet coat: hypromellose, lactose monohydrate, talc, macrogol 6000, propylene glycol, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E172).
- 200 mg tablet coat: hypromellose, lactose monohydrate, talc, macrogol 6000, propylene glycol, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E172).
- 250 mg tablet coat: hypromellose, lactose monohydrate, talc, macrogol 6000, propylene glycol, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E172), black iron oxide (E 172).

What PALEXIA SR looks like and contents of the pack

- PALEXIA SR 50 mg prolonged-release tablets are white film-coated oblong shaped prolonged-release tablets, measuring 6.5 mm x 15 mm, marked with Grünenthal logo on one side and “H1” on the other side.
- PALEXIA SR 100 mg prolonged-release tablets are pale yellow film-coated oblong shaped prolonged-release tablets, measuring 6.5 mm x 15 mm, marked with Grünenthal logo on one side and “H2” on the other side.
- PALEXIA SR 150 mg prolonged-release tablets are pale pink film-coated oblong shaped prolonged-release tablets, measuring 6.5 mm x 15 mm, marked with Grünenthal logo on one side and “H3” on the other side.
- PALEXIA SR 200 mg prolonged-release tablets are pale orange film-coated oblong shaped prolonged-release tablets, measuring 7 mm x 17 mm, marked with Grünenthal logo on one side and “H4” on the other side.
- PALEXIA SR 250 mg prolonged-release tablets are brownish red film-coated oblong shaped prolonged-release tablets, measuring 7 mm x 17 mm, marked with Grünenthal logo on one side and “H5” on the other side.

PALEXIA SR are packed in blisters.

In the UK, PALEXIA SR is available in boxes of 28 and 56 tablets.

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.

Manufacturer:

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

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 free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

- **Product name:** PALEXIA SR 50 mg prolonged-release tablets
- **Reference number:** PL 21727/0041
- **Product name:** PALEXIA SR 100 mg prolonged-release tablets
- **Reference number:** PL 21727/0042
- **Product name:** PALEXIA SR 150 mg prolonged-release tablets
- **Reference number:** PL 21727/0043
- **Product name:** PALEXIA SR 200 mg prolonged-release tablets
- **Reference number:** PL 21727/0044
- **Product name:** PALEXIA SR 250 mg prolonged-release tablets
- **Reference number:** PL 21727/0045

This leaflet was last revised in August 2013