

PALEXIA® SR 50 mg, 100 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 (see section 4).

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

Tapentadol - the active substance in PALEXIA SR is a strong painkiller which belongs to the class of opioids. PALEXIA SR is used for the treatment of severe chronic pain in adults 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 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 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 disturbed consciousness up to coma,
- have had a head injury or brain tumor
- suffer from liver or kidney problems (see 'How to take PALEXIA SR')
- 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).

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 SR 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 SR 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 SR

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 SR at the same time. Your doctor will tell you whether PALEXIA SR is suitable for you. Concomitant use of PALEXIA SR 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 SR 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 SR 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°C. Your doctor can advise you on this.

- Taking PALEXIA SR 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 SR 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 SR together with strong inhibitors or inducers (e.g. rifampicin, phenobarbital or 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 SR 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.

Please keep your doctor informed about all medicines you are 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. 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 SR may cause drowsiness, dizziness and blurred vision and may impair your reactions. This may especially happen when you start taking PALEXIA SR, when your doctor changes your dosage or when you drink alcohol or take tranquilizers.

Please ask your doctor whether it is permitted to drive a car or use machines.

PALEXIA SR 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 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 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 12 hours.

Total daily doses of PALEXIA SR greater than 500 mg tapentadol 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 SR is not suitable for children and adolescents below the age of 18 years.

How and when should you take PALEXIA SR

PALEXIA SR is for oral use.

Always swallow the tablets whole, with sufficient liquid. Don't chew it, break it or crush it – this could lead to overdosing, because the drug will be released into your body too quickly. You may take the tablets on an empty stomach or with meals.

The empty shell of the tablet may not be digested completely and thus be seen in stool. This should not worry you, since the drug (active substance) of the tablet has already been absorbed in your body and what you see is just the empty shell.

How long should you take PALEXIA SR

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

If you take more PALEXIA SR 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 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 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, constipation, dizziness, drowsiness, headache. **Common (may affect up to 1 in 10 people):** decreased appetite, anxiety, depressed mood, sleep problem, nervousness, restlessness, disturbance in attention, trembling, muscle twitches, flushing, shortness of breath, vomiting, diarrhoea, indigestion, itching, increased sweating, rash, feeling of weakness, fatigue, feeling of body temperature change, mucosal dryness, accumulation of water in the tissue (oedema).

Uncommon (may affect up to 1 in 100 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), weight loss, disorientation, confusion, excitability (agitation), perception disturbances, abnormal dreams, euphoric mood, depressed level of consciousness, memory impairment, mental impairment, fainting, sedation, balance disorder, difficulty in speaking, numbness, abnormal sensations of the skin (e.g. tingling, prickling), abnormal vision, faster heartbeat, slower heartbeat, palpitations, decreased blood pressure, abdominal discomfort, hives, delay in passing urine, frequent urination, sexual dysfunction, drug withdrawal syndrome (see 'If you stop taking PALEXIA SR'), feeling abnormal, irritability.

Rare (may affect up to 1 in 1,000 people): drug dependence, thinking abnormal, epileptic fits, near fainting, coordination abnormal, dangerously slow or shallow breathing (respiratory depression), impaired gastric emptying, feeling drunk, feeling of relaxation.

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 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 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 after 'EXP'. 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** substance 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).

The **other** ingredients are:

- Tablet core: Hypromellose 2208/100000, microcrystalline cellulose, colloidal anhydrous silica oxide, magnesium stearate.
- 50mg tablet coat: hypromellose 2910/06, lactose monohydrate, talc, macrogol 6000, propylene glycol, titanium oxide (E171).
- 100 mg tablet coat: hypromellose 2910/06, lactose monohydrate, talc, macrogol 6000, propylene glycol, titanium oxide (E171), yellow iron oxide (E172)

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 are packed in blisters.

PALEXIA SR are sold in boxes of 60x1 tablets.

Manufacturers:

Grünenthal GmbH, Zieglerstrasse 6, 52078, Aachen, Germany or
Farmaceutici Formenti S.P.A., Orrigio, Italy or
Janssen Cilag SPA via C. Janssen, Borgo San Michele head office Via Michelangelo Buonarroti 23 200 93 Cologno Monzese Italy.

Product procured from within the EU, repackaged and distributed by the PPA Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

PPA Number: PPA 465/458/2-3

Palexia is a registered trademark of Grünenthal GmbH.

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

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

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