PATIENT INFORMATION LEAFLET FOR PALEXIA SR® RANGE

SCHEDULING STATUS

Schedule 6

PALEXIA® SR 50 mg prolonged release tablets

PALEXIA® SR 100 mg prolonged release tablets

PALEXIA® SR 150 mg prolonged release tablets

PALEXIA® SR 200 mg prolonged release tablets

PALEXIA® SR 250 mg prolonged release tablets

Tapentadol

Contains sugar (lactose monohydrate).

Read all of this leaflet carefully before you start taking PALEXIA SR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PALEXIA SR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

The active substance in PALEXIA SR is tapentadol. Tapentadol is a painkiller which belongs to the class of opioids.

PALEXIA SR is used in adults for the treatment of moderate to severe long term pain that can only be adequately managed with an opioid painkiller. Only to be used by patients aged 18 years or older.

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

Do not take PALEXIA SR

- If you are hypersensitive (allergic) to the active ingredient tapentadol, or any of the other ingredients of PALEXIA SR. PALEXIA SR contains lactose monohydrate (See PALEXIA SR contains)
- 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 of the lower stomach
- In cases of poisoning with alcohol, sleeping pills, pain relievers or medicines that affect mood and emotions (see Other medicines and PALEXIA SR)
- If you have a head injury
- If you have severe kidney or liver impairment
- If you have inflammation of your pancreas (pancreatitis)
- If you are pregnant or breastfeeding your baby
- If you are taking or have taken a type of medicine known as monoamine oxidase inhibitor (MAOI) during the last 14 days. MAOIs are used for the treatment of depression (see Other medicines and PALEXIA SR)

Warnings and precautions

Take special care with PALEXIA SR

- 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 an epileptic fit or if you are at risk of having epileptic fits
- If you suffer from liver or kidney problems (See How to take PALEXIA SR)
- If you suffer from a pancreatic disease or disease of the bile duct (biliary tract disease)
- If you 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.

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.

If any of the above applies to you, talk to your doctor before you take PALEXIA SR.

Other medicines and PALEXIA SR

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines)

- Do not take PALEXIA SR with monoamine oxidase inhibitors (MAOIs - certain medicines for the treatment of depression). Tell your doctor if you are taking MAOI or have taken a MAOI during the last 14 days.
- Your breathing may become dangerously slow or shallow (respiratory depression) if you are also taking certain sleeping tablets or tranquillisers (e.g. benzodiazepines), 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 that you might faint, if you take PALEXIA SR with other medicines acting on the brain. 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 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.
- PALEXIA SR may not work well if taking with morphine like medicines (e.g. those containing 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.

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. You can take PALEXIA SR with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

Do not take PALEXIA if you are pregnant.

Do not take PALEXIA during childbirth because it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn. PALEXIA 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.

Breast-feeding

Do not take PALEXIA during breastfeeding of your baby, because it may pass into 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. Drinking alcohol or taking tranquillisers will make these effects worse.

PALEXIA SR contains lactose

Lactose monohydrate is an ingredient in PALEXIA SR tablets. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PALEXIA SR.

3. How to take PALEXIA SR

Do not share medicines prescribed for you with any other person. Always take PALEXIA SR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with PALEXIA SR will last. Do not stop treatment because your pain is likely to return. If you have the impression that the effect of PALEXIA SR is too strong or too weak, tell your doctor or pharmacist.

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 too 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 on an empty stomach or with food. Do not chew, break or crush the tablet, as it may result in overdose due to the quick release of PALEXIA SR in your body.

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 as 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

Not recommended for children and adolescents below the age of 18 years.

If you take more PALEXIA SR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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.

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 wish to stop treatment, please tell your doctor first before stopping treatment.

Patients who have been taking PALEXIA SR 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 the size of 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 consult your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Not all side-effects reported for PALEXIA SR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PALEXIA SR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking PALEXIA SR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- PALEXIA SR may cause allergic reactions (less frequent). 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 (less frequent). Elderly and weak patients are more susceptible to this.

These are all very serious side-effects. If you have them, you may have had a serious allergic reaction to PALEXIA SR. You may need urgent medical attention or hospitalisation.

Frequent:

- Feeling sick (nausea)
- Constipation
- Dizziness, drowsiness, headache.
- 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)

Less frequent:

- 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, low blood pressure
- Stomach discomfort, delay in passing urine, passing urine more often than usual
- Sexual dysfunction
- Drug withdrawal effects (See If you stop taking PALEXIA SR)
- Feeling strange, irritable
- Addiction
- Thinking abnormal, epileptic fits, near fainting, uncoordinated, feeling drunk or relaxed
- Delayed emptying of the stomach (impaired gastric emptying)
- Increased blood pressure.
- Delirium

Suicidal thoughts have been reported in patients taking PALEXIA SR.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PALEXIA SR.

5. How to store PALEXIA SR

Store all medicines out of reach of children.

Store at or below 30 °C.

Blisters must be kept in the cartons until required for use.

Do not use PALEXIA SR after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PALEXIA SR contains

The active substance in PALEXIA SR is tapentadol.

Each PALEXIA® SR 50 mg prolonged release tablet contains tapentadol hydrochloride equivalent to 50 mg tapentadol.

Each PALEXIA® SR 100 mg prolonged release tablet contains tapentadol hydrochloride equivalent to 100 mg tapentadol.

Each PALEXIA® SR 150 mg prolonged release tablet contains tapentadol hydrochloride equivalent to 150 mg tapentadol.

Each PALEXIA® SR 200 mg prolonged release tablet contains tapentadol hydrochloride equivalent to 200 mg tapentadol.

Each PALEXIA® SR 250 mg prolonged release tablet contains tapentadol hydrochloride equivalent to 250 mg tapentadol

Other ingredients:

Tablet core: Colloidal anhydrous silica, hypromellose, magnesium stearate, microcrystalline cellulose

Tablet coat: Hypromellose, lactose monohydrate, macrogol 6 000, propylene glycol, talc

Colourants include: Titanium dioxide (E171), yellow iron oxide (E 172: 100, 150, 200 and 250 mg tablets only), red iron oxide (E 172: 150, 200 and 250 mg tablets only), black iron oxide (E 172: 250 mg tablets only)

What PALEXIA SR looks like and contents of the pack

PALEXIA SR 50 mg: White oblong film coated tablets engraved with the Grűnenthal logo on one side and “H1” on the other side.

PALEXIA SR 100 mg: Pale yellow oblong film coated tablets engraved with the Grűnenthal logo on one side and “H2” on the other side.

PALEXIA SR 150 mg: Pale pink oblong film coated tablets engraved with the Grűnenthal logo on one side and “H3” on the other side.

PALEXIA SR 200 mg: Pale orange oblong film coated tablets engraved with the Grűnenthal logo on one side and “H4” on the other side.

PALEXIA SR 250 mg: Brownish red oblong film coated tablets engraved with the Grűnenthal logo on one side and “H5” on the other side.

PALEXIA SR prolonged release tablets are packed in white opaque PVC/PVDC blisters, seal with a sealing foil consisting of a laminate of paper, polyethylene therephthalate (PET) and aluminium.

Each carton contains 20, 30 or 56 tablets.

Holder of Certificate of Registration

JANSSEN PHARMACEUTICA (PTY) LTD

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The leaflet was revised in

10 May 2022

Registration numbers

PALEXIA® SR 50 mg: 48/2.9/0131

PALEXIA® SR 100 mg: 48/2.9/0132

PALEXIA® SR 150 mg: 48/2.9/0133

PALEXIA® SR 200 mg: 48/2.9/0134

PALEXIA® SR 250 mg: 48/2.9/0135