

SCHEDULING STATUS

Schedule 6

PALEXIA® 50 mg tablets

PALEXIA® 75 mg tablets

PALEXIA® 100 mg tablets

Tapentadol

Contains lactose

Read all of this leaflet carefully before you start taking PALEXIA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PALEXIA 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 is and what it is used for
2. What you need to know before you use PALEXIA
3. How to use 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 active substance in PALEXIA is tapentadol. Tapentadol is a painkiller which belongs to the class of opioids.

PALEXIA is used for the short term treatment of acute moderately severe post-operative pain in patients aged 18 years and older. The duration of use should not exceed 10 days.

2. What you need to know before you use PALEXIA

Do not use PALEXIA if you:

- Are hypersensitive (allergic) to the active ingredient tapentadol, or any of the other ingredients of PALEXIA. PALEXIA contains lactose. (see WHAT PALEXIA CONTAINS).
- Have asthma or if your breathing is dangerously slow or shallow (respiratory depression, hypercapnia).
- Have paralysis of the gut.
- Have acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions) (see "Other medicines and Palexia").
- Have a head injury.
- Have severe kidney or liver impairment.
- Have inflammation of your pancreas (pancreatitis).
- Are pregnant or breastfeeding your baby.
- Are taking or have taken monoamine oxidase (MAO) inhibitors (certain medicines for the treatment of depression) during the last 14 days (see "Other medicines and Palexia").

Warnings and precautions

Take special care with PALEXIA if you

- Have slow or shallow breathing.
- Suffer from increased pressure in the brain or disturbed consciousness.

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- Have had an epileptic fit or if you have an increased risk of having epileptic fits or if you are taking other medicines known to increase the risk of seizures because the risk of a fit may increase.
- Suffer from a liver or kidney disease (see “How to take PALEXIA”).
- Suffer from a pancreatic or biliary tract disease.

In such cases please consult your doctor before taking PALEXIA.

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

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines)

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.

Your breathing may become dangerously slow or shallow (respiratory depression) if you are also taking certain sleeping tablets or tranquillisers (e.g. benzodiazepines), or pain relievers

such as morphine and codeine (also as cough medicine) in combination with PALEXIA. If this happens tell your doctor.

If you are taking other medicines acting on the brain in combination with PALEXIA your consciousness may be decreased, you may feel drowsier or feel that you might faint. If this happens tell your doctor.

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.

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.

Taking PALEXIA together with other types of medicines related to morphine e.g., nalbuphine or 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 PALEXIA from your body, may influence how well PALEXIA 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 with food, drink and alcohol

Food does not influence the effect of these tablets. Do not drink alcohol whilst taking PALEXIA because some side effects such as drowsiness may be increased.

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

PALEXIA may cause drowsiness, dizziness and blurred vision and may impair your reactions. Drinking alcohol or taking tranquillisers will make these effects worse.

PALEXIA contains lactose

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

3. How to take PALEXIA

Do not share medicines prescribed for you with others.

Always take PALEXIA exactly as your doctor has told you. You should 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 50 – 100 mg every 4 to 6 hours.

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.

How and when to 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 as your doctor has told you. PALEXIA should not be taken for longer than 10 days.

Elderly patients

In elderly patients (above 65 years) usually no dose adjustment is necessary. However, the excretion of PALEXIA may be delayed in some patients of this age group. If this applies to you, your doctor may recommend a different dosage regimen.

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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.

Children

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

If you take more PALEXIA 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.

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

The following may be experienced: pin-point pupils, vomiting, drop in blood pressure, fast heart beat, 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

Please tell your doctor first before stopping treatment.

Patients who have been taking PALEXIA 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.

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 this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PALEXIA, please consult your doctor, pharmacist or other healthcare professional for advice.

PALEXIA can have side effects. The following side effects may happen.

Important side effects or symptoms to look out for and what to do if you are affected:

PALEXIA 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. Elderly and weak patients are more likely to develop this.

If you are affected by these important side effects contact a doctor immediately

Frequent side effects:

- Nausea

- Vomiting
- Dizziness
- Drowsiness
- Headache
- 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.

Less frequent side effects:

- Depressed mood
- Disorientation
- Excitability (agitation)

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- 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 heart beat
- 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 “Effects when treatment with PALEXIA is stopped”)
- Accumulation of water in the tissue (oedema)
- Feeling abnormal
- Feeling drunk
- Irritability

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- Feeling of relaxation
- Allergic reaction
- Thinking abnormal
- Epileptic fit
- Depressed level of consciousness
- Coordination abnormal
- Slower heart beat
- Impaired gastric emptying
- Increased blood pressure
- Delirium

Suicidal thoughts have been reported in patients taking PALEXIA.

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.

5. How to store PALEXIA

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.

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Do not use PALEXIA 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 contains

The active substance in PALEXIA is tapentadol.

Each PALEXIA 50 mg tablet contains 50 mg tapentadol (as hydrochloride).

Each PALEXIA 75 mg tablet contains 75 mg tapentadol (as hydrochloride).

Each PALEXIA 100 mg tablet contains 100 mg tapentadol (as hydrochloride).

Other ingredients:

Croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, opadry white, opadry yellow, opadry pink, povidone.

What PALEXIA looks like and contents of the pack

Palexia 50 mg: White round biconvex film coated tablets engraved with the Grünenthal logo on one side and "H6" on the other side.

Palexia 75 mg: Pale yellow round biconvex film coated tablets engraved with the Grünenthal logo on one side and "H7" on the other side.

Palexia 100 mg: Pale pink round biconvex film coated tablets engraved with the Grünenthal logo on one side and "H8" on the other side.

PALEXIA Tablets are packed in white opaque PVC/PVDC blisters, sealed to aluminium foil.

Each carton contains 28 or 30 tablets.

Applicant: JANSSEN PHARMACEUTICA (PTY) LTD
Product Proprietary Name : Palexia Range



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Holder of Certificate of Registration

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The leaflet was revised in

25 October 2022

Registration numbers

PALEXIA® 50 mg: 47/2.9/0994

PALEXIA® 75 mg: 47/2.9/0995

PALEXIA® 100 mg: 47/2.9/0996