

PALEXIA[®] IR

immediate release tablets

Tapentadol (as hydrochloride) (*Ta-pen-ta-dol*)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about PALEXIA[®] IR.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having PALEXIA[®] IR against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PALEXIA[®] IR is used for

PALEXIA[®] (tapentadol) IR is used to relieve moderate to severe pain. This strong pain reliever belongs to a group of medicines known as opioid analgesics.

This medicine is available only with a doctor's prescription.

Your doctor may have prescribed PALEXIA[®] IR for another reason. **Ask your doctor if you have any questions about why PALEXIA[®] IR has been prescribed for you.**

Before you take PALEXIA[®] IR

When you must not take it

You must not take PALEXIA[®] IR if you:

- are allergic to tapentadol or any of the ingredients listed at the end of this leaflet. Signs of allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue
- 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)
- are taking medicine for depression containing a monoamine oxidase inhibitor (MAOI) medicine (such as Nardil, Parnate) or have taken a MAOI within the last 14 days. Ask your doctor or pharmacist if any of your medicines is an MAOI.

Do not take PALEXIA[®] IR if the packaging is torn or shows signs of tampering or the tablets do not look quite right.

Do not take PALEXIA[®] IR if the expiry date on the pack has passed.

You should only start taking PALEXIA[®] IR under direct supervision of your doctor.

Before you start to take it

Tell your doctor if you:

- have slow or shallow breathing
- have sleep-related breathing disorders
- suffer from increased pressure in the brain or disturbed consciousness up to coma
- have had a head injury or a brain tumour
- have had an epileptic fit or seizure or if you have an increased risk of having epileptic fits or seizures
- suffer from a liver or kidney disease
- suffer from a pancreatic or biliary tract disease including pancreatitis
- are breastfeeding
- are pregnant, or planning to become pregnant
- have an addiction or history of abuse of alcohol, opioids or other drugs
- have been told that you have an intolerance to some sugars. Lactose is an ingredient in these tablets.

Tell your doctor if you are breast-feeding. You should not take PALEXIA[®] IR if you are breast-feeding as it may pass into your breast milk.

You should not take PALEXIA[®] IR during childbirth because it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn. Your doctor will discuss the risks and benefits of using PALEXIA[®] IR.

There is a risk of abuse or addiction with pain medicines

such as PALEXIA® IR. If you have abused drugs in the past, you may have a higher chance of developing abuse or addiction again while using PALEXIA® IR.

Taking other medicines

Tell your doctor if you are using any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and PALEXIA® IR may interfere with each other. These medicines include:

- medicines for depression, sleeplessness or mental conditions such as selective serotonin reuptake inhibitors (SSRI's), serotonin-norepinephrine reuptake inhibitors (SNRI's), tricyclic anti-depressants (TCAs), monoamine oxidase inhibitor (MAOIs) and triptans
- other pain relievers such as morphine or codeine
- some cough medicines
- general anaesthetics such as propofol or midazolam (examples are Propofol™ or Midazolam™)
- medicines that slow the brain activity (central nervous system (CNS) depressants or phenothiazines). These medicines can be used to treat anxiety, muscle tension, pain, insomnia, acute stress reactions, panic attacks or seizure disorders such as sleeping pills, tranquilizers, hypnotics or sedatives (examples are Stelazine™, Largactil™, Valium™, Temaze™, or Xanax™).

Taking these medicines with PALEXIA® IR may increase the risk of possible side effects (see **Side Effects**). Your breathing may become seriously slow or shallow (respiratory depression) and your blood pressure may decrease. Your consciousness may be decreased, you may feel drowsier or feel that you might faint. If this happens tell your doctor.

Do not take PALEXIA® IR with alcohol.

Some side effects such as drowsiness may be increased.

Other medications can also interfere with PALEXIA® IR and make you feel drowsy. Ask your doctor or pharmacist for more information.

How to take PALEXIA® IR

You should only start taking PALEXIA® IR under the direct supervision of your doctor.

Your doctor will tell you how much you should take, when and how often. It is important that you take this medicine as directed by your doctor.

If you are unsure ask your doctor or pharmacist.

How much to take

The usual dose is 1 tablet 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.

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

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.

Patients with severe liver problems should not take these tablets. If you have moderate problems, your doctor will

recommend a different dosage regimen.

Patients with severe kidney problems should not take these tablets.

Carefully follow all directions given to you by your doctor and pharmacist. These directions may differ from the information in this leaflet.

When and how should you take the tablets

PALEXIA® IR tablets should be swallowed whole with water. They may be taken, before, with, or after food.

Do not chew, divide or break the tablets. Chewing, dividing or breaking the tablets will release the medicine quickly and side effects may then occur.

How long to take it

Depending on the medical condition for which you require PALEXIA® IR, your doctor may tell you to take it for only a day or two or longer, up to a few months or more.

Take the tablets every day for as long as your doctor tells you to. If you stop taking PALEXIA® IR too soon, your pain is likely to return.

If you forget to take it

If you forget to take a dose, you can take it as soon as you remember. The next dose should be taken after four or six hours, or as prescribed by your doctor.

Do not take a double dose to make up for the dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or the **Poisons Information Centre (131 126)** or go to accident and emergency at your nearest hospital, if you think that you or

anyone else may have taken too much PALEXIA® IR. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many PALEXIA® IR tablets, this may result in vomiting, pin-point pupils, fast heartbeat, difficulty breathing or stopping breathing, drop in blood pressure, epileptic fits, convulsion, disturbed consciousness, collapse or loss of consciousness (coma). **If you experience any of these, seek urgent medical attention.**

While you are taking PALEXIA® IR

Things you must do

Be sure to keep all of your doctor's appointments so that your progress can be checked.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking PALEXIA® IR.

Tell your doctor if you believe that PALEXIA® IR is not helping your condition. Your doctor may need to change the dose.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think it is not working effectively and change your treatment unnecessarily.

If you become pregnant while you are taking PALEXIA® IR, tell your doctor immediately.

If you plan to have surgery, even at the dentist's, tell your doctor, anaesthetist or dentist that you are taking this medicine. It may affect other medicines used during surgery.

Things you must not do

If you wish to stop treatment, please tell your doctor first before stopping treatment. 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 in the dose.

Some people may feel unwell if they suddenly stop taking PALEXIA® IR. If you suddenly stop taking PALEXIA® IR you may experience withdrawal symptoms such as:

- restlessness
- watery eyes or runny nose
- yawning
- sweating or chills
- muscle pain
- dilated pupils
- irritability or anxiety
- backache or joint pain
- weakness
- abdominal cramps
- difficulty in sleeping
- nausea, loss of appetite
- vomiting or diarrhea
- increases in blood pressure, breathing or heart rate.

Do not give PALEXIA® IR to anyone else, even if they have the same condition as you.

Do not take PALEXIA® IR for any other complaints unless your doctor tells you to.

Things to be careful of

Do not drive or operate heavy machinery until you know how PALEXIA® IR affects you.

PALEXIA® IR can make you sleepy, dizzy, or lightheaded.

Do not drink alcohol while you are taking PALEXIA® IR tablets.

Drinking alcohol while taking PALEXIA® IR may make you feel more sleepy and increase the risk of serious side effects, such as shallow breathing, with the risk of stopping breathing and loss of consciousness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PALEXIA® IR.

Like all medicines, PALEXIA® IR can cause some unwanted side effects in some people. Sometimes they are serious, most of the time they are not. Side effects not listed in this leaflet may occur in some patients. You may need to get medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Very common:

- nausea
- vomiting
- dizziness
- drowsiness
- headache.

Common:

- decreased appetite
- anxiety
- confusion
- hallucination
- difficulty sleeping
- abnormal dreams
- trembling
- flushing or reddening of the face and neck
- constipation
- diarrhoea
- indigestion
- dry mouth
- itching
- increased sweating
- rash
- muscle cramps
- feeling of weakness
- fatigue
- feeling of body temperature change.

Uncommon:

- depressed mood
- disorientation
- excitability (agitation)
- 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 or irregular heart beat
- decreased blood pressure
- dangerously slow or shallow breathing
- shortness of breath
- abdominal discomfort
- hives
- sensation of heaviness
- delay in passing urine
- frequent urination
- drug withdrawal syndrome (see “Things you must not do”)
- accumulation or retention of water in the tissues (oedema)
- feeling abnormal
- feeling drunk
- irritability
- feeling of relaxation.

Rare:

- allergic reaction
- thinking abnormal thoughts
- epileptic fit
- depressed level of consciousness
- abnormal coordination
- slower heart beat
- impaired gastric emptying.

If any of the following happen, tell your doctor or go to accident and emergency at your nearest hospital immediately:

- skin rash (red spots or patches), itching, hives
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- chest tightness, wheezing or pain in the chest
- heart palpitations
- faintness or collapse
- hallucinations
- seizures, fits or convulsions.

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

If you notice any unwanted effects not mentioned in this

leaflet, please inform your doctor, or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using PALEXIA® IR

Storage

Keep PALEXIA® IR tablets in the blister pack until it is time to take them.

Keep your tablets in a cool, dry place where the temperature stays below 30°C.

Do not store PALEXIA® IR in the bathroom or near a sink.

Do not leave them in a car or on a window sill

Heat and dampness can destroy some medicines.

Keep PALEXIA® IR tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Note the expiry date on the pack. Do not use after this expiry date.

Disposal

If your doctor tells you to stop taking PALEXIA® IR or the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product Description

There are 3 distinct strengths of PALEXIA® IR tablets:

PALEXIA® IR 50 mg tablets

White round shaped film-coated tablets of 7 mm diameter, marked with Grünenthal logo on one side and “H6” on the other side.

PALEXIA® IR 75 mg tablets

Pale yellow round shaped film-coated tablets of 8 mm diameter, marked with Grünenthal logo on one side and “H7” on the other side.

PALEXIA® IR 100 mg tablets

Pale pink round shaped film-coated tablets of 9 mm diameter, marked with Grünenthal logo on one side and “H8” on the other side.

PALEXIA® IR tablets are supplied in boxes of 5, 10, 14, 20, 28, 30, 40, 50, 56, 60, 90 and 100 tablets.

All strengths and pack sizes may not be available.

PALEXIA® IR tablets are sealed in a blister foil pack.

Ingredients

Active ingredients

PALEXIA® IR 50 mg tablets - each tablet contains 50 mg tapentadol (as hydrochloride).

PALEXIA® IR 75 mg tablets - each tablet contains 75 mg tapentadol (as hydrochloride).

PALEXIA® IR 100 mg tablets - each tablet contains 100 mg tapentadol (as hydrochloride).

Inactive ingredients

PALEXIA® IR tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- lactose
- croscarmellose sodium
- povidone (K30)
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide (E171)
- macrogol 3350
- talc
- iron oxide yellow (E172) (75 and 100 mg tablets only)
- iron oxide red (E172) (75 and 100 mg tablets only)

- iron oxide black (E172) (100 mg tablets only).

PALEXIA® IR contains lactose.

PALEXIA® IR does not contain:

- gluten
- preservative.

Further information

You can obtain more information from your doctor or pharmacist.

Australian sponsor:

Seqirus Pty Ltd
ABN 26 160 735 035
63 Poplar Road
Parkville, VIC 3052
Australia

PALEXIA® IR is distributed in

Australia by:

Seqirus(Australia) Pty Ltd
ABN 66 120 398 067
63 Poplar Road
Parkville, VIC 3052
Australia

PALEXIA® IR is manufactured by:

Grünenthal GmbH, Germany

Australian Registration Numbers:

PALEXIA® IR 50 mg tablets
AUST R 165310

PALEXIA® IR 75 mg tablets
AUST R 165317

PALEXIA® IR 100 mg tablets
AUST R 165318

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