

PALEXIA® IR

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using PALEXIA® IR?

PALEXIA® IR contains the active ingredient tapentadol. PALEXIA® IR is used to relieve severe pain.

For more information, see Section [1. Why am I using PALEXIA® IR?](#) in the full CMI.

2. What should I know before I use PALEXIA® IR?

Do not use if you have ever had an allergic reaction to PALEXIA® IR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PALEXIA® IR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PALEXIA® IR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PALEXIA® IR?

- The usual dose of PALEXIA® IR is 1 tablet every 4 to 6 hours.
- The tablets must be swallowed whole with water.

More instructions can be found in Section [4. How do I use PALEXIA® IR?](#) in the full CMI.

5. What should I know while using PALEXIA® IR?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using PALEXIA® IR.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.• Tell your doctor if you believe that PALEXIA® IR is not helping your condition.• If you become pregnant while taking this medicine, tell your doctor immediately.• Keep all of your doctor's appointments so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not give this medicine to anyone else, even if they have the same condition as you.• Do not take this medicine for any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Do not drive, operate heavy machinery or use any machines or tools until you know how PALEXIA® IR affects you.• PALEXIA® IR can make you sleepy, dizzy, or lightheaded.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while you are taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C. Keep PALEXIA® IR tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using PALEXIA® IR?](#) in the full CMI.

6. Are there any side effects?

PALEXIA® IR tablets may cause nausea, constipation, dizziness, drowsiness and headache.

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice: loss of consciousness, breathing changes (slow or shallow breathing), or signs of allergic reaction (skin rash (red spots or patches), itching, shortness of breath, swelling of the face, lips, mouth, tongue or throat). PALEXIA® IR poses risk of abuse, misuse and addiction.

This is not a complete list of all possible side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING

Limitations of use

PALEXIA® IR should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

PALEXIA® IR poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

PALEXIA® IR can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting PALEXIA® IR and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using PALEXIA® IR

Using PALEXIA® IR with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using PALEXIA® IR.

PALEXIA® IR

Active ingredient: *tapentadol (as hydrochloride)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PALEXIA® IR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PALEXIA® IR.**

Where to find information in this leaflet:

- [1. Why am I using PALEXIA® IR?](#)
- [2. What should I know before I use PALEXIA® IR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PALEXIA® IR?](#)
- [5. What should I know while using PALEXIA® IR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PALEXIA® IR?

PALEXIA® IR contains the active ingredient tapentadol (as hydrochloride). PALEXIA® IR is a strong pain reliever which belongs to a group of medicines known as opioid analgesics.

PALEXIA® IR is used to relieve severe pain.

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.

2. What should I know before I use PALEXIA® IR?

Warnings

Do not use PALEXIA® IR if:

- you are allergic to tapentadol, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have asthma or if your breathing is dangerously slow or shallow (respiratory depression, hypercapnia)
- you have paralysis of the gut
- you have acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)
- you are taking a medicine for depression which contains a monoamine oxidase inhibitor (MAOI) medicine such as AURORIX® (moclobemide) or PARNATE® (tranylcypromine). or have taken a MAOI within the last 14 days. Ask your doctor or pharmacist if any of your medicines are a MAOI.

Check with your doctor if you:

- have or have had any other medical conditions such as:
 - slow or shallow breathing
 - sleep-related breathing disorders
 - suffer from increased pressure in the brain or disturbed consciousness up to coma

- a head injury or a brain tumour
 - an epileptic fit or seizure or if you have an increased risk of having epileptic fits or seizures
 - liver or kidney disease
 - pancreatic or biliary tract disease including pancreatitis
 - an addiction or history of abuse of alcohol, opioids or other drugs
 - an intolerance to some sugars. Lactose is an ingredient in these tablets.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

You should only start taking PALEXIA® IR under direct supervision of your doctor due to the following risks:

Addiction

You can become addicted to PALEXIA® IR even if you take it exactly as prescribed. PALEXIA® IR may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking PALEXIA® IR. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking PALEXIA® IR suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to PALEXIA® IR may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

You should not take PALEXIA® IR during pregnancy unless your doctor has told you to do so. Taking PALEXIA® IR during pregnancy may lead to withdrawal symptoms in the newborn baby.

You should not take PALEXIA® IR during labour as it can cause breathing problems and signs of withdrawal in the newborn.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

You should not take PALEXIA® IR if you are breastfeeding as it may pass into your breast milk.

Paediatric Use

PALEXIA® IR is not recommended for use in children and adolescents below 18 years of age.

Patients with liver problems

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 kidney problems

Patients with severe kidney problems should not take these tablets.

3. What if I am taking other medicines?

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

Some medicines may interfere with PALEXIA® IR and affect how it works. 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 DIPRIVAN® (propofol) or HYPNOVEL® (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®).
- a group of medicines called anticholinergics. These medicines can be used to treat a wide range of medical conditions including asthma, a respiratory condition called chronic obstructive pulmonary disorder (COPD), Parkinson's Disease, cardiovascular disease, urinary incontinence (loss of bladder control), psychiatric disorders including schizophrenia, anxiety, depression, allergies and travel sickness/nausea.

Taking these medicines with PALEXIA® IR may increase the risk of possible side effects (see Section [6. Are there any 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.

Other medications can also interfere with PALEXIA® IR and make you feel drowsy (see the boxed Warning information at the start of this document). Ask your doctor or pharmacist for more information.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PALEXIA® IR.

4. How do I use PALEXIA® IR?

How much to take

- The usual dose of PALEXIA® IR 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 not as expected, talk to your doctor or pharmacist.
- 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.
- The time you will need to take PALEXIA® IR differs between individuals depending on how severe your pain is, how you respond to PALEXIA® IR and the cause of your pain.
- Follow the instructions provided and use PALEXIA® IR until your doctor tells you to stop.

How to take PALEXIA® IR 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.

If you forget to use PALEXIA® IR

PALEXIA® IR should be used regularly at the same time each day.

If you miss your dose at the usual time, 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.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you are not sure what to do, talk to your doctor or pharmacist.

If you use too much PALEXIA® IR

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, call triple

zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used PALEXIA® IR that was prescribed for you. If someone takes an overdose, they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

If you think that you or someone else may have taken too much PALEXIA® IR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while using PALEXIA® IR?

Things you should 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.
- 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, surgeon, anaesthetist or dentist that you are taking this medicine. It may affect other medicines used during surgery.

Call your doctor straight away if you:

Do not feel well while taking PALEXIA® IR.

Remind any doctor, dentist or pharmacist you visit that you are using PALEXIA® IR.

Things you should not do

- Do not stop using this medicine suddenly. 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 (see 'Withdrawal' section above).

- 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.

Driving or using machines

Do not drive, operate heavy machinery or use any machines or tools until you know how PALEXIA® IR affects you.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Looking after your medicine

- Keep PALEXIA® IR tablets in the blister pack until it is time to take them.
- Store your tablets in a place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If the medicine is damaged or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering, or the tablets do not look quite right.

Do not take this medicine after the expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of the time they are not serious, however, sometimes they are serious and may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal and mouth related:</p> <ul style="list-style-type: none">• Mild abdominal problems such as nausea, constipation, decreased appetite, indigestion, vomiting, diarrhoea, abdominal discomfort, dry mouth. <p>Neurological and behaviour related:</p> <ul style="list-style-type: none">• Dizziness, drowsiness or fatigue.• Headache.• Anxiety or depressed mood.• Irritability.• Difficulty sleeping or abnormal dreams.• Nervousness or restlessness.• Feeling abnormal. <p>Muscle and limb related:</p> <ul style="list-style-type: none">• Trembling, muscle twitches. <p>General body related:</p> <ul style="list-style-type: none">• Flushing or reddening of the face and neck.• Itching, rash or hives.• Increased sweating.• Abnormal sensations of the skin (e.g. tingling, prickling).• Feeling of body temperature change.• Swelling or oedema. <p>Sleep-related breathing disorders:</p> <ul style="list-style-type: none">• PALEXIA® IR can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction related: Signs of allergic reaction may include a skin rash (red spots or patches), itching, hives, shortness of breath or swelling of the face, lips, mouth, throat or tongue.</p> <p>Heart and lung related:</p> <ul style="list-style-type: none"> • Difficulty breathing, shortness of breath or dangerously slow or shallow breathing. • Chest tightness, wheezing or pain in the chest. • Changes in your heartbeat, including heart palpitations, irregular heartbeat or faster or slower heartbeat. • Decreased blood pressure. <p>Neurological and behaviour related:</p> <ul style="list-style-type: none"> • Depressed level of consciousness. • Sedation. • Feeling drunk or feeling of relaxation. • Sensation of heaviness. • Drug withdrawal syndrome (see “Withdrawal” section above). • Drug dependence. • Near fainting or faintness. • Fainting or collapse. • Seizures, fits or convulsions. • Epileptic fit. • Disorientation • Confusion. • Excitability (agitation) or euphoric mood. • Disturbance in attention. • Hallucinations. • Memory impairment. • Thinking abnormal thoughts. <p>General body related:</p> <ul style="list-style-type: none"> • Difficulty speaking. • Numbness. <p>Gastrointestinal related:</p> <ul style="list-style-type: none"> • Severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system. • Difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time. • Impaired gastric emptying. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects (continued)	What to do
<p>Urinary related:</p> <ul style="list-style-type: none"> • Delay in passing urine. • Frequent urination. <p>Eye related:</p> <ul style="list-style-type: none"> • Abnormal vision. <p>Muscle and limb related:</p> <ul style="list-style-type: none"> • Abnormal coordination or difficulty in controlling movements. • Feeling of weakness. • Muscle cramps. <p>Hormone related:</p> <ul style="list-style-type: none"> • Androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops. • Adrenal insufficiency symptoms such as weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What PALEXIA® IR contains

Active ingredient (main ingredient)	Tapentadol (as hydrochloride)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • microcrystalline cellulose • lactose monohydrate • croscarmellose sodium
Other ingredients (inactive ingredients) (continued)	<ul style="list-style-type: none"> • povidone (K30) • magnesium stearate • polyvinyl alcohol • titanium dioxide (E171) • macrogol 3350

	<ul style="list-style-type: none"> • purified 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).
Potential allergens	Lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What PALEXIA® IR looks like

There are 3 distinct strengths of PALEXIA® IR tablets:

PALEXIA® IR 50 mg tablets (AUST R 165310)

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 (AUST R 165317)

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 (AUST R 165318)

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

The registered pack sizes for PALEXIA® IR tablets are: 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.

Who distributes PALEXIA® IR

Australian sponsor:

Seqirus Pty Ltd
 ABN 26 160 735 035
 655 Elizabeth Street
 Melbourne VIC 3000 Australia

Telephone: 1800 642 865
www.cslseqirus.com.au

PALEXIA® IR is distributed in Australia by:

Seqirus (Australia) Pty Ltd
 Melbourne, Victoria, Australia

PALEXIA® IR is manufactured by:

Grünenthal GmbH, Germany

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This leaflet was prepared in December 2025.