

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.

1. Why am I taking ANKSILON?

ANKSILON tablets contain the active ingredient buspirone hydrochloride. ANKSILON is used to treat anxiety over short periods of time.

For more information, see Section [1. Why am I taking ANKSILON?](#) in the full CMI.

2. What should I know before I take ANKSILON?

Do not use if you have ever had an allergic reaction to ANKSILON 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 take ANKSILON?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ANKSILON 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 take ANKSILON?

Your doctor will tell you how much ANKSILON to take, and how often, depending on your condition and. Follow their instructions carefully.

More instructions can be found in Section [4. How do I take ANKSILON?](#) in the full CMI.

5. What should I know while taking ANKSILON?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ANKSILON.• Tell your doctor or pharmacist if you find out that you are pregnant.• Keep all appointments with your doctor so that your condition can be monitored, your medicine dosage can be adjusted or stopped.
Things you should not do	<ul style="list-style-type: none">• Do not change your dosage or stop taking ANKSILON without your doctor's advice.• Do not eat grapefruit or drink grapefruit juice while taking ANKSILON.
Driving or using machines	<ul style="list-style-type: none">• ANKSILON may cause dizziness, drowsiness, headache, light-headedness or nausea. Avoid driving or operating machinery if ANKSILON affects you this way.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C in a cool dry place away from moisture, heat or sunlight. It is best to keep the tablets in the blisters and box until you take them.

For more information, see Section [5. What should I know while taking ANKSILON?](#) in the full CMI.

6. Are there any side effects?

Side effects include dizziness, headache, drowsiness, feeling light-headed, nausea, feeling sick (vomiting), dry mouth, stomach pain, passing either loose/watery or dry/hard stools, unusual tiredness or weakness, insomnia, nightmares, nervousness, excitement, agitation, anger/hostility, feeling distracted, fever, sore throat, blocked nose, heavy sweating/clamminess. ANKSILON can cause serious side effects including severe allergic reaction, chest pain, fast pounding heartbeat, lack of coordination, numbness, tingling, pain or weakness in muscles, hands or feet, uncontrolled body movement, stiffness of arms or legs, depression, confusion, fainting, hallucinations, difficulties in passing urine, rash, blurred vision, ringing in the ears. When many of these symptoms occur together, it may be a sign of Serotonin Syndrome.

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.

ANKSILON®

Active ingredient(s): *bupirone hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking ANKSILON?

ANKSILON tablets contain the active ingredient **bupirone hydrochloride**. Bupirone hydrochloride is an anxiolytic, a medicine used to treat anxiety over short periods of time.

2. What should I know before I take ANKSILON?

Warnings

Do not take ANKSILON if:

- you are allergic to bupirone hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine
- you have or have had severe liver disease
- you have severe kidney problems
- you have acute angle-closure glaucoma, an eye condition with severe eye pain and severe headache
- you have myasthenia gravis, a disorder that causes muscle weakness, difficulty chewing or swallowing and slurred speech
- you have epilepsy

Do not take ANKSILON if the expiry date printed on the pack is passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if:

- you have or have had any other medical conditions such as kidney or liver problems, convulsions, fits or seizures
- take other medicines such as a benzodiazepine, monoamine oxidase inhibitor, sedative or hypnotic to manage anxiety, depression or other illness
- take medicines for any other problem
- you are dependent on drugs or alcohol.

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?](#)

Pregnancy and breastfeeding

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

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

Children and adolescents

Information on the safety of bupirone hydrochloride in children and adolescents is limited, therefore it is not recommended for use in patients below 18 years of age.

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 ANKSILON and affect how it works, or be affected by ANKSILON, including:

- monoamine oxidase inhibitors (MAOI) such as phenelzine, tranylcypromine
- selective serotonin re-uptake inhibitors (SSRI) like fluoxetine, fluvoxamine, paroxetine, sertraline
- other serotonergic drugs including tryptophan, triptans, tramadol, buprenorphine, linezolid, lithium, St John's wort
- benzodiazepines like diazepam, alprazolam, temazepam
- other antidepressants, sleeping tablets or medicines to calm nerves or improve moods
- antipsychotics such as haloperidol
- antibiotics like erythromycin, rifampicin
- antifungals like itraconazole, ketoconazole
- antivirals such as ritonavir
- calcium channel blockers to treat high blood pressure or angina like diltiazem or verapamil
- anticonvulsants such as phenytoin, phenobarbital, carbamazepine
- baclofen, a muscle relaxant
- antihistamines

Grapefruit or its juice should be avoided while taking ANKSILON.

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

4. How do I take ANKSILON?

How much to take

Your doctor will tell you how much to take each day and when to take it.

The starting dose is usually one 5 mg tablet taken three times a day. Your doctor may increase the dose by one 5 mg tablet a day every 2 to 3 days. Most people will need a total of 20 to 30 mg a day, taken in two or three doses. No more than six 10 mg tablets should be taken in 24 hours.

Elderly people should take no more than three 10 mg tablets in 24 hours.

Follow your doctor's instructions carefully, including when to stop taking ANKSILON for your condition. If you are unsure about the dosage, ask your doctor or pharmacist.

When to take

Take your ANKSILON dose at about the same times each day. Although it does not matter if you take ANKSILON before or after food, you should take it consistently with food or without food for best effect.

Taking the tablets consistently this way will also help you remember when to take the medicine.

How to take it and for how long

Swallow the tablets with a glass of water.

Continue taking the medicine for as long as your doctor tells you to. Ask your doctor if you are not sure how long to take it.

If you forget to take ANKSILON

ANSILON should be taken regularly at the same times each day. If you missed your dose but the next one is still more than 6 hours away, take it immediately.

If it is almost time for your next dose however, 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 you missed.

If you have trouble remembering when to take your tablets or are not sure what to do, ask your doctor or pharmacist for help.

If you take too much ANKSILON

If you think that you have taken too much ANKSILON, 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.

5. What should I know while taking ANKSILON?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ANKSILON.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine.
- If you are going to have surgery that needs a general anaesthetic, tell the doctors or dentist that you are taking this medicine.
- If you become pregnant, tell your doctor or pharmacist immediately.
- Keep all of your doctor's appointments so that your progress can be checked or your dose can be adjusted.

Things you should not do

- Do not give this medicine to anyone else, even if they have the same condition as you
- Do not take ANKSILON to treat any other complaints unless your doctor tells you to.
- Do not change your dosage or stop taking ANKSILON without checking with your doctor or pharmacist.
- Do not eat grapefruit or drink grapefruit juice.

Driving or using machines

Be careful before you drive, use any machines or tools, or do anything else that could be dangerous until you know how ANKSILON affects you.

ANKSILON may cause dizziness, headache, drowsiness, light headedness or nausea in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

It is not wise to take alcohol with any medicine.

Looking after your medicine

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

Store below 25°C 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 the tablets in the blisters and box until you need to take them.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not take 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 them are minor and temporary. However, some side effects 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.

Side effects

Less serious side effects	What to do
<ul style="list-style-type: none">dizziness, headache, drowsiness, feeling light-headednausea, feeling sick (vomiting), dry mouth, stomach pain, passing either loose/watery or dry/hard stoolsunusual tiredness or weaknessinsomnia, nightmaresnervousness, excitement, agitation, anger/hostility, feeling distractedfever, sore throat, blocked noseheavy sweating/clamminess	Speak to your doctor if you have any of these side effects and they worry you.

Serious side effects	What to do
<ul style="list-style-type: none">allergic reactions - signs include shortness of breath, wheezing, or difficulty breathing; swelling of the face, lips, tongue or throat; rash, itching or hives on the skinchest painfast pounding heartbeatlack of coordination, numbness, tingling, pain or weakness in muscles, hands or feetuncontrolled body movementstiffness of arms or legsdepression, confusion, fainting, hallucinationsdifficulties in passing urinerashblurred visionringing in the ears	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.

Some of these side effects may be signs of a condition called 'Serotonin Syndrome'.

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.

You may experience some nausea, insomnia, dizziness or mild feelings of sadness when you stop taking ANKSILON.

7. Product details

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

What ANKSILON tablets contain

Active ingredient (main ingredient)	buspirone hydrochloride
Other ingredients (inactive ingredients)	lactose monohydrate sodium starch glycolate Type A microcrystalline cellulose colloidal anhydrous silica magnesium stearate
Potential allergens	sugars (as lactose)

Do not take this medicine if you are allergic, or have an intolerance, to any of these ingredients.

What ANKSILON looks like

ANKSILON 5 mg tablets are white or almost white, oval biconvex tablets debossed with 'ORN 30' on one side and a score on the other side (AUST R 422891).

It comes in boxes of 60 or 100 tablets.

ANKSILON 10 mg tablets are white or almost white, oval biconvex tablets debossed with 'ORN 31' on one side and a score on the other side (AUST R 422890).

It comes in boxes of 60 or 100 tablets.

Not all pack sizes may be available.

Who distributes ANKSILON

Orion Pharma (Aus) Pty Limited
Level 24, Tower 3, 300 Barangaroo Avenue
Sydney NSW 2000, Australia
Telephone: 1800 861 913

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