

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 UROCARB?

UROCARB contains the active ingredient bethanechol chloride. UROCARB is used to treat certain disorders of the urinary tract or bladder that may be caused by surgery, delivering a baby or other conditions.

For more information, see Section 1. Why am I taking UROCARB? in the full CMI.

2. What should I know before I take UROCARB?

Do not use if you have ever had an allergic reaction to bethanechol chloride 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 UROCARB? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with UROCARB 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 UROCARB?

The usual dose is 1 to 3 tablets, taken three to four times a day. Take UROCARB on an empty stomach. Swallow tablets whole
with a full glass of water or let them dissolve under your tongue.

More instructions can be found in Section 4. How do I take UROCARB? in the full CMI.

5. What should I know while taking UROCARB?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are taking UROCARB. Be careful when getting up suddenly from a sitting or lying position.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how UROCARB affects you. • UROCARB may cause dizziness in some people.
Looking after your medicine	Keep your medicine in a cool, dry place where it stays below 30°C.

For more information, see Section 5. What should I know while taking UROCARB? in the full CMI.

6. Are there any side effects?

Side effects are rare, but are more likely to occur when the dose is increased.

Speak to your doctor if you have any side effects that worry you. Side effects may include stomach cramps or pain, nausea, diarrhoea, headache, fall in blood pressure with fast heartbeat, flushed or sweating skin, wheezing or asthma, blurred vision, urinary urgency or teary eyes.

Seizures have been reported but it is not clear whether these were caused by UROCARB.

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.

UROCARB®

Active ingredient(s): bethanechol chloride

Consumer Medicine Information (CMI)

This leaflet provides important information about taking UROCARB. 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 UROCARB.

Where to find information in this leaflet:

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

1. Why am I taking UROCARB?

UROCARB contains the active ingredient bethanechol chloride. UROCARB has a similar action to a natural chemical in the body called acetylcholine. It causes the smooth muscle in the bladder to contract and empty.

UROCARB is used to treat certain disorders of the urinary tract or bladder, such as urinary retention (trouble urinating) that may be caused by surgery, delivering a baby or other conditions.

2. What should I know before I take UROCARB?

Warnings

Do not take UROCARB if:

- you are allergic to bethanechol chloride, 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
- you have an overactive thyroid
- you have blocked coronary arteries
- you have slow heartbeat or low blood pressure
- you have epilepsy or other seizure disorder
- you have Parkinson's disease
- you have a kidney infection
- you have an ulcer, blockage or recent surgery on your stomach or intestines
- you have a bladder obstruction
- you are pregnant or likely to become pregnant

Check with your doctor if you:

- have any other medical conditions
- have had a recent bladder or kidney infection
- 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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. UROCARB may cause muscle contractions that could lead to a miscarriage.

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

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 UROCARB and affect how it works. These include:

- Cholinergic drugs, especially cholinesterase inhibitors, that block the normal breakdown of acetylcholine and are most commonly used to treat Alzheimer's disease or dementia.
- Medicines that affect the parasympathetic nervous system used to treat some conditions of the gut, eyes, heart or nerve-muscle disorders. These medicines may not work as effectively when used with UROCARB.
- Procainamide or quinidine, medicines used to treat irregular heartbeats.
- A group of medicines called ganglionic blocking agents.

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

4. How do I take UROCARB?

How much to take

- The usual dose is 1 to 3 tablets, taken three to four times a day
- Follow the instructions provided and take UROCARB until your doctor tells you to stop.

When to take UROCARB

 UROCARB should be taken on an empty stomach as nausea and vomiting could occur if taken too soon after eating.

How to take UROCARB

 Swallow tablets whole with a full glass of water or let them dissolve under your tongue.

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If you forget to take UROCARB

UROCARB should be taken regularly at the same times each day.

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 you missed.

If you take too much UROCARB

If you think that you have taken too much UROCARB, 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 UROCARB?

Things you should do

Call your doctor straight away if you:

• Become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are taking UROCARB.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how UROCARB affects you.

UROCARB may cause dizziness in some people.

Looking after your medicine

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

Store it in a cool dry place below 30°C, 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 windowsills.

Keep it where young children cannot reach it.

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 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.

Possible side effects

Possible side effect	What to do
 feeling unwell stomach cramps or pain urgency to pass urine nausea diarrhoea headache flushed or sweating skin wheezing or asthma 	Speak to your doctor if you have any side effects and they worry you.

Possible side effect	What to do
 blurred vision or teary eyes seizures fall in blood pressure with fast heart rate 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any serious side effects.

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 UROCARB contains

Active ingredient (main ingredient)	bethanechol chloride
Other ingredients (inactive ingredients)	lactose monohydrate acacia amaranth erythrosine magnesium stearate wheat starch hydrogenated vegetable oil
Potential allergens	lactose, sugars, gluten

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

What UROCARB looks like

UROCARB is a round, light pink tablet with a break line on one side. It is supplied in bottles of 100 tablets. Each tablet contains 10 mg bethanechol chloride.

(Aust R 14861).

Who distributes UROCARB

Mayne Pharma International Pty Ltd

1538 Main North Road

Salisbury South, SA 5106

UROCARB is a registered trademark of

Mayne Pharma International Pty Ltd.

This leaflet was prepared in July 2021.

CMI Version: 4.0