QUILONUM SR

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 using QUILONUM SR?

QUILONUM contains the active ingredient lithium carbonate. QUILONUM SR is used to treat mental illness. It is taken both to treat and prevent episodes of mood swing, in a condition called either manic-depression or bipolar disorder.

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

2. What should I know before I use QUILONUM SR?

Do not use if you have ever had an allergic reaction to QUILONUM SR 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 QUILONUM SR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with QUILONUM SR 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 QUILONUM SR?

- Follow your doctor's instructions about how and when to take QUILONUM SR.
- The usual dose of QUILONUM SR is one 450mg tablet twice a day.
- Swallow the tablets whole, with cold water and preferably with food.
- Do not break in half, chew or crush the tablets, or try to dissolve them.

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

5. What should I know while using QUILONUM SR?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using QUILONUM SR. If you forget to take QUILONUM SR, take it as soon as you remember. Do not double the dose to make up for any missed or forgotten dose. Maintain a normal diet and fluid intake, particularly an adequate and constant salt and water intake. 	
Things you should not do	 Do not stop using this medicine suddenly. Do not give this medicine to anyone else, even if their symptoms seem similar to yours. Do not use QUILONUM SR to treat any other complaints unless your doctor says to. 	
Driving or using machines	 Be careful driving or operating machinery until you know how QUILONUM SR affects you. Lithium may cause dizziness, sleepiness, poor coordination and hallucination. 	
Drinking alcohol	 Be careful when drinking alcohol while you are taking QUILONUM SR. If you drink alcohol while you are taking it side effects such as drowsiness may become worse. 	
Looking after your medicine	 Keep QUILONUM SR tablets in its blister pack until it is time to take them. Do not leave them in a car, on a window sill or in the bathroom. 	

For more information, see Section 5. What should I know while using QUILONUM SR? in the full CMI.

6. Are there any side effects?

Mild side effects may disappear without stopping treatment. These include mild nausea, loose bowel motions, tiredness and dizziness. Tell your doctor if you notice any serious side effects including severe or persistent nausea, vomiting or diarrhoea, extreme tiredness, blurred vision and lack of balance or difficulty walking.

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.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems. [Include if applicable]

QUILONUM SR

Active ingredient(s): Lithium carbonate

Consumer Medicine Information (CMI)

This leaflet provides important information about using QUILONUM SR. 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 QUILONUM.

Where to find information in this leaflet:

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

1. Why am I using QUILONUM SR?

QUILONUM SR contains the active ingredient lithium carbonate. QUILONUM SR is a powerful mood stabiliser, however the exact way lithium works to stabilise a person's mood is not known. It helps you to have more control over your emotions and cope better.

QUILONUM SR is used to treat mental illness. It is taken both to treat and prevent episodes of mood swing, either up (mania) or down (depression), in a condition called either manic-depression or bipolar disorder.

Your doctor may have prescribed QUILONUM SR for another reason.

QUILONUM SR tablets are not addictive.

2. What should I know before I use QUILONUM SR?

Warnings

Do not use QUILONUM SR if:

- you are allergic to lithium carbonate, 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 taken lithium before and become unwell, tell your doctor before starting these tablets.
- you have severe kidney or heart disease.
- you are weakened by illness or dehydrated.
- you have a low level of sodium in your blood.
- you have an untreated underactive thyroid gland or Addison's disease.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- · have any other medical conditions
- you are having, or going to have electroconvulsive (electric shock) therapy
- you have a condition called Brugada syndrome, or someone in your family has Brugada syndrome (a genetic disease that affects the heart)
- take any medicines for any other condition
- are allergic to foods, dyes, preservatives or any other medicines.

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.

If QUILONUM SR is taken during the first 12 weeks of pregnancy, when organs are formed, the baby may be born with birth defects involving the heart and blood vessels.

Use of QUILONUM SR towards the end of pregnancy may produce serious unwanted effects in the newborn baby. These unwanted effects usually last for 1 to 2 weeks after the baby has been born.

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

Do not breastfeed while you are taking this medicine.

Use in Children

There is no specific information to recommend the use of QUILONUM SR in children under 12 years.

Use in Elderly Patients

Your doctor will determine the appropriate dose for elderly patients.

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.

In particular tell your doctor if you are taking any of the following medicines which:

- changes urine output (diuretics, or fluid tablets)
- change the acidity of urine (sodium bicarbonate)
- lower blood pressure or treat heart conditions (such as methyldopa, "calcium channel blockers" and "ACE inhibitors")
- treat wheezy breathing (such as theophylline or aminophylline)
- control fits or convulsions (such as carbamazepine or phenytoin). It may cause brain damage due to lithium toxicity.
- treat depression (such as fluoxetine or imipramine)
- treat arthritis (non-steroidal anti-inflammatory drugs, such as indomethacin and piroxicam, as well as "COX II inhibitors" such as celecoxib and rofecoxib
- contains metronidazole ("anti-infective")
- decrease appetite
- contain a steroid (i.e. prednisolone)
- treat certain mental condition (i.e. haloperidol or ziprasidone)
- angiotensin II receptor antagonists (i.e. irbesartan (Avapro, Karvea), candesartan (Atacand).

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

4. How do I use QUILONUM SR?

How much to take / use

- Follow the instructions provided and use QUILONUM SR until your doctor tells you to stop.
- The usual dose of QUILONUM SR is one 450mg tablet twice a day.
- If necessary, your doctor may increase or decrease the dose you take each day.

When to take / use QUILONUM SR

- Keep taking your QUILONUM SR for as long as your doctor tells you to.
- Do not stop taking QUILONUM SR or change the dose without first checking with your doctor.

How to take / use

- Swallow the tablet(s) whole, with cold water and preferably with food.
- Do not break in half, chew or crush the tablets, or try to dissolve them.

If you forget to use QUILONUM SR

QUILONUM SR should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

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 use too much QUILONUM SR?

If you think that you have used too much QUILONUM SR, you may need urgent medical attention.

Symptoms of overdose include anorexia, persistent nausea and vomiting, blurred vision, delirium, muscle twitch, coma and a dangerous decrease of blood pressure which can cause rapid shallow breathing, cold clammy skin, rapid weak pulse, dizziness, weakness and fainting. In severe cases, fits (convulsions), kidney failure and death may occur.

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 using QUILONUM SR?

Things you should do

- Tell your doctor if you, for any reason, have not taken your medicine exactly as directed.
- Keep all of your doctor's appointments so that your progress can be checked. Unwanted effects can occur with changes in your body function or in your condition, it is important that you are monitored and have regular blood tests.
- It is important to maintain a normal diet and fluid intake, particularly an adequate and constant salt and water intake.
- It may be necessary to stop lithium if you develop another illness.

All thoughts of suicide must be taken seriously. Tell your doctor or a mental health professional immediately if you have any suicidal thoughts or other mental/mood changes.

Remind any doctor, dentist or pharmacist you visit that you are using QUILONUM SR.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use QUILONUM SR to treat any other complaints unless your doctor says to.
- Do not stop taking QUILONUM SR without talking to your doctor or pharmacist.

Driving or using machines

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

Lithium may cause dizziness, sleepiness, poor coordination and hallucinations. If you are affected you should not drive or operate machinery.

Drinking alcohol

Be careful when drinking alcohol while you are taking QUILONUM SR.

If you drink alcohol while you are taking it side effects such as drowsiness may become worse.

Looking after your medicine

 Keep QUILONUM SR tablets in its blister pack until time to take them.

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.

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.

Less serious side effects

Less serious side effects	What to do
 mild nausea loose bowel motions taste impairment abdominal discomfort tiredness weakness dizziness slurred speech fine tremor of the hands muscle twitching or jerking muscle or joint pain larger than usual urine volumes mild constant thirst worsening of acne or psoriasis mild allergic rash hair loss weight gain cold hands and feet swelling of hands, ankles or feet excessive salivation 	These mild side effects may disappear without stopping treatment Tell your doctor or pharmacist If you experience any of the following after taking QUILONUM SR.

- loss of appetite
- changes in sexual function.

Serious side effects

Serious side effects		What to do	
•	severe or persistent nausea,	Call your doctor	
	vomiting, or diarrhoea	straight away,	
•	drowsiness	or go straight	
•	extreme tiredness	to the	
•	blurred vision	Emergency	
•	ringing in the ears	Department at	
•	lack of balance or difficulty in	your nearest	
	walking	hospital if you	
•	passage of very large volumes of	notice any of	
	urine with raging thirst	these serious	
•	seizures or fits	side effects.	
•	acute renal failure (kidney		
	disease where you pass little or		
	no urine. Other symptoms		
	include drowsiness, nausea,		
	vomiting and breathlessness)		
•	changes in rhythm or rate of		
	heart beat		
•	impair or loss of consciousness.		
•	Wheezing, swelling of the		
	lips/mouth, difficulty in		
	breathing, hayfever, lumpy rash		
	(hives) or fainting. These could		
	be symptoms of an allergic		
	reaction.		

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 QUILONUM SR contains

Active ingredient (main ingredient)	Each QUILONUM SR tablet contains 450mg of the active ingredient lithium carbonate.
Other ingredients (inactive ingredients)	Colouring agent titanium dioxide, maize starch, lactose monohydrate, gelatin, purified talc, povidone, carmellose calcium, calcium behenate, magnesium stearate, macrogol 6000 and Eudragit E 100.
Potential allergens	Lactose

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

What QUILONUM looks like

QUILONUM SR is a white tablet in blister packaging containing 100 tablets. Each tablet has break lines on both sides of the tablet.

(AUST R 53377)

Who distributes QUILONUM SR?

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street St Leonards NSW 2065 Australia.

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