

QUILONUM SR(R)

Tablets

lithium carbonate

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take Quilonum SR tablets.

This leaflet answers some common questions about Quilonum SR. It does not contain all of the available information.

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

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking Quilonum SR against the risks this medicine could have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What is Quilonum SR used for?

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.

Before you take Quilonum SR

Do not take if:

You must not take Quilonum SR if:

- * **you have ever had an allergic reaction (See "Side-Effects") to lithium or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")**
- * **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**

Tell your doctor if:

You must tell your doctor if:

- * **you are allergic to foods, dyes, preservatives or any other medicines.**

- * **you are breastfeeding, pregnant or trying 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.

Do not breast-feed while you are taking this medicine.

- * **you are taking any other medicines, including medicines you buy without a prescription. 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 methyl dopa, "calcium channel blockers" and "ACE inhibitors")**
 - **treat wheezy breathing (such as theophylline or aminophylline)**
 - **control fits or convulsions (such as carbamazepine or phenytoin)**
 - **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 (ie prednisolone)
- treat certain mental condition (ie haloperidol or ziprasidone)
- angiotensin II receptor antagonists (ie irbesartan (Avapro, Karvea), candesartan (Atacand)

How do I take Quilonum SR?

Follow your doctor's instructions about how and when to take Quilonum SR.

Please read the label carefully. If you have any questions about Quilonum SR and how to take it, please ask your doctor or pharmacist.

How much to take

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.

How to take it

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.

How long to take it for

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.

Use in children and elderly patients

There is no specific information to recommend the use of Quilonum SR in children under 12 years. Your doctor will determine the appropriate dose for elderly patients.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Quilonum SR, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor, pharmacist or nearest hospital. Be sure to show the doctor the pack of tablets.

While you are taking Quilonum SR

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. 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 doses.

- * Keep all of your doctor's appointments so that your progress can be checked. Because unwanted effects can occur with changes in your body function or in your condition, it is important that you are monitored closely by your doctor 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.

Things you must 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.

Things to be careful of

Be careful driving or operating machinery until you know how Quilonum SR affects you. Lithium may cause dizziness, sleepiness, poor co-ordination and hallucinations. If you are affected you should not drive or operate machinery.

What are the side-effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Quilonum SR, even if the problem is not listed below.

Like other medicines, Quilonum SR can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Tell your doctor or pharmacist if you experience any of the following after taking Quilonum SR.

Mild side effects which may disappear without stopping treatment include:

- * 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
- * dry mouth
- * loss of appetite
- * changes in sexual function.

Tell your doctor immediately if you notice any of the following:

- * severe or persistent nausea, vomiting, or diarrhoea
- * drowsiness
- * extreme tiredness
- * blurred vision
- * ringing in the ears
- * lack of balance or difficulty in walking
- * passage of very large volumes of urine with raging thirst
- * seizures or fits
- * 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.**

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor or pharmacist if you notice any side effects from your medicine which are not mentioned here.

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

How do I store Quilonum SR?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Do not leave in a car, on a window sill or in the bathroom.

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

Return any unused or expired medicine to your pharmacist.

Product description

What Quilonum SR looks like

Quilonum SR comes as white tablets in blister packaging containing 100 tablets. Each tablet has breaklines on both sides of the tablet.

Ingredients

Quilonum SR contains the active ingredient lithium carbonate.

Quilonum SR tablets also contain inactive ingredients, including the colouring agent titanium dioxide, maize starch, lactose, gelatin, talc, povidone, carmellose calcium, calcium behenate, magnesium stearate, macrogol 6000, Eudragit E 100.

Supplier

Your Quilonum SR tablets are supplied by:
 GlaxoSmithKline Australia Pty Ltd
 1061 Mountain Highway
 Boronia
 Victoria, 3155
 Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations.

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The information provided applies only to Quilonum SR(R) tablets.

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Issue 4