#### **Consumer Medicine Information**

### The formulation of Lithicarb has changed. Please consult your doctor before taking your tablets.

#### What is in this leaflet

This leaflet answers some common questions about Lithicarb. It does not contain all the information that is known about Lithicarb. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lithicarb against the benefits they expect it will 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 Lithicarb is used for

Lithicarb is used to both treat and prevent episodes of a condition called manic-depressive or bipolar disorder, in which there are sustained mood swings either up (manic) or down (depression).

It is also used in the treatment of schizo-affective illness and chronic schizophrenia.

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

Your doctor, however, may have prescribed Lithicarb for another purpose.

# Ask your doctor if you have any questions about why Lithicarb has been prescribed for you.

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

There is no evidence that it is addictive.

### Before you take it

# When you must not take it Do not take Lithicarb if you have an allergy to:

- · any medicine containing lithium
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

## Do not take Lithicarb if you have or have had:

- · severe heart or kidney disease
- low activity of the adrenal gland (e.g. Addison's disease)
- an underactive thyroid gland
- low levels of sodium in your body (e.g. if you are dehydrated or on a low salt diet).

# Do not take Lithicarb after the expiry date (EXP) printed on the pack.

Do not take it if the packaging is torn or shows signs of tampering.

# Do not take it to treat any other complaints unless your doctor has instructed you to do so. Before you start to take it

A medical examination and some laboratory tests are usually performed before you begin therapy with Lithicarb. They are usually repeated at

regular intervals while you continue to take this medicine.

Tell your doctor if you are allergic to any other medicines, foods, preservatives or dyes. Tell your doctor if you have or have had any of the following medical conditions:

- conditions for which you take diuretics (fluid tablets)
- vomiting or diarrhoea
- · two infections occurring at the same time
- you have a condition called Brugada syndrome, or someone in your family has Brugada syndrome (a genetic disease that affects the heart)

It may not be safe for you to take Lithicarb if you have any of these medical conditions.

Do not take Lithicarb if you are pregnant, plan to become pregnant or are breastfeeding unless you and your doctor have discussed the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Lithicarb.

#### Taking other medicines

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

Lithicarb interacts with many other medicines. This can cause a change in the blood levels of either the lithium or of the other medicine, increasing the chance of side effects or lithium toxicity. Lithium toxicity may occur if the level of lithium in your blood becomes too high. If you are taking a medication which interacts with Lithicarb your blood lithium levels will need to be monitored closely.

Some medicines in common use that may interfere with Lithicarb include:

- medicines for removal of fluid (diuretics)
- some medicines for high blood pressure and other heart drugs (e.g. captopril, enalapril, calcium channel blockers, methyldopa, Atacand and Cozaar)
- · some types of tranquillisers (e.g. diazepam)
- some medicines for depression (e.g. fluoxetine, imipramine)
- some medicines for arthritis or pain (e.g. indomethacin, piroxicam, celecoxib, rofecoxib)
- · appetite suppressants
- some medicines for epilepsy (e.g. carbamazepine and phenytoin)
- medicines used to treat respiratory illness (e.g. theophylline)
- medicines that change the acidity of the urine (e.g. sodium bicarbonate)
- medicines used to treat certain mental conditions (e.g. haloperidol)
- ziprasidone, which can interact with lithium to affect the heart
- medicines containing steroids (e.g. prednisolone)
- medicines used to treat glaucoma (e.g. acetazolamide)
- medicines used to treat skin disorders (e.g. urea)
- some antibiotics (e.g. metronidazole).

These medicines may be affected by Lithicarb or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor or pharmacist has a more complete list of medicines to be careful with or avoid while taking Lithicarb.

# If you have not told your doctor about any of these things, tell them before you take Lithicarb.

#### Things to be aware of

Lithicarb should always be taken with care and under your doctor's supervision because serious side effects may occur if the level of lithium in your blood becomes too high (lithium toxicity). This can happen if you are taking too much lithium or if there are major changes to your normal health or lifestyle.

There are a number of things you can do during therapy with Lithicarb to help prevent lithium toxicity, such as:

- maintain a normal diet with adequate salt and fluid
- · avoid reducing your salt intake quickly
- avoid heavy exercise which may lead to excessive sweating and water loss
- watch for signs of lithium toxicity if you have an infection or have symptoms such as fever, vomiting or diarrhoea
- watch for signs of lithium toxicity if your regular dose of Lithicarb is increased or changed or if you start taking another medication.

# If you are not aware of the signs of lithium toxicity you should ask your doctor.

You and your family should be able to recognise the signs of lithium toxicity and know what to do if they occur.

## Use in children

### Do not give Lithicarb to children.

This medicine is not recommended for children as there is no specific information about such use.

## Use in elderly

Elderly patients may be more sensitive to the effects or side effects of this medicine. If you are elderly you need to watch carefully for signs of side effects or lithium toxicity. Elderly patients may require a lower dosage than younger patients.

### How to take it

#### How much to take

Follow all directions given to you by your doctor or pharmacist carefully.

# Your doctor will tell you how much Lithicarb to take.

The dose required to reach an effective level in the blood varies between individuals. For this reason the dose needs to be adjusted to suit you.

In the early stages of your treatment your doctor will arrange several blood tests to establish your blood level of lithium and the dose of Lithicarb that is correct for you. You will need to have regular blood tests to monitor your blood lithium level.

Your body's requirements of lithium may change and it may be necessary for your doctor to change the amount of Lithicarb taken to effectively control your mood swings.

#### How to take it

Lithicarb should be taken with a meal or snack to prevent stomach upset.

#### When to take it

# In order for Lithicarb to work properly, spread out the recommended dose evenly throughout the day.

This will help keep the amount of lithium in your blood constant.

# Do not miss any doses and do not stop taking the medicine even if you feel better.

Missing doses may make your symptoms worse.

### How long to take it

# Continue taking Lithicarb for as long as your doctor tells you.

Lithicarb is not a cure. To control mood swings you may need to take it for a long period of time. Only after several months or even years can you and your doctor decide whether taking it is still necessary.

#### What to expect

When you start taking Lithicarb your mood swings should become less frequent, less severe and less prolonged.

Sometimes it must be taken for one to several weeks before you begin to feel better. However, it may take six to twelve months before the full benefits of lithium therapy become apparent. To maximise its effectiveness it is important that you take the prescribed dose of Lithicarb regularly.

### If you forget to take it

If you miss a dose and it is more than two hours before your next dose is due, take it straight away, then continue as you normally would.

If it is less than 2 hours to your next dose, skip the dose you have missed but be sure to take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Lithicarb. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

# While you are taking it

## Things you must do

# Lithium blood level tests

When you first start taking Lithicarb, you may require blood tests as often as twice a week. Once your lithium levels are stable, you should need tests about 4 times a year to check that your blood lithium level is stable. If your Lithicarb dose is changed or if you have signs of lithium toxicity you may need more frequent blood tests.

The blood test must be done twelve hours after a dose, usually before you have taken your morning tablets.

# Take Lithicarb exactly as your doctor has prescribed

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lithicarb.

Tell your doctor immediately if you become pregnant while taking Lithicarb.

Tell all doctors, dentists and pharmacists who are treating you, that you are taking Lithicarb.

### Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

# Do not stop taking Lithicarb suddenly unless advised by your doctor.

If you stop taking it suddenly your mood swings may return. If you want to stop taking Lithicarb, your doctor will tell you how to do it gradually over several weeks or months.

### Things to be careful of

# Be careful driving or operating machinery until you know how Lithicarb affects you.

This medicine may cause drowsiness, poor coordination and blurred vision in some patients, especially when you first start to take it. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous.

# Be careful when drinking alcohol while you are taking Lithicarb.

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

#### Side effects

# Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lithicarb.

Lithicarb helps most people with mood swings or schizophrenia, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

# Tell your doctor if you notice any of the following and they worry you:

- stomach upset with mild nausea (feeling sick) and diarrhoea
- · feeling dazed, dizzy or lightheaded
- muscle weakness
- · fine tremor of the hands
- fluid retention
- thirst
- passing more urine than usual
- unusual tiredness or weakness
- loss of appetite
- vomiting
- · increased saliva
- stomach pain
- stomach problems with pain, nausea, vomiting, vomiting blood and blood in the bowel motions
- · constipation
- · slurred speech
- slightly altered taste
- dry mouth
- headache
- impotence
- rash
- worsening of skin diseases such as acne or psoriasis
- numbness, tingling and colour change in fingers and toes when exposed to cold.

These are all common side effects of Lithicarb. Most of these will improve or resolve with time.

When Lithicarb is taken for long periods of time the following side effects can occur:

- thyroid changes (goitre)
- weight gain
- mild forgetfulness

#### · hair thinning.

Your doctor may suggest some dietary or lifestyle changes to help reduce these effects.

#### Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:

- · irregular heart beat
- excessive thirst
- passing large amounts of urine
- · severe stomach cramps or pain
- · vomiting or diarrhoea
- severe drowsiness or dizziness
- ringing in the ears
- confusion
- · staggering and slurred speech
- · severe tremor
- · increased muscle twitches or weakness
- · blurred vision or agitation
- swelling of the face, mouth lips, tongue or throat which may cause difficulty in breathing or swallowing.

These are all serious side effects. They are possible signs of high levels of lithium in the blood (lithium toxicity). You may need urgent medical attention or hospitalisation.

# Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other side effects while taking Lithicarb.

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

# After taking it

#### Storage

Keep Lithicarb tablets in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink or stove. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

### Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres

above the ground is a good place to store medicines.

#### Disposal

If your doctor tells you to stop taking this medicine, or the expiry date has passed, ask your pharmacist what to do with any tablets you may have left.

# Product description

# What it looks like

Lithicarb tablets are white to off-white ovalshaped bevel edged film coated tablets, with breakline on one side and plain on the other side The tablets are available in bottles of 200.

# Ingredients

## Active ingredient:

Each tablet contains 250 mg lithium carbonate.

## Inactive ingredients:

- starch maize
- dextrin
- lactose
- macrogol 6000
- sodium starch glycollate A
- talc purified
- · sodium lauryl sulphate
- · magnesium stearate
- hypromellose

Lithicarb tablets do not contain sucrose, tartrazine or any other azo dyes.

# Sponsor

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos St St Leonards NSW 2065 Australia Australian Registration Number: AUST R 49625 This leaflet was updated in October 2015.