

## SPRIOTONE

### *Spironolactone 25mg and 100mg Tablets*



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## What is in this leaflet

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This leaflet answers some common questions about SPIROTONE.

It does not contain all the information available on this medicine. 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 using SPIROTONE against the benefits expected it will have for you.

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

**Keep this leaflet. You may want to read it again.**

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## What SPIROTONE is used for and how it works

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Your SPIROTONE tablets contain the active ingredient spironolactone. It belongs to a group of medicines known as diuretics.

SPIROTONE is used to lower high blood pressure, also called hypertension. It treats fluid build-up in the body which can occur in some heart, liver or kidney conditions. It helps bring potassium levels in the blood back to normal when the levels become too low. It also treats a condition called hyperaldosteronism and excess facial or body hair in women.

Your doctor may, however, prescribe SPIROTONE for another reason. Ask your doctor if you have

any questions about why SPIROTONE has been prescribed for you.

There is no evidence that SPIROTONE is addictive.

SPIROTONE is available on prescription from your doctor.

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## Before you take SPIROTONE

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### *When you must not take it*

**Do not take SPIROTONE if:**

- You are allergic to spironolactone or any other ingredients listed at the end of this leaflet
- You have kidney problems
- You have high potassium levels in your blood
- You are not producing or passing urine

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.

### *Before you take it*

Tell your doctor:

- If you have kidney or liver problems
- If you are pregnant or planning to become pregnant
- If you are breastfeeding or planning to breastfeed

### *Taking other medicines*

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health

food shop, tell your doctor or pharmacist.

Medicines that may interfere with SPIROTONE include:

- Medicines used to treat high blood pressure and some other heart conditions
- Diuretics, which are fluid removing medicines also known as water tablets
- Digoxin, a medicine used to treat heart failure
- Tablets, preparations or supplements which contain potassium
- Salt substitutes which contain potassium
- Aspirin
- Non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- Carbenoxolone, a medicine used to treat mouth ulcers
- Regional or general anaesthetics
- Cholestyramine, a medicine used to lower cholesterol levels in the blood
- Ammonium chloride, which is contained in some cough and cold medicines

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SPIROTONE.

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## How to take SPIROTONE properly

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## How much to take

Your doctor will tell you how much SPIROTONONE you need to take. It is important that you take SPIROTONONE as directed by your doctor. Do not take more than the recommended dose.

The usual dose for adults with high blood pressure is 50mg to 100mg per day which may be gradually increased at two weekly intervals up to 200mg per day. The daily dose may be given either in divided doses or as a single daily dose. Treatment should be continued for at least two weeks since an adequate response may not occur before this time.

For other conditions, your doctor will tell you how many tablets you need to take each day and when to take them. This depends on your condition and whether or not you are taking other medicines.

## How long to take it

Continue taking SPIROTONONE for as long as your doctor tells you to.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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## While you are taking SPIROTONONE

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

Tell your doctor or pharmacist that you are taking SPIROTONONE before you start any new medicine.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking SPIROTONONE.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking SPIROTONONE.

If you are going to have any blood tests, tell your doctor that you are taking SPIROTONONE.

Do not take SPIROTONONE to treat any other complaints unless your doctor tells you to.

Do not stop taking SPIROTONONE or lower the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

SPIROTONONE may cause drowsiness or confusion in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that SPIROTONONE does not affect your performance.

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## Side effects

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

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- Feeling sick, vomiting
- Stomach cramps or pain, diarrhoea
- Headache
- Drowsiness, lack of energy
- Menstrual period changes in women
- Post-menopausal bleeding
- Unusual hair loss or thinning
- Excessive hair growth

These are the more common side effects of spironolactone.

**Tell your doctor as soon as possible if you notice any of the following:**

- Lumps in the breasts
- Breast enlargement in men
- Breast pain
- Confusion or dizziness
- Leg cramps
- Skin rash or hives

- Unsteadiness when walking
- Signs of infrequent infections such as fever, chills, sore throat or mouth ulcers
- Change in sex drive
- impotence (inability to achieve or maintain an erection)

**Tell your doctor immediately if you experience any of the following:**

- Vomiting blood or material that looks like coffee grounds
- Bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- Unsteadiness when walking
- Shortness of breath and swelling of the legs from fluid build (may be due to hyperkalaemia, which is very serious)

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

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

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## In case of overdose

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You should only take the number of tablets that you have been told.

**Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any SPIROTONONE by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the container of SPIROTONONE with you if you can.**

Keep telephone numbers for these places handy.

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## Storage conditions

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Do not take this medicine after the expiry date shown on the label or if the packaging shows signs of tampering.

Keep your SPIROTONE tablets in the container until it is time to take them.

Store below 30°C and out of reach of children. Avoid exposure to heat, light and moisture.

Do not store SPIROTONE, or any other medicine, in the bathroom or near a sink.

### ***Disposal***

If your doctor tells you to stop taking SPIROTONE or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

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## **Product Description**

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### ***What SPIROTONE tablets look like***

SPIROTONE 25mg tablets are pale orange round tablets, marked with  $\alpha$  on one side and  $\frac{SP}{1}$  on the other.

SPIROTONE 100mg tablets are pale orange round tablets, marked with  $\alpha$  on one side and  $\frac{SP}{2}$  on the other.

Each SPIROTONE tablet contains the active ingredient, spironolactone.

Each SPIROTONE tablet also contains quinoline yellow, sunset yellow, erythrosine, polysorbate, peppermint oil, povidone, microcrystalline cellulose, maize starch, sodium starch glycollate, talc, magnesium stearate and lactose.

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## **If you want to know more**

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Should you have any questions regarding this product, please contact your doctor or pharmacist.

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Telephone: (09) 579 2792

### ***Date of information***

9 August 2010  
(Based on datasheet dated 21 July 2010)