

SPIROLON 25 F.C TABLET

Spirolactone (25mg)

What is in this leaflet:

1. What Spirolon is used for
2. How Spirolon works
3. Before you take Spirolon
4. How to take Spirolon
5. While you are using Spirolon
6. Side effects
7. Storage and Disposal of Spirolon
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Spirolon is used for

It is indicated for the following illnesses:

- Congestive cardiac failure
- Hepatic cirrhosis with ascites and oedema
- Nephrotic syndrome (a kidney disorder that causes too much fluid in your body)
- Diagnosis and treatment of primary aldosteronism (extra fluid in your body caused by too much of a hormone called 'aldosterone')

If you have these illnesses, Spirolon will help your body to get rid of the extra fluid.

How Spirolon works

Spirolon belongs to a group of medicines called 'diuretics' – you may know these as 'water' tablets. You may have gone to your doctor because you had swollen ankles or were short of breath. This can happen when your heart's pumping action has become weak because of too much fluid in your body. This is called 'congestive heart failure'. Pushing extra fluid around your body means your heart has to work harder. Your doctor has given you Spirolon to help you lose the extra fluid from your body. This will mean your heart has to do less work. You lose the extra

fluid as urine, so you may need to go to the toilet more often while you are taking Spirolon.

Before you use Spirolon

When you must not use it

Do not take Spirolon tablets if you:

- If you are hypersensitive to spironolactone or to any of the excipients of the product
- If you suffer from anuria (cannot pass urine)
- If you suffer from a severe kidney disease
- If you suffer from hyperkalaemia (raised blood potassium levels)
- If you are breast-feeding
- If you are taking potassium sparing diuretics or potassium supplements.

Before you start to use it

You must tell your doctor if you:

- If you are pregnant.
- If you suffer from kidney or liver disease.
- If you are taking any other diuretics in combination with Spirolon which may cause low sodium levels (hyponatraemia) in the blood.

If you experience reduced kidney function or kidney failure you may have severe increases in the levels of potassium in your blood. This can affect the way your heart functions and in extreme cases this can be fatal.

Taking other medicines

Always tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without prescription. Consult your doctor. It may be necessary to adjust the dose if you are taking any of the following:

- If you are taking antihypertensive drugs including ACE inhibitors.
- If you are taking other diuretics.

- If you are taking potassium supplements.
- If you are going to have an operation where you will be given an anesthetic, tell the doctor in charge that you are taking Spirolon.

How to use Spirolon

How much to use

Always take Spirolon exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The pharmacist's label on the pack also gives this information. The number of tablets you need to take depends on your illness. This medicine should be taken once a day with food.

Adults:

The adult dose varies from 100mg to 400mg spironolactone a day. If you are not sure how much to take, ask your doctor or pharmacist.

Elderly:

Your doctor will start you on a low starting dose and gradually increase the dosage as needed to obtain the desired effect.

Children:

If you are giving Spirolon to a child, the number of tablets you give will depend on the child's weight. Your doctor will work out the number of tablets that you should give. The usual dose for children is 3mg daily per kg body weight in divided doses.

When to use it

This medicine should be taken with food.

The tablets are swallowed unchewed with some water. Please follow your doctor's instruction

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How long to use it

It is important to keep taking Spirolon until your doctor tells you to stop, even if you start to feel better. If you stop taking the tablets too soon, your condition may get worse.

If you forget to use it

If you have to take the medicine on a regular basis and you miss a dose, you should take the missed dose as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for a missed dose.

If you use too much (overdose)

In case you have taken a dose larger than normal, contact your doctor or go to the nearest hospital immediately. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using it

Things you must do

- Consult your doctor or pharmacist before taking any medication.
- In case of overdose contact your doctor immediately.
- Keep this leaflet in a safe place. You may need to read it again.
- If you have any question, ask your doctor or your pharmacist.

Things you must not do

This medicine was prescribed for you personally and you should not pass it on to others. It can be harmful, even when their symptoms are the same as yours.

You should not use spironolactone if you are allergic to it, or if you have kidney disease, high levels of potassium in your blood, or if you are unable to urinate. Do not use potassium supplements or other

diuretics while you are taking spironolactone.

Drinking alcohol can increase certain side effects of spironolactone.

Do not use salt substitutes or low-sodium milk products that contain potassium. These products could cause your potassium levels to get too high while you are taking Spirolon.

Avoid a diet high in salt. Too much salt will cause your body to retain water and can make this medication less effective. Avoid becoming overheated or dehydrated during exercise and in hot weather. Follow your doctor's instructions about the type and amount of liquids you should drink. In some cases, drinking too much liquid can be as unsafe as not drinking enough.

Things to be careful of

Pregnancy:

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant as your doctor will need to judge whether you should be prescribed Spirolon.

Consult your doctor or pharmacist before taking any medication.

Breast-feeding:

Spirolon should not be used if you are breast-feeding.

You should discuss the use of Spirolon with your doctor, who will advise you to consider an alternative method of feeding your baby while you are taking this medicine.

Consult your doctor or pharmacist before taking any medication.

Caution is advised when driving or operating machinery as drowsiness and dizziness have been associated with Spirolon treatment and may affect your ability to drive or operate machinery safely.

Side effects

As with all medicines Spirolon may cause undesirable effects although not everybody gets them. Tell your doctor immediately if you experience any of the

following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- Irregular heartbeat, tingling sensation, paralysis or difficulty in breathing; which may be symptoms of raised potassium levels in your blood. Your doctor will conduct regular blood tests to monitor potassium and other electrolyte levels. He or she may stop your treatment if necessary.

Other side effects of Spirolon

- Nausea, stomach upset
- Disturbances in body electrolytes
- Excessive growth of breast tissue in men (gynaecomastia), this goes away when treatment is stopped, and breast lumps, breast pain
- Skin rash, generalized itchiness
- Skin allergy with development of itchiness and weals (urticaria),
- General weakness, muscle cramps

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

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Storage and Disposal of Spirolon

Storage

Store below 25°C protected from light and moisture and in a safe place away from the reach of children.

Disposal

Product expiry date is shown on the inner and outer packaging. In case the expiry date has lapsed, do not use.

Product Description

What it looks like

Yellow, round, film-coated tablets, scored with Remedica's logo on one side and embossed with "SP 25" on the other side

Ingredients

Active ingredient: Spironolactone

Inactive ingredient: Pregelatinised Starch, Microcrystalline Cellulose, Macrogol 6000, Polysorbate 80, Sodium Starch Glycolate, Sodium Lauryl Sulphate, Colloidal Silicon Dioxide, Magnesium Stearate, Menthol, Hypromellose, Macrogol 400, Titanium Dioxide, Talc, Quinoline Yellow E104, Lactose, Maize starch and Povidone.

MAL No.: MAL19890617A

Manufacturer

Remedica Ltd, Limassol Industrial Estate, Limassol, Cyprus, EU.

Product Registration Holder

LF Asia (Malaysia) Sdn Bhd (719-V)
Lot 6, Persiaran Perusahaan, Seksyen 23, 40300 Shah Alam,
Selangor Darul Ehsan

Date of Revision

30/08/2013