

Urospir™ 25 mg/5 ml Oral Solution

spironolactone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


What is in this leaflet:

1. What Urospir is and what it is used for
2. What you need to know before you take Urospir
3. How to take Urospir
4. Possible side effects
5. How to store Urospir
6. Contents of the pack and other information

1. What Urospir is and what it is used for

Urospir contains the active substance spironolactone. Urospir 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 Urospir 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 Urospir.

You can also take Urospir for the following illnesses:

- 'Nephrotic syndrome' - a kidney disorder that causes too much fluid in your body
- 'Ascites' - too much fluid in your abdomen and 'oedema' - accumulation of fluid beneath skin or in one or more cavities of the body that produces swelling, for example caused by cirrhosis of the liver
- 'Malignant ascites' - fluid containing cancer cells that collect in the abdomen
- 'Primary aldosteronism' - extra fluid in your body caused by too much of a hormone called 'aldosterone'.

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

You must talk to a doctor if you do not feel better or if you feel worse.

Children should only be treated under guidance of a paediatric specialist.

2. What you need to know before you take Urospir

Do not take Urospir if:

you are allergic to spironolactone or any of the other ingredients of this medicine (listed in section 6)

- you cannot pass urine
- you have severe kidney disease
- you have Addison's disease; (a hormone deficiency characterised by extreme weakness, loss of weight and low blood pressure)
- you have hyperkalaemia (raised blood potassium levels)
- you are breast-feeding
- you are taking water tablets (potassium sparing diuretics) or any potassium supplements
- you are taking eplerenone (a medicine for high blood pressure).

Children with moderate to severe kidney disease must not take Urospir.

Warnings and precautions

Talk to your doctor or pharmacist before taking Urospir if:

- you suffer from kidney disease especially children with hypertension or liver disease. Your doctor will routinely assess you particularly if you are elderly
- you have difficulty passing urine
- you have a disease that can result in electrolyte balance disturbance in your blood such as potassium or sodium
- you have severe heart failure
- you are pregnant

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.

Concomitant administration of Urospir with certain medicines, potassium supplements and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.

Other medicines and Urospir

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may wish to alter your dose of Urospir if you are taking any of the following:

- digoxin or carbenoxolone
- medicines for high blood pressure including angiotensin-converting enzyme (ACE) inhibitors
- other diuretics
- non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, indomethacin, mefenamic acid or ibuprofen
- potassium supplements
- heparin or low molecular weight heparin (medicines used to prevent blood clots)
- antipyrene
- medicines known to cause hyperkalaemia (raised blood potassium levels)
- trimethoprim and trimethoprim-sulfamethoxazole

Urospir reduces your responsiveness to noradrenaline. If you are going to have an operation where you will be given an anaesthetic, tell the doctor in charge that you are taking Urospir. Tell your doctor, if you are using abiraterone for treatment of prostate cancer.

Urospir with food, drink and alcohol

See section 3 'How to take Urospir'.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Urospir should not be used if you are breast-feeding. You should discuss the use of Urospir with your doctor, who will advise you to consider an alternative method of feeding your baby while you are taking this medicine.

Driving and using machines

Take care if you drive or operate machinery. Drowsiness and dizziness have been associated with Urospir treatment and this may affect your ability to drive or operate machinery safely.

3. How to take Urospir

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

There are differences in the way spironolactone is absorbed from the stomach, between Urospir and spironolactone tablets. In case of switching between Urospir and tablets or other spironolactone formulations this should be done under the close supervision of the doctor.

Taking this medicine

- Each millilitre (ml) of Urospir oral solution contains 5 milligrams (mg) spironolactone.
- Take this medicine by mouth.
- Always use the syringe supplied with the pack. Do not use a different syringe as it may be made of polystyrene or PVC and may react with the medicine.
- Ensure that the syringe is dry before use. This is because the medicine is preservative free and the contents of the bottle should not come into contact with water.
- Spironolactone should be taken with food.
- This product is not currently recommended for administration via enteral feeding tubes.

Adults

The adult dose varies from 25 mg (5 ml) to 400 mg spironolactone a day, depending on the condition being treated.

If you are not sure how much to take, ask your doctor or pharmacist.

Urospir can only be used for a single dose of up to 100 mg (20 ml). If you need to take more than 100 mg of spironolactone (more than 20 ml) a day, this should be taken in two equally divided doses.

Urospir is only suitable for doses up to 200 mg a day (20 ml twice a day). If you need to take a dose higher than 200 mg a day your doctor will prescribe a different product.

Elderly

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

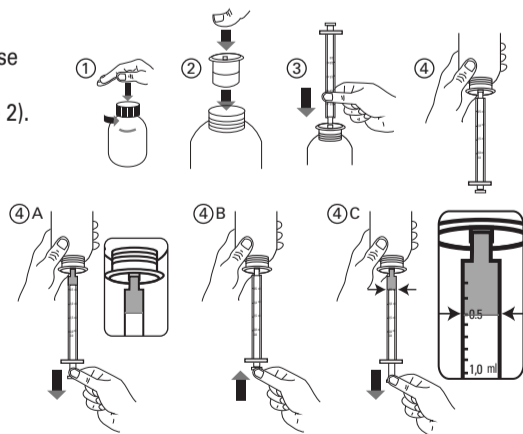
Use in children and adolescents

If you are giving Urospir to a child, the amount of liquid you give will depend on the child's weight. Your doctor will work out the amount of liquid that you should give.

Measuring your dose

Instructions for use of the syringe

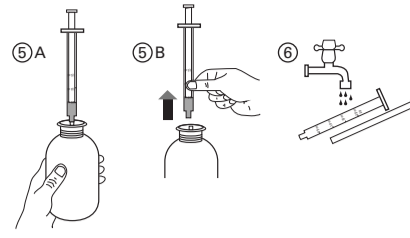
- Open the bottle: press the cap and turn it anticlockwise (Figure 1).
- Insert the syringe adaptor into the bottle neck (Figure 2).
- Take the syringe and put it in the adaptor opening (Figure 3).
- Turn the bottle upside down (Figure 4).
- Fill the syringe with a small amount of solution by pulling the piston down (Figure 4A). Then push the piston upward in order to remove any possible bubbles (Figure 4B). Finally, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. The top flat edge of the piston should be in line with the graduation mark you are measuring to (Figure 4C).



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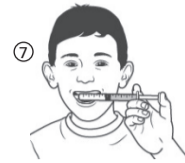
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- Turn the bottle the right way up (Figure 5A).
- Remove the syringe from the adaptor (Figure 5B).
- Put the end of the syringe into your mouth and push the piston slowly back in to take the medicine.
- Wash and dry the syringe before you use it again (Figure 6).



When giving this medicine to a child:

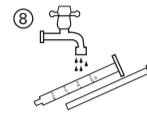
- Make sure that your child is sitting up or standing
 - Put the syringe into your child's mouth, placing the barrel-opening in the area between the gums and the inside of the cheek (see Figure 7).
 - Push the plunger slowly, giving your child time to swallow the medicine as it squirts out. Do not push the plunger too quickly as the medicine may come out too quickly and your child may choke.
- Give your child a drink in order to ensure that all the medicine is washed down
- Close the bottle with the plastic screw cap - leave the syringe adaptor in the bottle.



Should a child find the taste unpleasant, the product can be mixed into a small amount of milk, yoghurt or ice cream. Ensure this is taken immediately after its preparation and make sure your child drinks or eats all of it to get the complete dose of medicine.

The table below will help you measuring the exact dose prescribed by your doctor. Each 1 ml = 5 mg

Measure Amount (ml)	Amount of spironolactone (mg)
0.1 ml	0.5 mg
0.5 ml	2.5 mg
1 ml	5 mg
2.5 ml	12.5 mg
3 ml	15 mg
5 ml	25 mg



If you take more Urospir than you should

If you accidentally take too many doses, contact your doctor or nearest hospital accident and emergency department immediately. The symptoms of an overdose are feeling drowsy, dizzy, feeling dehydrated and you may feel confused. You may also feel or be sick, suffer from diarrhoea and may have skin rashes that will appear as flat red areas of skin with overlapping small raised bumps. Changes in your blood sodium and potassium levels may leave you feeling weak and suffering from tingling, prickling or numbness of the skin and/or muscle spasms but these symptoms are unlikely to be associated with severe overdosage.

If you forget to take Urospir

If you forget to take your dose, take it as soon as you remember, unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Urospir

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side 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.

- itchy skin and blistering of the skin around the lips and the rest of the body, red or purple rash spreading and forming blisters (Stevens-Johnson syndrome)
- detachment of the top layer of skin from the lower layers of skin, all over the body (toxic epidermal necrolysis -TEN)
- skin rash, fever and swelling (which could be symptoms of something more serious, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- yellow skin and eyes (jaundice)
- spironolactone can cause impairment of liver function
- irregular heartbeat which can be fatal, tingling sensation, paralysis (loss of muscle function) 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. They may stop your treatment if necessary.

List of other side effects of spironolactone by frequency:

Very common: may affect more than 1 in 10 people

- raised potassium in the blood

Common: may affect up to 1 in 10 people

- confusion
- dizziness
- vomiting or feeling sick
- itching of the skin
- rash
- muscle or leg cramps
- kidney failure or abnormal function
- breast enlargement in men
- breast pain (in men)
- feeling generally unwell

Uncommon: may affect up to 1 in 100 people

- changes in the breast such as breast lumps
- disturbances in body electrolytes such as high blood calcium
- abnormal functioning of the liver
- skin allergy with development of itchy skin and hives, nettle like rash
- menstrual problems in women
- breast pain (in women)

Not known: frequency cannot be estimated from the available data

- lowered white blood cell count in blood
- reduced number of cells that fight infection – white blood cells which make infections more likely
- reduced number of cells that help with blood clotting which increases risk of bleeding or bruising
- change in sex drive for both men and women
- digestion problems, stomach upset
- skin condition presenting with fluid-filled blisters (pemphigoid)
- hair loss
- excessive hair growth.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Urospir

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Do not refrigerate. Store in the original packaging (bottle) in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not use 1 month after you first open this medicine. Take it back to the pharmacy.
- Do not use Urospir if you notice the medicine has separated into two layers or appears cloudy. This is because there may be water in the medicine. Talk to your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Urospir contains

The active substance is spironolactone. Each 5 ml of the solution contains 25 mg spironolactone. The other ingredients are medium chain triglycerides and peppermint oil.

What Urospir looks like and the contents of the pack

Urospir oral solution is a clear colourless to pale yellow non aqueous liquid. It comes in a brown glass bottle holding 150 ml of solution with a 5 ml syringe and bottle adaptor.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. Tel: + 44 (0) 113 244 1400

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