Package leaflet: Information for the patient

ZADA PHARMACEUTICALS

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 more 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.

SPILAK®25mgFilm-coatedTablets
SPILAK®50mg Film-coatedTablets
spironolactone

What is in this leaflet

1. What SPILAK is and what it is used for
SPILAK contains the active substance spironolactone. **SPILAK** 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 **SPILAK** 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 **SPILAK**. You can also take **SPILAK** for the following illnesses: 'Nephrotic syndrome' -a kidney disorder that causes too much fluid in your body 'Ascites' -too much fluid in your abdomenand '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, **SPILAK** 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 SPILAK
Do not take SPILAK 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 watertablets (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 **SPILAK**.
Warnings and precautions
Talk to your doctor or pharmacist before taking **SPILAK** if:
you suffer from kidney disease especially children with hypertension or liver disease.Your doctor will routinely assess youparticularly if you are elderly
you have difficulty passing urine
you have a disease that can result in electrolyte balance disturbance in your bloodsuch 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 **SPILAK** 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 SPILAK
Tell your doctoror pharmacistif you are taking, have recently takenor might takeany other medicines.Your doctor may wish to alter your dose of **SPILAK** if you are taking any of the following:
digoxin or carbenoxolone
medicines for high blood pressureincluding angiotensin-converting enzyme (ACE)inhibitors
other diuretics non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin, indomethacin, mefenamic acid oribuprofen
potassium supplements
heparin or low molecular weight heparin (medicinesused to prevent blood clots) antipyrine
medicines known to cause hyperkalaemia (raised blood potassium levels)
trimethoprim and trimethoprim-sulfamethoxazole
SPILAK 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 **SPILAK**.
SPILAK with food,drinkand alcohol
See section 3 'How to take **SPILAK**'.

Pregnancy,breast-feeding and fertility
If you are pregnantor 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.

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

3. How to take SPILAK
Always take this medicineexactly as your doctoror pharmacist has told you. 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. Recommended doseThis medicine should be taken once a day with food.Adults The adult dose varies from 25mg to 400mg spironolactone a day,depending on the condition being treated. 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.

Use in childrenand adolescents
If you are giving **SPILAK** 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. If you take more **SPILAK** than you should If you accidentally take too many tablets, 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 mayhave 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 tobe associated with severe overdosage.
If you forget to take SPILAK
If you forget to take your tablet, 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 SPILAK
It is important to keep taking SPILAK 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4.Possible side effects
Like all medicines, this medicinecan 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.
Itchiness 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)
SPILAK can cause impairment of liver function
Irregular heart beat 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 **SPILAK** by frequency:
Verycommon: 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 itchiness andhives, 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 conditionpresenting 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(see details below).
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SPILAK
Keep this medicine out of the sight and reach of children.Do not store your tablets above 30oC.Do not use this medicine after the expiry date which is stated on the blister, cartonor bottle label after EXP.
The expiry date refers to the last day of that month.
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 SPILAK contains
The active substance is spironolactone.
Each **SPILAK** 25mg tablet contains 25mg of spironolactone.
Each **SPILAK** 50mg tablet contains50mg of spironolactone.
The other ingredients are : calcium hydrogen phosphate dihydrate, lactose monohydrate, pregelatinized corn starch, povidone, sodium starch glycolate, sodium lauryl sulfate, magnesium stearate.
Contents of the pack
Box of 30 tablets of 25 mg spironolactone in blister pack (3 blister x 10 tablets)
Box of 30 tablets of 50 mg spironolactone in blister pack (3 blister x 10 tablets)

Manufacturer and marketing authorisation holder
ZADA Pharmaceuticals Ltd.
Donji Bistarac b.b.
75 300 Lukavac

Marketing authorisation number(s)
Spilak, film-coated tablets, 30x25 mg:
04-07.3-2-4704/16
Spilak, film-coated tablets, 30x50 mg:
04-07.3-2-4705/16

Date of first authorisation/renewal of the authorisation
Spilak, film-coated tablets, 30x25 mg: 21.04.2017.
Spilak, film-coated tablets, 30x50 mg: 21.04.2017.