PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ALDACTONE® 25 tablets

ALDACTONE® 100 tablets

Spironolactone

Sugar free

Read all of this leaflet carefully before you start taking ALDACTONE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ALDACTONE has been prescribed for you personally and you should not share it with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ALDACTONE is and what it is used for

ALDACTONE belongs to a group of medicines called diuretics (water tablets) and is used to treat hypertension (high blood pressure) and congestive heart failure (a condition in which the heart's function as a pump is inadequate to meet the body's needs). ALDACTONE is also used to treat aldosteronism

(extra fluid in your body caused by too much of a hormone called aldosterone). ALDACTONE will help your body to get rid of the extra fluid.

2. What you need to know before you take ALDACTONE

Do not take ALDACTONE:

- if you are hypersensitive (allergic) to spironolactone or to any of the other ingredients of ALDACTONE (listed in section 6)
- if you have severe kidney disease
- if you cannot pass urine
- if you have hyperkalaemia (raised blood potassium levels)
- if you are taking eplerenone (a medicine for high blood pressure)
- if you have Addison's disease (a disorder in which your body produces insufficient amounts of certain hormones)
- İf you are pregnant or breastfeeding

Warnings and precautions

Take special care with ALDACTONE:

- if you are taking other water tablets in the same class (potassium sparing diuretics) as ALDACTONE, certain blood pressure medicines, nonsteroidal anti-inflammatory drugs (NSAIDs), heparin, low molecular weight heparin, other medicines or conditions known to cause high potassium levels in the blood, or potassium supplements, salt substitutes containing potassium or if you are on a diet rich in potassium as this may lead to severely high potassium levels in the blood (hyperkalaemia)
- if you suffer from kidney or liver disease
- if you have severe heart failure. It is very important that your potassium levels are managed and monitored as high potassium levels in the blood (hyperkalaemia) may be fatal

Other medicines and ALDACTONE

Always tell your health care provider if you are taking other medicines. (This includes all complementary or traditional medicines.)

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

- Other medicines known to cause high potassium levels in the blood
- Other diuretics or medicines for high blood pressure
- Digoxin (used to treat heart conditions)
- Non-steroidal anti-inflammatory drugs (NSAIDs) including aspirin, indomethacin, mefenamic acid and antipyrine
- Ammonium chloride or cholestyramine as it may cause increased levels of potassium in the blood
- Carbenoxolone as it may affect the way ALDACTONE works
- Potassium supplements and electrolytes
- Heparin or low molecular weight heparin

ALDACTONE 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 ALDACTONE.

Tell your doctor, if you are using abiraterone for treatment of prostate cancer.

Tell your doctor, if you are using mitotane for treatment of malignant tumours of the adrenal glands. ALDACTONE should not be used together with mitotane.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take ALDACTONE if you are pregnant or breastfeeding your baby. You should discuss the use of ALDACTONE 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

Caution is advised when driving or operating machinery as sleepiness and dizziness has been reported in patients taking ALDACTONE.

It is not always possible to predict to what extent ALDACTONE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ALDACTONE affects them.

3. How to take ALDACTONE

Do not share medicines prescribed for you with any other person.

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

Adults

The usual adult dose varies from 25 mg to 400 mg per day and will depend on the type of condition you are being treated for. ALDACTONE may be prescribed in divided doses or as a single daily dose.

Children

If ALDACTONE is given to children, the number of tablets will depend on the child's weight. The tablets may be crushed and given in a suspension if necessary.

Your doctor will tell you how many ALDACTONE tablets to take and how long your treatment with will last. Do not stop treatment early. If you have the impression that the effect of ALDACTONE is too strong or too weak, tell your doctor or pharmacist.

If you take more ALDACTONE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

The symptoms of an overdose may include feeling drowsy, confused, feeling sick, vomiting, dizziness or diarrhoea.

If you forget to take ALDACTONE

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ALDACTONE can have side effects.

Not all side effects reported for ALDACTONE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ALDACTONE, please consult your health care provider for advice.

Tell your doctor immediately if you experience the following symptoms after taking ALDACTONE:

- irregular heartbeat, muscle weakness, difficulty in breathing which may be symptoms of too much potassium in your blood (hyperkalaemia). Your doctor may stop your treatment if necessary.
- detachment of the top layer of skin from the lower layers of skin, all over the body (toxic epidermal necrolysis - TEN)
- 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)
- skin rash, fever and swelling (which could be symptoms of something more serious called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))

Tell your doctor if you notice any of the following:

Frequent side effects:

- confusion
- dizziness
- nausea

- itching of the skin
- rash
- muscle cramps
- acute kidney failure
- breast enlargement in men
- breast pain (in men)
- feeling generally unwell

Less frequent side effects:

- non-cancerous breast lumps in males
- disturbances in body electrolytes such as high blood calcium
- abnormal liver function
- skin allergy with itchiness and hives
- menstrual disorders
- breast pain (in women)

Other side effects:

- lowered white blood cell count as shown in blood tests (agranulocytosis)
- reduced number of blood cells that fight infection (leukopenia)
- reduced number of blood platelets that help with clotting which increases risk of bleeding or bruising (thrombocytopenia)
- changes in sex drive
- digestion problems or upset stomach
- hair loss
- excessive hair growth

If any of these side effects continue, are severe or bother you, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc,org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ALDACTONE.

5. How to store ALDACTONE

- Store all medicines out of reach of children.
- Store in a dry place at or below 25 °C.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ALDACTONE contains

- The active substance is spironolactone.

  ALDACTONE 25: Each tablet contains 25 mg spironolactone.

  ALDACTONE 100: Each tablet contains 100 mg spironolactone.
- The other ingredients are calcium sulfate dihydrate, hydroxypropyl methylcellulose, magnesium stearate, maize starch, Opaspray® white, peppermint flavour, polyethylene glycol and povidone.

What ALDACTONE looks like and contents of the pack

ALDACTONE 25 tablets: White, round, biconvex, film coated tablets stamped “Searle 39” on one side and plain on the other with a characteristic peppermint odour.

ALDACTONE 100 tablets: White, round, biconvex, film coated tablets stamped “Searle 134” on one side and plain on the other with a characteristic peppermint odour.

ALDACTONE tablets are available in blister packs containing 30, 60 or 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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