Approved Patient Information Leaflet for Medicines for Human Use: AIZEMPA

SCHEDULING STATUS: S4

AIZEMPA 10 mg film coated tablets

AIZEMPA 25 mg film coated tablets

Empagliflozin

Contains sugar: lactose monohydrate

AIZEMPA 10 mg film coated tablets

Each film-coated tablet contains 42,96 mg lactose monohydrate.

AIZEMPA 25 mg film coated tablets

Each film-coated tablet contains 107,40 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking AIZEMPA

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

What is in this leaflet

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

1. What AIZEMPA is and what it is used for

AIZEMPA contains the active substance empagliflozin.

AIZEMPA works by blocking a protein in the kidneys called sodium glucose cotransporter 2 (SGLT2). This causes blood sugar (glucose) to be removed in your urine. Thereby AIZEMPA lowers the amount of sugar in your blood.

AIZEMPA is used for:

Type 2 diabetes mellitus

- AIZEMPA is used to treat 'type 2 diabetes' in adults (aged 18 years and older) to improve blood sugar (glucose) control together with diet and exercise.
- AIZEMPA can be used alone or can also be taken with other medicines used to lower your blood sugar. These may be medicines taken by mouth or insulin given by injection.

Prevention of cardiovascular events

- AIZEMPA is also used in adults with 'type 2 diabetes' with an increased cardiovascular risk (health problems due to your heart and blood vessels), to lower the risk of dying from a heart attack or other events related to your heart or blood vessels, or to reduce the risk of being admitted to hospital for heart failure.

Heart failure

- AIZEMPA is used to treat heart failure in adults with or without type 2 diabetes, to reduce the risk of cardiovascular death and to reduce hospitalisation for heart failure.
- AIZEMPA also helps to slow down the worsening of kidney function.

2. What you need to know before you take AIZEMPA

Do not take AIZEMPA:

- if you are hypersensitive (allergic) to empagliflozin or any of the other ingredients of AIZEMPA (listed in section 6).
- if you have type 1 diabetes.
- if you have increased levels of ketone bodies in your urine or blood (see Warnings and precautions).

- if you have moderate or severe kidney problems or have kidney failure and are on renal dialysis.
- if you are pregnant or if you are breast feeding your baby.

Warnings and precautions

Stop taking AIZEMPA and contact a doctor or the nearest hospital immediately:

- if you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, contact a doctor or the nearest hospital straight away.

These symptoms could be a sign of "*diabetic ketoacidosis*" – a rare, but serious, sometimes life-threatening problem you can get with diabetes because of increased levels of "ketone bodies" in your urine or blood, seen in tests. The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.

Talk to your doctor, pharmacist or nurse before taking AIZEMPA, and during treatment:

- if you have "type 1 diabetes". This type usually starts when you are young, and your body does not produce any insulin. You should not take AIZEMPA if you have type 1 diabetes.
- if you have serious kidney or liver problems – your doctor may ask you to take a different medicine.
- if you might be at risk for dehydration:
    - if you are being sick, have diarrhoea or fever, or if you are not able to eat or drink
    - if you are taking medicines that increase urine production (diuretics) or lower blood pressure
    - if you are over 75 years old.

  Your doctor may ask you to stop taking AIZEMPA until you recover to prevent loss of too much body fluid. Ask about ways to prevent dehydration.
- if you are 85 years old or older as you should not start taking AIZEMPA.
- if you have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking AIZEMPA until you have recovered.

Fournier´s gangrene

Talk to your doctor immediately if you develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier´s gangrene which destroys the tissue under the skin. Fournier's gangrene has to be treated immediately.

Foot care

It is important to check your feet regularly and adhere to any other advice regarding foot care given by your health care professional.

Urine glucose

Because of how AIZEMPA works, your urine will test positive for sugar while you are taking AIZEMPA.

Kidney function

Your kidneys should be checked before you start taking AIZEMPA and at least 6-monthly during treatment, and also if you are taking AIZEMPA together with other medicine that may have a negative impact on kidney function.

Children and adolescents

AIZEMPA is not recommended for children and adolescents under 18 years, because it has not been studied in these patients.

Other medicines and AIZEMPA

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

- if you are taking medicines that increase urine production (diuretics). Your doctor may ask you to stop taking AIZEMPA.
- if you are taking other medicines that lower the amount of sugar in your blood such as insulin or a "sulphonylurea" medicine. Your doctor may want to lower the dose of these other medicines, to prevent your blood sugar levels from getting too low (hypoglycaemia).

- if you are taking lithium because AIZEMPA can lower the amount of lithium in your blood.

Pregnancy and breastfeeding

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. Do not use AIZEMPA if you are pregnant. It is unknown if AIZEMPA is harmful to the unborn child. Do not use AIZEMPA if you are breast-feeding. It is not known if AIZEMPA passes into human breast milk.

Driving and using machines

AIZEMPA has minor influence on the ability to drive and use machines.

Taking this medicine in combination with medicines called sulphonylureas or with insulin can cause blood sugar levels to drop too low (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you feel dizzy while taking AIZEMPA.

AIZEMPA contains lactose:

If you have an intolerance to some sugars, contact your doctor before taking AIZEMPA.

AIZEMPA contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

3. How to take AIZEMPA

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

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

Type 2 Diabetes

The recommended starting dosage of AIZEMPA is one 10 mg tablet once a day. Your doctor may tell you to increase the dose to 25 mg once a day if your blood glucose is not adequately controlled with a dose of 10 mg per day.

Your doctor will prescribe the strength that is right for you. Do not change your dose unless your doctor has told you to.

Heart failure

The dosage of AIZEMPA is one 10 mg tablet once a day.

Duration of administration

Continue to take AIZEMPA as long as your doctor prescribes it so you can continue to help control your blood sugar. Your doctor may prescribe AIZEMPA together with other diabetes medicines. Remember to take all medicines as directed by your doctor to achieve the best results for your health.

Diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise program recommended by your healthcare professional while taking AIZEMPA.

Check your blood sugar as your healthcare professional tells you if you have the impression that the effect of AIZEMPA is too strong, or too weak, talk to your doctor, pharmacist or nurse.

Method of administration

- Swallow the tablet whole with water.
- You can take the tablet with or without food.
- You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

If you take more AIZEMPA than you should

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

If you forget to take AIZEMPA

What to do if you forget to take a tablet depends on how long it is until your next dose.

- If it is 12 hours or more until your next dose, take AIZEMPA as soon as you remember. Then take your next dose at the usual time.
- If it is less than 12 hours until your next dose, skip the missed dose. Then take your next dose at the usual time.
- Do not take a double dose of AIZEMPA to make up for a forgotten dose.

If you stop taking AIZEMPA

Do not stop taking AIZEMPA without first consulting your doctor, unless you suspect you have ketoacidosis (see diabetic ketoacidosis under “warnings and precautions”). Your blood sugar levels may increase when you stop taking AIZEMPA.

4. Possible side effects

AIZEMPA can cause side effects

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

Stop taking AIZEMPA and see a doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following serious or potentially serious side effects:

- any sign of an allergic reaction (hypersensitivity) such as skin rash, hives, and swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing, and wheezing and shortness of breath.
- any sign of ketoacidosis such as
    - increased levels of 'ketone bodies' in your urine or blood
    - rapid weight loss

- feeling sick or being sick
- stomach pain
- excessive thirst
- fast and deep breathing
- confusion
- unusual sleepiness or tiredness
- a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat.

This may occur regardless of your blood glucose (sugar) level. Your doctor may decide to temporarily or permanently stop your treatment with AIZEMPA.

Contact your doctor as soon as possible if you notice any of the following side effects:

- Low blood sugar (hypoglycaemia), seen frequently when taking AIZEMPA with a sulphonylurea or with insulin.

  The signs of low blood sugar may include:
  - jitteriness, sweating, feeling very anxious or confused, fast heartbeat
  - excessive hunger, headache.
- Urinary tract infection

  The signs of urinary tract infection are:
  - burning sensation when passing urine
  - urine that appears cloudy
  - pain in the pelvis, or mid-back pain (when kidneys are infected).
- Dehydration

  The signs of dehydration are not specific, but may include:
  - unusual thirst
  - light-headedness or dizziness upon standing
  - fainting or loss of consciousness.

Other side effects while taking AIZEMPA**:**

Frequent

- genital yeast infection (thrush)
- passing more urine than usual or needing to pass urine more often
- itching
- rash or red skin – this may be itchy and include raised bumps, oozing fluid or blisters
- thirst
- blood tests may show an increase in blood fat (cholesterol) levels in your blood
- constipation.

Less frequent

- hives
- straining or pain when emptying the bladder
- blood tests may show a decrease in kidney function (creatinine or urea)
- blood tests may show increases in the amount of red blood cells in your blood (haematocrit)
- inflammation of the kidneys (tubulointerstitial nephritis).

Frequency unknown

- necrotising fasciitis of the perineum or Fournier´s gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 AIZEMPA**.**

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za.

5. How to store AIZEMPA

Store all medicines out of reach of children.

Store at or below 25 °C

Keep the blister packs in the outer carton until required for use.

Keep the blister packs in the outer carton until required for use.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What AIZEMPA contains

- The active substance is empagliflozin.
- The other ingredients are:
    - *Tablet core*: lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate
    - *Film coating*: hypromellose, titanium dioxide, talc, macrogol, iron oxide yellow.

What AIZEMPA looks like and contents of the pack

AIZEMPA 10 mg: Pale Yellow, round, biconvex film-coated tablets debossed with "10" on one side and "A" on other side

AIZEMPA 25 mg: Pale Yellow, oval, biconvex film-coated tablets debossed with "25" on one side and "A" on other side

AIZEMPA 10 and 25 mg is available in PVC/PVDC-peel push blister pack or HDPE Container with 33 mm CR closure

Pack sizes of 10, 28, 30, 56, 60, 90 film-coated tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Registration numbers

AIZEMPA 10 mg: 54/21.2/0651

AIZEMPA 25 mg: 54/21.2/0652

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: https://austell.co.za/product-info/

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