BAXFENDY™ Film-Coated Tablet

Baxdrostat (1mg, 2mg)

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What BAXFENDY is used for

BAXFENDY contains the active ingredient substance baxdrostat, which is a type of medicine called an "aldosterone synthase inhibitor". BAXFENDY is used to treat high blood pressure (hypertension) in adults. BAXFENDY is used in addition to other high blood pressure medicines when these other medicines are not lowering your blood pressure enough.

How BAXFENDY works

BAXFENDY works by blocking the aldosterone synthase enzyme in your adrenal glands. This causes the body to produce lower levels of the hormone called aldosterone. As a result, your blood pressure is lowered.

Before you use BAXFENDY

- *When you must not use it*

Do not take this medicine if:

- you are allergic to baxdrostat or any other ingredients of this medicine listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- *Before you start to use it*

Talk to your doctor or pharmacist before taking BAXFENDY if you:

- have high potassium levels in your blood.
- have kidney problems.
- have diabetes.
- have severe liver problems.

Pregnancy

Before taking BAXFENDY, tell your doctor if you are pregnant, think you may be pregnant, or trying to become pregnant.

You should not take this medicine if you are planning to become pregnant or during pregnancy since there might be a risk to your unborn baby. If you become pregnant while being treated with BAXFENDY, tell your doctor.

If you are a woman of childbearing age, you should use effective birth control during treatment with BAXFENDY. Talk to your doctor or nurse about suitable methods of contraception.

Breast-feeding

Before taking BAXFENDY, tell your doctor if you are breast-feeding or planning to breast-feed. It is not known if this medicine passes into human breast milk. Your doctor will discuss with you if you should stop treatment with BAXFENDY while you are breast-feeding, or if you should stop breast-feeding.

Children and adolescents

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

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed or any herbal medicines (for example St. John's wort).

In particular, tell your doctor if you are taking:

- Medicines that may increase the level of potassium in your blood, for example spironolactone, eplerenone, finerenone, amiloride, triamterene or potassium supplements. Your doctor may need to check the potassium level in your blood.

Your doctor will tell you which medicines you can take.

How to use BAXFENDY

Always take BAXFENDY exactly as your doctor has instructed you. You should check with your doctor, nurse or pharmacist if you are unsure.

- *How much to use*

BAXFENDY is taken by mouth.

- The recommended dose is one 2 mg tablet each day. Your doctor will prescribe the strength that is right for you and may consider 1 mg as the appropriate dose for you.
- Always take BAXFENDY exactly as your doctor has instructed you.

- *When to use it*

- You can take your 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.

Your doctor will prescribe BAXFENDY with other medicines. Remember to take these other medicines as your doctor has told you. This will help get the best results for your health.

- *How long to use it*
Only stop taking BAXFENDY if your doctor has told you. If you stop taking BAXFENDY, your blood pressure may increase again.

- *If you forget to use it*
If you forget to take a tablet, take the next tablet on the next day, at your regular time. Do not take a double dose in the same day to make up for a forgotten tablet.

- *If you use too much (overdose)*
If you have taken more BAXFENDY tablets than you should, talk to a doctor, nurse, or pharmacist immediately.

While you are using BAXFENDY

- *Things you must do*
If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking BAXFENDY.

Tell your doctor immediately if you become pregnant while using this medication.

Take BAXFENDY only with a doctor's prescription.

Your doctor may want to perform blood tests to check your potassium levels during treatment with BAXFENDY.

Remind any doctor, dentist or pharmacist that you visit that you are using BAXFENDY.

- *Things you must not do*
Do not stop taking BAXFENDY unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not take BAXFENDY to treat any other complaints unless your doctor tells you to.

Do not give BAXFENDY to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*
Driving and using machines

It is unlikely that BAXFENDY will affect your ability to drive and use machines, although some people may feel dizzy when taking BAXFENDY.

Side effects

Like all medicines, BAXFENDY can have side effects.

The following side effects may happen with this medicine:

Very common (may affect more than 1 in 10 people):
- High potassium levels in your blood (hyperkalaemia)
  Possible signs of high potassium levels in the blood may include weakness or tiredness, feeling sick (nausea), numbness in the hands and lips, muscle cramps, dizziness, chest pain, or a change of heart rate.

Your doctor or nurse will do blood tests to check your potassium levels during treatment with BAXFENDY. Your potassium levels may be checked more often if you have a higher risk of developing high potassium, for example if you have kidney problems or if you take other medicines that can increase potassium (see also section 'Taking other medicines'). Based on the results, your doctor may decide to temporarily interrupt treatment with BAXFENDY.

Common (may affect up to 1 in 10 people):
- Low sodium levels in your blood (hyponatremia)
  Possible signs of low sodium levels in the blood may include feeling sick (nausea), tiredness, headache, confusion, muscle weakness, spasms or cramps.
- Dizziness
- Low blood pressure (hypotension)
  Possible signs of low blood pressure may include dizziness, light-headedness, or fainting.
- Muscle spasms

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of BAXFENDY

- *Storage*
- Keep out of the reach and sight of children.

- Keep in the original package in a cool dry place where the temperature stays below 30℃.
- For polypropylene /polypropylene (PP) blister pack in aluminium flow wrap, it should be used within 3 months of opening the flow wrap.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

BAXFENDY is available as film-coated tablets and comes in two strengths:

- BAXFENDY 1 mg film-coated tablets are pink, biconvex and round, with a diameter of 6mm. They have "BX" on one side and "1" on the other side.
- BAXFENDY 2 mg film-coated tablets are yellow, biconvex and round, with a diameter of 7.5 mm. They have "BX" on one side and "2" on the other side.

Available in Alu-Alu blister (2 x 14 tablets) or PP-PP blister with foil wrap (1 x 28 tablets). Not all packs may be marketed.

- *Ingredients*

- Active ingredient
  - Baxdrostat 1 mg or 2 mg

- Inactive ingredients

Core tablet:
- croscarmellose sodium
- anhydrous lactose
- magnesium stearate
- microcrystalline cellulose.

Film coating:
- polyethylene glycol 3350
- polyvinyl alcohol
- talc
- titanium dioxide
- ferric oxide red (only in 1 mg strength tablets)
- ferric oxide yellow (only in 2 mg strength tablets).

- MAL numbers

- 1mg: MALXXX
- 2mg: MALXXX

Manufacturer

AstraZeneca AB, Gartunavagen, Sodertalje, Sweden.

Product Registration Holder

AstraZeneca Sdn. Bhd.
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