Package leaflet: Information for the user

JERAYGO 12.5 mg film-coated tablets
JERAYGO 25 mg film-coated tablets
aprocitentan

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

In addition to this leaflet, a patient card is included in the carton of this medicine. This card contains important safety information that you need to know before, during and after treatment with this medicine.

- 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 JERAYGO is and what it is used for

JERAYGO contains the active substance called aprocitentan, which belongs to the class of medicines called “endothelin receptor antagonists”.

This medicine is used to treat hypertension (high blood pressure) in adults whose blood pressure cannot be adequately controlled by at least three other medicines (so-called resistant hypertension).

This medicine works by helping to stop the blood vessels from tightening; as a result, the blood vessels relax and blood pressure is lowered.

2. What you need to know before you take JERAYGO

Do not take JERAYGO
- if you are allergic to aprocitentan, or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant, if you are planning to become pregnant, or if you could become pregnant because you are not using a reliable form of birth control (contraception). See section 2, ‘Pregnancy and breast-feeding’.
- if you are breast-feeding. See section 2, ‘Pregnancy and breast-feeding’.
- if you have severe liver disease. See section 2, ‘Warnings and precautions’.

Warnings and precautions
Tell your doctor if you have any of the following conditions before starting treatment or if you develop the following signs while taking this medicine.

Liver problems
Like other medicines of the same class, JERAYGO might cause liver injury. Your doctor should do blood tests to check that your liver is working properly before starting treatment and may also check during treatment. Tell your doctor immediately if you develop symptoms of liver problems including:
- nausea (feeling sick) or vomiting;
- fever;
- pain in the upper right area of your abdomen (belly);
- jaundice (yellowing of your skin or the whites of your eyes);
- dark-coloured urine;
- itching of your skin;
- unusual tiredness or exhaustion;
- loss of appetite.

Oedema (swelling/fluid retention)
If you have signs of oedema when using this medicine, such as unusual weight gain or swelling of the ankles, feet or legs, especially in the early weeks of the treatment, tell your doctor immediately. They will help you manage this side effect.

Heart disease
JERAYGO is not recommended in patients with unstable or severe cardiac disease. Tell your doctor immediately if you develop any of the following symptoms:
- shortness of breath;
- waking up with shortness of breath at night;
- getting tired easily after light physical activity such as walking;
- rapid increase in your weight;
- swollen ankles or feet;
- chest pain and discomfort.

Anaemia (low number of red blood cells)
Decreases in haemoglobin (the protein in red blood cells that carries oxygen around the body) and haematocrit (the amount of blood that is made up of red blood cells), which can result in anaemia, have occurred with this medicine and other endothelin receptor antagonists. Tell your doctor if you develop symptoms of anaemia during treatment including:
- dizziness;
- fatigue/malaise/weakness;
- fast heart rate, palpitations;
- pallor.

Kidney problems
Patients with moderate kidney function decrease may have an increased risk of developing oedema and anaemia during treatment. Treatment with JERAYGO is not recommended in patients with severe kidney function decrease.

Patients aged 75 or older
If you are 75 years or older, you may have a higher risk of developing oedema, anaemia, and cardiovascular conditions during treatment. As a result, your doctor should monitor your levels of haemoglobin and any symptoms of oedema or heart disease.

Children and adolescents
This medicine is not for children and adolescents below 18 years of age, because JERAYGO has not been tested in this age group.

Other medicines and JERAYGO
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. It is especially important that you tell your doctor if you are also taking methotrexate (medicine used to treat cancer, rheumatoid arthritis or psoriasis) or tizanidine (medicine used to treat muscle spasms). JERAYGO may interfere with the effects of these medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, do not take this medicine.

Babies exposed to JERAYGO in the womb may be harmed.
- **Do not take** this medicine if you are pregnant or if you are planning to become pregnant.
- If you become pregnant or think that you may be pregnant while you are taking this medicine, or shortly after stopping it (up to one month), **see your doctor immediately**.
- If you are a woman who could become pregnant, use a reliable form of birth control (contraception) while you are taking this medicine and for one month after you stop treatment. This medicine could reduce the effectiveness of hormonal contraceptives, therefore it is recommended to add a barrier method. Talk to your doctor about this.
- If you are a woman who could become pregnant, your doctor will recommend that you take a pregnancy test before you start taking this medicine, every month while you are taking this medicine, and once in the month after you stopped taking the medicine.

This information is summarised in your patient card, which is attached to the packaging of this medicine.

If you become pregnant, stop taking this medicine (see section 2, 'Do not take JERAYGO').

It is not known if JERAYGO is transferred to breast milk. Do not breast-feed while you are taking this medicine (see section 2, 'Do not take JERAYGO'). Talk to your doctor about this.

Driving and using machines
JERAYGO can cause side effects such as headache or low blood pressure (hypotension) (listed in section 4), which may affect your ability to drive and use machines.

JERAYGO contains lactose and sodium
This medicine contains a sugar called lactose. If you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take JERAYGO

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

Your doctor will determine the dose of JERAYGO that you should take. The recommended dose is one 12.5 mg tablet once a day. Then, the dose may be increased to one 25 mg tablet once a day, if you do not have relevant side effects and if your doctor judges that your blood pressure should be further decreased.

Tablets are designed to be swallowed whole. You can take this medicine with or without meals.

If you take more JERAYGO than you should
If you take more of this medicine than you should, contact your doctor immediately.

If you forget to take JERAYGO
If you forget to take this medicine, take your usual dose the next day and do not take a double dose to make up for a missed dose. Two doses should not be taken on the same day.

If you stop taking JERAYGO
You need to keep taking this medicine to control your high blood pressure (hypertension). Do not stop taking JERAYGO unless you have agreed this with your doctor.

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. The following side effects may happen with this medicine:

Very common (may affect more than 1 in 10 people):
- Oedema (swelling, for example, of the ankles and feet) / Fluid retention (see section 2, 'Warnings and precautions')

Common (may affect up to 1 in 10 people):
- Anaemia (low number of red blood cells or reduced haemoglobin) (see section 2, 'Warnings and precautions')
- Hypersensitivity (allergic reactions)
- Dyspnoea (shortness of breath)
- Headache
- Upper respiratory tract (nose and throat) infections

Uncommon (may affect up to 1 in 100 people):
- Hypotension (low blood pressure)
- Elevated liver tests
- Flushing (redness of the skin)
- Decrease in kidney filtration rate when starting treatment
- Weight increase when starting treatment

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 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 JERAYGO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and package (bottle or blister) after "EXP". The expiry date refers to the last day of that month.

Store in original package (bottle or blisters) in order to protect from moisture. Keep the bottle closed tightly in order to protect from moisture.

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 protect the environment.

6. Contents of the pack and other information

What JERAYGO contains
The active substance is aprocitentan.

JERAYGO 12.5 mg film-coated tablets
Each tablet contains 12.5 mg of aprocitentan.

JERAYGO 25 mg film-coated tablets
Each tablet contains 25 mg of aprocitentan.

The other ingredients are:
Tablet cores: croscarmellose sodium (see section 2 "JERAYGO contains lactose and sodium"), hydroxypropylcellulose, lactose monohydrate (see section 2 "JERAYGO contains lactose and sodium"), magnesium stearate, and microcrystalline cellulose.

Film coating: poly(vinyl alcohol) (E1203), hydroxypropylcellulose (E463), triethyl citrate, talc (E553b), colloidal hydrated silica (E551), titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172), iron oxide black (E172).

What JERAYGO looks like and contents of the pack

JERAYGO 12.5 mg is supplied as yellow to orange, round biconvex (6 mm diameter) film-coated tablet (tablet), debossed with "AN" on one side and plain on the other side.

JERAYGO 25 mg is supplied as pink, round biconvex (6 mm diameter) film-coated tablet (tablet), debossed with "AN" on one side and "25" on the other side.

JERAYGO (12.5 mg and 25 mg) is available in bottles of 30 film-coated tablets and in blister packs of 10 × 1 film-coated tablets in perforated unit dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Idorsia Pharmaceuticals Deutschland GmbH
Marie-Curie-Strasse 8
79539 Lörrach
Germany

Manufacturer
Idorsia Pharmaceuticals UK Ltd
20 Eastbourne Terrace
London
W2 6LG

Idorsia Pharmaceuticals Deutschland GmbH
Marie-Curie-Strasse 8
79539 Lörrach
Germany

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