▼This medicinal product 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 “Possible side effects” for how to report side effects.

Patient Information

Read this leaflet carefully before taking / using this medicine. This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

Keep this leaflet. You may need to read it again.

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.

JERAYGO film-coated tablets

What is JERAYGO and what is it used for?

Subject to prescription by a doctor

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.

Do not take JERAYGO

- if you are allergic to aprocitentan, or any of the other ingredients of this medicine (listed in the section “What JERAYGO contains”).
- 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 “Can JERAYGO be used during pregnancy or breast-feeding?”.
- if you are breast-feeding. See section “Can JERAYGO be used during pregnancy or breast-feeding?”
- if you have severe liver disease. See section “When is caution required when taking JERAYGO?”.

When is caution required when taking JERAYGO?

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 under 18 years of age because JERAYGO has not been tested in this age group.

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’.

Driving and using machines

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

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.

Can JERAYGO be used during pregnancy or 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. 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 “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 “Do not take JERAYGO”). Talk to your doctor about this.

How to take JERAYGO?

Do not deviate from the prescribed dosage. If you believe that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

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.

Children and adolescents

The use and safety of JERAYGO in children and adolescents under 18 years have not been investigated to date. JERAYGO should therefore not be used in this age group.

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.

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 “When is caution required when taking JERAYGO?”).

Common (may affect up to 1 in 10 people):

- Anaemia (low number of red blood cells or reduced haemoglobin) (see Section “When is caution required when taking JERAYGO?”).
- 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 particularly includes any possible side effects not listed in this leaflet.

What else needs to be observed ?

Shelf life

Do not use this medicine after the expiry date (“EXP”) stated on the container.

Storage conditions

Do not store above 25°C.

Shelf-life after opening: 3 months.

Store in the original packaging (bottles or blisters) to protect from moisture.

Keep the container (bottles) tightly closed to protect from moisture.

Keep out of the reach of children.

Further information
Your doctor or pharmacist can give you more information. These individuals possess the comprehensive information for healthcare professionals.

What JERAYGO contains

Active substance

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.

Excipients

The other ingredients are:

Tablet cores: croscarmellose sodium (see section “JERAYGO contains lactose and sodium”), hydroxypropylcellulose, lactose monohydrate (see section “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).

Marketing authorisation number

70047 (Swissmedic)

Where can you get JERAYGO? What packs are available?

In pharmacies only on presentation of a medical prescription.

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.

Marketing Authorisation Holder

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This package leaflet was last revised by the medicines agency (Swissmedic) in June 2026