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EPAR summary for the public

Kinzalmono

telmisartan

This is a summary of the European public assessment report (EPAR) for Kinzalmono. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Kinzalmono.

What is Kinzalmono?

Kinzalmono is a medicine that contains the active substance telmisartan. It is available as tablets (20, 40 and 80 mg).

What is Kinzalmono used for?

Kinzalmono is used to treat essential hypertension (high blood pressure) in adults. 'Essential' means that the hypertension has no obvious cause.

Kinzalmono is also used to prevent cardiovascular problems (problems with the heart and blood vessels) such as heart attacks or strokes. It is used in patients who have had problems due to blood clots in the past (such as heart disease, a stroke or artery disease) or who have type 2 diabetes that has damaged an organ (such as the eyes, heart or kidneys).

The medicine can only be obtained with a prescription.

How is Kinzalmono used?

For the treatment of essential hypertension, the usual recommended dose of Kinzalmono is 40 mg once a day, but some patients may benefit from using 20 mg once a day. If the target blood pressure is not reached, the dose can be increased to 80 mg, or another medicine for hypertension can be added, such as hydrochlorothiazide.



For the prevention of cardiovascular problems, the recommended dose is 80 mg once a day. The doctor should monitor the patient's blood pressure closely when starting Kinzalmono, and may decide to adjust the patient's blood pressure-lowering medication. Patients with severely reduced kidney function should receive a lower starting dose of 20 mg once a day. Patients with mild or moderately reduced liver function should not receive doses higher than 40 mg a day.

How does Kinzalmono work?

The active substance in Kinzalmono, telmisartan, is an 'angiotensin II receptor antagonist', which means that it blocks the action of a hormone in the body called angiotensin II. Angiotensin II is a powerful vasoconstrictor (a substance that narrows blood vessels). By blocking the receptors to which angiotensin II normally attaches, telmisartan stops the hormone having an effect, allowing the blood vessels to widen. This allows the blood pressure to drop, reducing the risks associated with high blood pressure, such as having a heart attack or stroke. It also allows the heart to pump blood more easily, which can help to reduce the risk of future cardiovascular problems.

How has Kinzalmono been studied?

For the treatment of essential hypertension, Kinzalmono has been studied in 2,647 patients who took Kinzalmono either alone or in combination with hydrochlorothiazide. Various doses of Kinzalmono were compared with placebo (a dummy treatment) and with other medicines for hypertension (atenolol, lisinopril, enalapril and amlodipine). The main measure of effectiveness was the reduction in diastolic blood pressure (the blood pressure measured between two heartbeats).

For the prevention of cardiovascular problems, 80 mg Kinzalmono once a day has been studied in one main study involving almost 26,000 patients aged 55 years or over who had heart or artery disease, had had a stroke, or had diabetes and were at high risk of cardiovascular problems. Kinzalmono was compared with ramipril (another medicine to prevent cardiovascular problems), and with the combination of both medicines. The main measure of effectiveness was the reduction in the number of patients who died or were admitted to hospital, or who had a heart attack or stroke. The patients were followed up for an average of four and a half years.

What benefit has Kinzalmono shown during the studies?

In the treatment of essential hypertension, Kinzalmono was more effective than placebo at reducing diastolic blood pressure and had similar effects to the other medicines for hypertension.

In the prevention of cardiovascular problems, Kinzalmono had a similar effect to ramipril, with around 17% of patients dying, being admitted to hospital because of cardiovascular problems, or having a heart attack or stroke. The combination of the two medicines was no more effective than either medicine taken alone and was linked to an increased risk of side effects.

What is the risk associated with Kinzalmono?

Side effects with Kinzalmono are not common. However, the following side effects are seen in between 1 and 10 patients in 1,000: upper respiratory tract infection (colds) including inflammation of the throat and sinuses, urinary tract infection (infection of the structures that carry urine) including bladder infection, anaemia (low red blood cell counts), hyperkalaemia (high blood potassium levels), depression, insomnia (difficulty sleeping), syncope (fainting), vertigo (a spinning sensation), bradycardia (slow heart rate), hypotension (low blood pressure), dyspnoea (difficulty breathing), cough, abdominal pain (stomach ache), diarrhoea, dyspepsia (heartburn), flatulence (gas), vomiting, hyperhidrosis (excessive sweating), pruritus (itching), rash, myalgia (muscle pain), back pain, muscle

spasms, renal impairment (reduced kidney function) including sudden kidney failure, chest pain, asthenia (weakness) and increased blood levels of creatinine (a marker of muscle breakdown). Hypotension may be more common in patients receiving Kinzalmono to prevent cardiovascular problems. For the full list of all side effects reported with Kinzalmono, see the package leaflet.

Kinzalmono must not be used in women who are more than three months pregnant. Its use during the first three months of pregnancy is not recommended. Kinzalmono must not be used in people who have severe liver problems or bile problems. In patients with type 2 diabetes or in patients with moderate or severe kidney impairment, Kinzalmono must also not be used in combination with aliskiren-containing medicines (also used to treat essential hypertension). For the full list of restrictions, see the package leaflet.

Why has Kinzalmono been approved?

The CHMP decided that Kinzalmono's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Kinzalmono?

A risk management plan has been developed to ensure that Kinzalmono is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Kinzalmono, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Kinzalmono

The European Commission granted a marketing authorisation valid throughout the European Union for Kinzalmono on 16 December 1998.

The full EPAR for Kinzalmono can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_Public_Assessment_Reports. For more information about treatment with Kinzalmono, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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