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EPAR summary for the public

Onduarp

telmisartan / amlodipine

This is a summary of the European public assessment report (EPAR) for Onduarp. 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 Onduarp.

What is Onduarp?

Onduarp is a medicine that contains two active substances, telmisartan and amlodipine. It is available as tablets (40 mg telmisartan/10 mg amlodipine, 40 mg telmisartan/5 mg amlodipine, 80 mg telmisartan/10 mg amlodipine and 80 mg telmisartan/5 mg amlodipine).

This medicine is the same as Twynsta, which is already authorised in the European Union (EU). The company that makes Twynsta has agreed that its scientific data can be used for Onduarp ('informed consent')

What is Onduarp used for?

Onduarp is used to treat essential hypertension (high blood pressure) in adults (aged 18 years or over). 'Essential' means that the hypertension has no obvious cause.

Onduarp is used in patients whose blood pressure is not adequately controlled by amlodipine alone. Onduarp can also be used in place of treatment with telmisartan and amlodipine in patients who are taking both medicines as separate tablets.

The medicine can only be obtained with a prescription.

How is Onduarp used?

Onduarp is taken by mouth as one tablet once a day and is used for long-term treatment. The maximum dose is one tablet of the highest strength (80/10 mg) once a day.

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For a patient whose blood pressure is not adequately controlled by amlodipine, separate tablets of amlodipine and telmisartan should be used to adjust the doses before switching to Onduarp. When appropriate, direct switch to Onduarp may be considered.

For a patient who has been taking telmisartan and amlodipine as separate tablets, the dose of Onduarp to be taken depends on the doses of telmisartan and amlodipine that he or she was taking before.

How does Onduarp work?

Onduarp contains two active substances, telmisartan and amlodipine. Both are medicines to lower the blood pressure that have been available in the European Union (EU) since the 1990s. They work in similar ways to reduce blood pressure by allowing the blood vessels to relax. By lowering the blood pressure, the risks associated with high blood pressure, such as having a stroke, are reduced.

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.

Amlodipine is a calcium channel blocker. It blocks special channels on the surface of cells called calcium channels, through which calcium ions normally enter the cells. When calcium ions enter the cells in the muscles of blood vessel walls, this causes contraction. By reducing the flow of calcium into the cells, amlodipine prevents the cells from contracting and this helps the blood vessels to relax.

How has Onduarp been studied?

The company presented information from scientific literature as well as results from studies with the medicine.

In one main study, 1,461 adults with hypertension were treated with combinations of telmisartan and amlodipine, with telmisartan or amlodipine alone, or with placebo (a dummy treatment). In two other main studies, 1,978 adults whose hypertension had not responded adequately to amlodipine were either given Onduarp or continued to take amlodipine at the same or a higher dose. The main measure of effectiveness in the three studies was the fall in diastolic blood pressure (blood pressure measured between two heartbeats) after eight weeks.

Studies were also carried to show that Onduarp tablets are absorbed in the same way in the body as separate tablets of amlodipine and telmisartan.

What benefit has Onduarp shown during the studies?

In the first study, the falls in diastolic blood pressure seen in patients taking combinations of telmisartan and amlodipine were greater than those seen in patients taking only one of the active substances or placebo.

In the two other studies, Onduarp was more effective at reducing diastolic blood pressure than continued treatment with amlodipine alone: depending on the strengths of Onduarp and amlodipine, the fall in diastolic blood pressure was greater in patients taking Onduarp by between 1.4 mmHg and 4.9 mmHg.

What is the risk associated with Onduarp?

The most common side effects with Onduarp (seen in between 1 and 10 patients in 100) are dizziness and peripheral oedema (swelling, especially of the ankles and feet). For the full list of all side effects reported with Onduarp, see the package leaflet.

Onduarp must not be used in people who are hypersensitive (allergic) to telmisartan, amlodipine, other medicines in the 'dihydropyridine derivatives' class or to any of the other ingredients. It must not be used in women who are more than three months pregnant. Onduarp must also not be used in patients who have severe liver or bile problems, shock (a steep fall in blood pressure), severe hypotension (low blood pressure), obstruction to blood flow from the left side of their heart or in patients with heart failure after having a myocardial infarction (heart attack).

Why has Onduarp been approved?

The CHMP noted that patients already taking the two active substances in separate tablets may be more likely to adhere to their treatment if prescribed Onduarp. In addition, studies showed that the medicine was effective in patients whose blood pressure is not adequately controlled by amlodipine alone. The Committee decided that Onduarp's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Onduarp

The European Commission granted a marketing authorisation valid throughout the European Union for Onduarp on 24 November 2011.

The full EPAR for Onduarp 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 Onduarp, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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