EMA/562547/2015
EMEA/H/C/000414

EPAR summary for the public

PritorPlus

telmisartan / hydrochlorothiazide

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

What is PritorPlus?

PritorPlus is a medicine that contains two active substances, telmisartan and hydrochlorothiazide. It is available as tablets (40 or 80 mg telmisartan and 12.5 mg hydrochlorothiazide; 80 mg telmisartan and 25 mg hydrochlorothiazide).

What is PritorPlus used for?

PritorPlus is used in adult patients who have essential hypertension (high blood pressure) that is not adequately controlled by telmisartan alone. 'Essential' means that the hypertension has no obvious cause.

The medicine can only be obtained with a prescription.

How is PritorPlus used?

PritorPlus is taken by mouth once a day with liquid, with or without food. The dose of PritorPlus to be used depends on the dose of telmisartan that the patient was taking before: patients who were receiving 40 mg telmisartan should take the 40/12.5 mg tablets, and patients who were receiving 80 mg telmisartan should take the 80/12.5 mg tablets. The 80/25 mg tablets are used in patients whose blood pressure is not controlled using the 80/12.5 mg tablets or who have been stabilised using the two active substances taken separately before switching to PritorPlus.

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How does PritorPlus work?

PritorPlus contains two active substances, telmisartan and hydrochlorothiazide.

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.

Hydrochlorothiazide is a diuretic, which is another type of treatment for hypertension. It works by increasing urine output, reducing the amount of fluid in the blood and reducing blood pressure.

The combination of the two active substances has an additive effect, reducing the blood pressure more than either medicine alone. By lowering blood pressure, the risks associated with high blood pressure, such as having a stroke, are reduced.

How has PritorPlus been studied?

PritorPlus has been studied in five main studies involving a total of 2,985 patients with mild to moderate hypertension. In four of these studies, PritorPlus was compared with placebo (a dummy treatment) and with telmisartan taken alone in a total of 2,272 patients. The fifth study compared the effects of remaining on the 80/12.5 mg tablet with switching to the 80/25 mg tablet in 713 patients who had not responded to the 80/12.5 mg tablet. In all studies, the main measure of effectiveness was the reduction in diastolic blood pressure (the blood pressure measured between two heartbeats).

What benefit has PritorPlus shown during the studies?

PritorPlus was more effective at reducing diastolic blood pressure than telmisartan taken alone and than placebo. In patients who were not controlled on the 80/12.5 mg tablet, switching to the 80/25 mg tablet was more effective in reducing diastolic blood pressure than remaining on the lower dose.

What is the risk associated with PritorPlus?

The most common side effect with PritorPlus (seen in between 1 and 10 patients in 100) is dizziness. For the full list of all side effects reported with PritorPlus, see the package leaflet.

PritorPlus 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. PritorPlus must also not be used in people who have severe liver, kidney or bile problems, blood potassium levels that are too low, or blood calcium levels that are too high. In patients with type 2 diabetes or in patients with moderate or severe kidney impairment, PritorPlus 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.

Care must be taken when using PritorPlus with other medicines that have an effect on blood potassium levels. The full list of these medicines is given in the package leaflet.

Why has PritorPlus been approved?

The CHMP decided that PritorPlus's benefits are greater than its risks for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on telmisartan alone. The Committee recommended that PritorPlus be given marketing authorisation.

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

A risk management plan has been developed to ensure that PritorPlus 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 PritorPlus, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about PritorPlus

The European Commission granted a marketing authorisation valid throughout the European Union for PritorPlus on 22 April 2002.

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

This summary was last updated in 08-2015.