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EPAR summary for the public

Neofordex

dexamethasone

This is a summary of the European public assessment report (EPAR) for Neofordex. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Neofordex.

For practical information about using Neofordex, patients should read the package leaflet or contact their doctor or pharmacist.

What is Neofordex and what is it used for?

Neofordex is a medicine used together with cancer medicines to treat adults with multiple myeloma who have developed symptoms. Multiple myeloma is a cancer of a type of white blood cell called plasma cells, which are part of the immune system (the body's natural defences).

Neofordex contains the active substance dexamethasone. It is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but Neofordex is available at a higher strength. The reference medicine for Neofordex is Dectancyl.

How is Neofordex used?

Neofordex can only be obtained with a prescription and treatment must be started and monitored by a doctor experienced in the management of multiple myeloma.

Neofordex is available as 40 mg tablets. The usual dose is 40 mg once a day, taken preferably in the morning. However, the dose and how frequently Neofordex is given varies depending on the medicines it is given with and the patient's condition. For further information, see the package leaflet.

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How does Neofordex work?

The active substance in Neofordex, dexamethasone, belongs to a group of medicines known as corticosteroids. In multiple myeloma, Neofordex is used together with cancer medicines to kill cancerous plasma cells. It does this by interacting with different proteins (nuclear factor kB and caspase 9) that regulate cell death. Neofordex may also reduce certain side effects of cancer treatment, such as nausea (feeling sick) and vomiting.

What benefits of Neofordex have been shown in studies?

Because the effects of high-dose dexamethasone in multiple myeloma are well established, the company for Neofordex presented studies from the literature on the use of dexamethasone for the treatment of multiple myeloma.

In addition, a bioequivalence study was carried out in 24 healthy volunteers which showed that Neofordex has comparable quality to the reference medicine, Dectancyl.

What are the risks associated with Neofordex?

The most common side effects with Neofordex (which may affect more than 1 in 10 people) include hyperglycaemia (high blood sugar levels), insomnia (difficulty sleeping), muscle pain and weakness, asthenia (weakness), tiredness, oedema (swelling) and weight increase. Less common but serious side effects include pneumonia (infection of the lungs) and other infections and psychiatric disorders such as depression. For the full list of all side effects reported with Neofordex, see the package leaflet.

Neofordex must not be used in patients with active viral disease (especially hepatitis, cold sores, shingles or chicken pox) or with uncontrolled psychoses (altered sense of reality). For the full list of restrictions, see the package leaflet.

Why is Neofordex approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Neofordex has been shown to have comparable quality to Dectancyl and the use of high-dose dexamethasone in multiple meyloma is well established. The CHMP therefore decided that Neofordex's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Further information can be found in the summary of the risk management plan.

Other information about Neofordex

The European Commission granted a marketing authorisation valid throughout the European Union for Neofordex on 16 March 2016.

The full EPAR and risk management plan summary for Neofordex 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 Neofordex, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2016.