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EPAR summary for the public

Norvir

ritonavir

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

What is Norvir?

Norvir is a medicine that contains the active substance ritonavir. It is available as an oral solution (80 mg/ml), as a powder for oral solution (100 mg sachets), as capsules (100 mg) and as tablets (100 mg).

What is Norvir used for?

Norvir is used in combination with other HIV medicines to treat patients over two years of age who are infected with human immunodeficiency virus type 1 (HIV 1), a virus that causes acquired immune deficiency syndrome (AIDS).

The medicine can only be obtained with a prescription.

How is Norvir used?

Treatment with Norvir should be given by a doctor who has experience in the treatment of HIV infection. It should be taken with food.

Norvir can be used as a ‘‘pharmacokinetic enhancer’ (booster’ to increase the blood levels of other antiviral medicines that belong to the same group as Norvir (protease inhibitors) called amprenavir, atazanavir, fosamprenavir, lopinavir, saquinavir, tipranavir and darunavir. The standard dose for adults is 100 or 200 mg, once or twice a day. The dose depends on which other protease inhibitor is being taken. For more information, see the package leaflet provided with the other medicine.

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Norvir can also be used as an HIV medicine, where it acts directly against the virus. The recommended dose for adults (aged 18 years or over) is 600 mg twice a day. For younger patients, the recommended dose depends on the body surface area (calculated using the patient's height and weight). Treatment should start with a low dose that is gradually increased over the first 14 days of treatment.

How does Norvir work?

When the active substance, ritonavir, acts as a 'booster' it does so by slowing down the rate at which certain antiviral medicines given in combination with ritonavir are broken down in the body. This causes an increase of antiviral levels in the blood of such medicines and thus it boosts their antiviral activity.

At higher doses, ritonavir acts as a 'protease inhibitor'. This means that it blocks a viral enzyme called protease, which is involved in the reproduction of HIV. When the enzyme is blocked, the virus does not reproduce normally, slowing down its rate of multiplication. Norvir, taken in combination with other antiviral medicines, reduces the amount of HIV in the blood and keeps it at a low level. Norvir does not cure HIV infection or AIDS, but it may delay the damage to the immune system and the development of infections and diseases associated with AIDS.

How has Norvir been studied?

Norvir has been studied as a booster in clinical studies that were designed to assess the effects of the antiviral medicines that it is used to boost. Information on these studies can be found in the EPAR summaries for the other medicines.

Norvir has been studied as an antiviral medicine in two main studies involving 1,446 patients. The first compared Norvir with placebo (a dummy treatment) in 1,090 adults, as an add-on to the antiviral medicines the patients were already taking. The main measure of effectiveness was based on the number of patients whose disease got worse or who died. The second study compared Norvir taken alone, zidovudine (another antiviral medicine) taken alone and the combination of Norvir and zidovudine in 356 adults who had not taken treatment for HIV infection before. The main measure of effectiveness was the change in the levels of HIV in the blood (viral load) and CD4 T cell levels in the blood (CD4 cell count). CD4 T cells are white blood cells that are important in helping to fight infections, but which are killed by HIV. The effects of Norvir as an antiviral medicine in combination with other antiviral medicines were also studied in four studies of children.

What benefit has Norvir shown during the studies?

In the first study of Norvir as an antiviral medicine, 16% of the Norvir-treated patients (86 out of 543) experienced a worsening of disease or died, compared with 33% of the patients taking placebo (181 out of 547). In the second study, patients taking Norvir had greater reductions in viral load and increases in CD4 cell counts than those taking zidovudine alone. The combination of Norvir and zidovudine was less effective than Norvir alone, although the reasons for this were unclear. Norvir, in combination with other antiviral medicines, also reduced viral loads in children.

What is the risk associated with Norvir?

When it is used as a booster, the side effects of Norvir depend on the other antiviral medicine being taken. Some medicines cannot be taken with Norvir when it is used in this way. See the package leaflet provided with the other medicine for full details.

When it is used as an HIV medicine, the most common side effects with Norvir (seen in more than 1 patient in 10) are dysgeusia (taste disturbances), paraesthesia (unusual tingling sensations) around the mouth and in the limbs, headache, dizziness, peripheral neuropathy (damage to the nerves in the limbs), pharyngitis (sore throat), mouth and throat pain, cough, abdominal pain (stomach ache), nausea (feeling sick), diarrhoea, vomiting, dyspepsia (heartburn), pruritis (itching), rash, joint and back pain, tiredness, flushing and feeling hot.

Norvir must not be used in patients who have severe problems with their liver or patients who are taking St John's wort (a herbal preparation used to treat depression) or medicines that are broken down in the same way as Norvir and are harmful at high levels in the blood. For the full list of all restrictions and side effects reported with Norvir, see the package leaflet.

Why has Norvir been approved?

The CHMP decided that Norvir'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 Norvir?

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

Other information about Norvir

The European Commission granted a marketing authorisation valid throughout the European Union for Norvir on 26 August 1996.

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

This summary was last updated in 07-2015.