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Norvir (*ritonavir*)

An overview of Norvir and why it is authorised in the EU

What is Norvir and what is used for?

Norvir is a medicine used to treat adults and children aged 2 years and older with a human immunodeficiency virus type 1 (HIV-1) infection. HIV-1 is a virus that causes acquired immune deficiency syndrome (AIDS). Norvir is used to enhance the activity of other medicines called protease inhibitors, including atazanavir, fosamprenavir, lopinavir, tipranavir and darunavir.

Norvir contains the active substance ritonavir.

How is Norvir used?

Norvir can only be obtained with a prescription and treatment should be prescribed by a doctor who has experience in treating people with HIV infection.

Norvir is taken by mouth once or twice a day, either as tablets or as a powder that is mixed with food or a liquid. The frequency and dose depend on the protease inhibitor Norvir is given with.

For more information about using Norvir, see the package leaflet or contact your doctor or pharmacist.

How does Norvir work?

The active substance in Norvir, ritonavir, enhances the activity of other HIV-1 medicines called protease inhibitors. These medicines block an enzyme (a type of protein) of HIV-1 called protease, which the virus needs to make new copies of itself.

When given together with protease inhibitors, ritonavir slows down the rate at which they are broken down in the body. This helps to keep their levels higher in the blood for longer, allowing them to work more effectively against the virus.

Norvir does not cure HIV-1 infections or AIDS. It delays the damage made by the virus to the immune system (the body's natural defences) and the development of infections and diseases associated with AIDS.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Norvir have been shown in studies?

Norvir has been evaluated in studies that looked at its effectiveness when used as a booster for other HIV-1 medicines. Information on these studies can be found in the medicine overviews of these other medicines (atazanavir, fosamprenavir, lopinavir, tipranavir or darunavir).

What are the risks associated with Norvir?

For the full list of side effects and restrictions with Norvir, see the package leaflet.

Because Norvir is used as a booster for other HIV-1 medicines, its side effects depend on the other medicine taken at the same time (atazanavir, fosamprenavir, lopinavir, tipranavir or darunavir). See the package leaflet provided with the other medicine for information on side effects.

Norvir must not be used in patients who have severe liver problems or in those taking St John's wort (a herbal preparation used to treat depression). It must also not be used with medicines that are broken down in the same way as Norvir, as this may increase their levels in the blood to harmful amounts.

Why is Norvir authorised in the EU?

In adults and children aged 2 years and older with an HIV-1 infection, Norvir has been shown to increase the blood levels of the other HIV-1 medicines it is used with. The European Medicines Agency therefore decided that Norvir's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Norvir have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Norvir are continuously monitored. Suspected side effects reported with Norvir are carefully evaluated and any necessary action taken to protect patients.

Other information about Norvir

Norvir received a marketing authorisation valid throughout the EU on 26 August 1996.

Further information on Norvir can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/norvir.

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