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Apretude (*cabotegravir*)

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

What is Apretude and what is it used for?

Apretude is a medicine used for preventing sexually transmitted HIV-1 infection (pre-exposure prophylaxis or PrEP) in adults and adolescents weighing at least 35 kg who are at high risk of being infected. It should be used in combination with safer sex practices, such as using condoms.

Apretude contains the active substance cabotegravir.

How is Apretude used?

The medicine can only be obtained with a prescription and treatment should be prescribed by a healthcare professional who has experience in the management of HIV PrEP.

Apretude is available as tablets and as a prolonged-release injection. 'Prolonged release' means that the active substance is released slowly over a few weeks after being injected. The injection must be given by a healthcare professional. It is given once a month for the first 2 injections, and then every 2 months.

Alternatively, people may start with the tablets, which are taken once a day for 1 month. Use of the tablets is expected to allow quicker recovery in case of side effects. If the tablets are tolerated without side effects, the individual should be switched to the injection after 1 month.

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

How does Apretude work?

Cabotegravir is an integrase inhibitor. It blocks an enzyme called integrase that the HIV-1 virus needs to make new copies of itself in the body. In case of exposure to the virus this will reduce the risk of the virus multiplying and spreading from the site of infection.

What benefits of Apretude have been shown in studies?

Two main studies have evaluated Apretude for pre-exposure prophylaxis. In one study Apretude was compared with standard PrEP (tenofovir disoproxil fumarate/emtricitabine) in HIV-negative cisgender

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men and transgender women who have sex with men. Of 2,278 people who took Apretude, 12 tested positive for HIV-1 infection around 3 years (153 weeks) after treatment. This compared with 39 out of 2,281 people who took the standard treatment.

The second study involved over 3,200 HIV-negative cisgender women and compared Apretude with standard PrEP (tenofovir disoproxil fumarate/emtricitabine). Of the individuals taking Apretude, 3 out of 1,613 tested positive for HIV-1 infection 1 year after treatment compared with 36 out of 1,610 of those taking standard PrEP.

What are the risks associated with Apretude?

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

The most common side effects with Apretude (which may affect more than 1 in 10 people) include injection site reactions, headache, diarrhoea and increase in the liver enzyme transaminase.

Apretude must not be used in people who have not been tested for HIV infection or who are positive for HIV infection. Apretude must also not be used together with some other medicines such as rifampicin, rifapentine, carbamazepine, oxcarbazepine, phenytoin or phenobarbital.

Why is Apretude authorised in the EU?

The main studies showed that Apretude is effective at reducing the risk of HIV infection and overall it was well tolerated. Injection site reactions were generally mild and their risk decreased over duration of use. More serious side effects resulting in altered thinking or behaviour have been uncommonly reported in people with a pre-existing psychiatric disease and are managed with recommendations for counselling before and during treatment.

The European Medicines Agency therefore decided that Apretude'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 Apretude?

The company that markets Apretude will provide a guide to doctors and individuals who use the medicine with information about the use of Apretude. Healthcare professionals will also receive a checklist to follow when prescribing and using the medicine and a reminder card to hand out to individuals receiving Apretude for PrEP.

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

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

Other information about Apretude

Apretude received a marketing authorisation valid throughout the EU on 15 September 2023.

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

This overview was last updated in 09-2023.