LAIS

LONG ACTING ANTIRETROVIRAL INJECTABLES

INFORMATION SHEET

LEGACY PROJECT

hanc
HIV/AIDS Network Coordination

LONG ACTING INJECTABLES

For many people, having HIV treatment and prevention options other than taking daily pills is important. Long acting injectables (LAIs) allow for the long-term slow release of medication into the body.

LAIs have the advantage of infrequent (less than daily) dosing and are intended to provide sustained medication levels in the body. LAIs are administered as injections to deposit medication into the muscle (typically of the arm or buttocks). LAIs are used as contraceptives and to treat a variety of other conditions. There are other antiretroviral products in development that require even less frequent dosing and may be administered through implants, rings, etc.

In January 2021, the US Food and Drug Administration (FDA) approved long-acting antiretroviral Injectables for the treatment of HIV, and, in December 2021, for pre-exposure prophylaxis (PrEP) to prevent HIV acquisition.

HOW ARE LONG-ACTING ANTIRETROVIRAL INJECTIONS PRESCRIBED FOR HIV TREATMENT IN ADULTS?

Every 1 or 2 months, a medical professional injects into the buttock (gluteus muscle) one shot of an antiviral drug called cabotegravir plus a shot of another antiviral drug called rilpivirine. The commercial name for this combination of injectable medications is CABENUVA and it is indicated for the treatment of HIV-1 infection in adults to replace their current oral regimen in people who are virologically suppressed (HIV-1 RNA <50 copies/mL), with no history of prior treatment failure and no known or suspected resistance to either cabotegravir or rilpivirine.

To ensure that the two-drug injectable can be well tolerated, the two drugs may be prescribed as oral pills to be taken daily for one month prior to starting the injectable regimen. The month of oral pills allows patients to monitor for any side effects to the drugs before receiving their first long-acting injections. CABENUVA can only be prescribed by a health care provider[1]. The two-drug injection was evaluated in two studies that found that it was very effective in keeping the levels of HIV low[2].

EVERY 1 OR 2 MONTH

MEDICAL PROFESSIONAL INJECTS

into the buttock (gluteus muscle)

CABENUVA

The commercial name for this combination of injectable medications Cabotegravir + Rilpivirine

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1 https://cabenuvahcp.com
2 Rizzardini G, Overton ET, Orkin C, et al. Long-acting injectable cabotegravir + rilpivirine for HIV maintenance therapy: week 48 pooled analysis of phase 3 ATLAS and FLAIR trials. J Acquir Immune Defic Syndr. 2020;85(4):498-506.

HOW ARE LONG-ACTING ANTIRETROVIRAL INJECTIONS PRESCRIBED FOR HIV PREVENTION IN ADOLESCENTS AND ADULTS?

Cabotegravir extended-release injectable suspension (APRETUDE) is administered first as two initiation injections (600 mg, 3 mL) administered one month apart, and then every two months thereafter. Cabotegravir oral tablets may be administered for one month before initiating the first injection to assess tolerability to the medication.

Cabotegravir extended-release injectable suspension for HIV prevention was approved by the FDA in December of 2021 for use in adults and adolescents[3].

Individuals must have a negative HIV-1 test prior to initiating the cabotegravir injectable prevention regimen.

The efficacy of cabotegravir extended-release injectable suspension as PrEP was evaluated in two studies conducted by the HIV Prevention Trials Network (HPTN). One study, HPTN 083, enrolled cisgender men and transgender women who have sex with cisgender men, and the HPTN 084 study enrolled cisgender women. The efficacy of cabotegravir extended-release injectable suspension as PrEP was found to be extremely effective at preventing the acquisition of HIV.

Talk to your health care provider to find out if cabotegravir extended-release injectable suspension (APRETUDE) is the right HIV prevention method for you.

3 Weighing at least 35 kg or 77 pounds.

ONGOING RESEARCH

(AS OF JANUARY 2022)

The International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) is conducting the study IMPAACT 2017 that evaluates the safety and efficacy of an injectable regimen containing two antiretroviral medications (cabotegravir + rilpivirine) in children and adolescents living with HIV.

The AIDS Clinical Trials Group (ACTG) is conducting two clinical studies that evaluate different longer-acting options for HIV treatment. The first study, ACTG 5357, is testing the injectable drug cabotegravir, in combination with an intravenous infusion of a broadly-neutralizing monoclonal antibody (VRC07-523LS) to see if they are safe and work well in keeping HIV levels low. The second study, ACTG 5359, tests CABENUVA (cabotegravir + rilpivirine), in people who have had difficulty managing their HIV with daily oral medications.

If interested in the A5359 study, click on the following link to find out more about it:
A5359: The LATITUDE Study
https://actgnetwork.org/studies/a5359-the-latitude-study/

IMPAACT

ACTG AIDS CLINICAL TRIALS GROUP

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