

APRETUDE prolonged-release suspension for injection

cabotegravir

Consumer Medicine Information

This leaflet provides important information about being given APRETUDE injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APRETUDE.**

Where to find information in this leaflet:

1. What is APRETUDE and what it is used for?
2. What should I know before I am given APRETUDE?
3. What if I am taking other medicines?
4. How APRETUDE is given to me?
5. What should I know while using APRETUDE?
6. Are there any side effects?
7. Product details

1. What is APRETUDE and what is it used for?

APRETUDE contains the active ingredient cabotegravir, which belongs to a group of antiretroviral medicines called integrase inhibitors (INIs).

APRETUDE is used to reduce the risk of getting HIV infection in people weighing 35 kg or more. This is called pre-exposure prophylaxis (PrEP).

2. What should I know before I am given APRETUDE?

Warnings

You must not be given APRETUDE:

- if you are allergic to cabotegravir, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can be given this medicine.
- if you are taking any of these medicines as they may affect the way APRETUDE works: rifampicin or rifapentine (to treat some bacterial infections such as tuberculosis), phenytoin, phenobarbital, carbamazepine or oxcarbazepine (also known as anticonvulsants used to treat epilepsy and prevent seizures).
- unless you have had a recent HIV test to confirm you are HIV negative. APRETUDE can only help reduce your risk of getting HIV before you are infected so, you must get tested to make sure you don't already have HIV infection before taking APRETUDE.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you

understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

If you are pregnant, or think you could be, or if you are planning to have a baby, don't receive APRETUDE injections without checking with your doctor. Your doctor will consider the benefit to you and the risk to your baby of receiving APRETUDE while you are pregnant.

If you are planning to have a baby, talk to your doctor in advance, as APRETUDE injection can stay in your system for up to 12 months or longer after the last injection of APRETUDE.

If you are thinking about breastfeeding, check with your doctor who will consider the benefit and risk to you and your baby.

It is not known whether the ingredients of APRETUDE can pass into breast milk and harm your baby. APRETUDE may still pass into breast milk for 12 months after the last injection of APRETUDE.

Allergic reaction

- APRETUDE contains cabotegravir, which is an integrase inhibitor. Other integrase inhibitors can cause a serious allergic reaction known as a hypersensitivity reaction. You need to know about important signs and symptoms to look out for while you're

receiving APRETUDE. See additional information under Section 6. Are there any side effects?

You must not be given APRETUDE injection after the expiry date shown on the pack.