CATIE-News

CATIE's bite-sized HIV and hepatitis C news bulletins.

**Descovy approved in Canada—key information**

10 May 2016

On April 29, 2016, Health Canada licensed the sale and use of a new fixed-dose combination of two anti-HIV drugs sold under the brand name Descovy and made by the pharmaceutical company Gilead Sciences. Descovy contains the following medicines:

- TAF (tenofovir alafenamide)
- FTC (emtricitabine).

Descovy is licensed for use in combination with other drugs for the treatment of HIV infection. Descovy is meant to be taken orally and can be taken with or without food. Descovy was generally well tolerated in clinical trials. Side effects were usually mild and temporary and included the following:

- headache
- tiredness or lack of energy
- nausea
- diarrhea.

Pharmacies in Canada should be able to order Descovy in late May or early June 2016.

**Many steps before Descovy**

Tenofovir was discovered during lab experiments conducted in the early 1990s. Subsequently, an oral formulation of the drug (tenofovir DF) was developed and marketed around 2001, first in the United States and later in other countries. The developer, Gilead Sciences, then began to create fixed-dose combinations of tenofovir DF and other drugs, such as the following:

- tenofovir DF + FTC (sold as Truvada)
- tenofovir DF + FTC + efavirenz (sold as Atripla)
- tenofovir DF + FTC + rilpivirine (sold as Complera)
- tenofovir DF + FTC + elvitegravir + cobicistat (sold as Stribild)

In the past decade, reports have emerged of side effects in some patients who use tenofovir DF, such as kidney injury and dysfunction and thinner-than-normal bones.

As part of its response to the issue of side effects, Gilead re-examined another formulation of tenofovir called TAF (tenofovir alafenamide) that had been sitting it in its laboratories since about 2001. Due to properties unique to TAF, a small dose of TAF is sufficient to exert the same antiviral effect as tenofovir DF in people. Furthermore, unlike tenofovir DF, when TAF is swallowed and absorbed, it does not accumulate in the blood. Instead, TAF builds up inside cells of the immune system, where it is converted into tenofovir (the active compound). As cells of the immune system are attacked by HIV, the accumulation of TAF inside these cells helps to protect them from infection. In the case of cells already infected with HIV, TAF helps to greatly reduce production of HIV when used in combination with other drugs.

Several years ago, Gilead began to conduct studies in order to compare most of the regimens listed above against combinations where tenofovir DF was replaced by TAF. In these and other studies, TAF-containing regimens were
found to be similar in terms of safety and effectiveness. Furthermore, TAF-containing regimens were less likely to be associated with new cases of kidney injury, and bone thinning was generally less common.

Encouraged by these results, Gilead began the process of gradually introducing TAF-based formulations of its existing products. The first TAF-containing medicine, a fixed-dose formulation called Genvoya, was licensed in Canada in 2015. Genvoya is an entire regimen in one pill and contains the following medicines:

- TAF + FTC + elvitegravir + cobicistat

Descovy has now become the second fixed-dose pill that contains TAF.

**Inside Descovy**

Descovy is supplied as rectangular-shaped tablets and comes in two colour-coded strengths as follows:

- grey tablets stamped “210” on one side; these contain 10 mg TAF and 200 mg FTC
- blue tablets stamped “225” on one side; these contain 25 mg TAF and 200 mg FTC

The strength of Descovy used depends on the rest of a person’s anti-HIV regimen. In general, in patients who are taking HIV protease inhibitors, Gilead recommends the lower strength (“210”) tablets of Descovy. The company recommends the higher strength “225” tablets when Descovy is used with other classes of anti-HIV drugs, such as the following:

- non-nukes (NNRTIs) – including efavirenz (Sustiva, Stocrin), rilpivirine (Edurant)
- integrase inhibitors – including dolutegravir (Tivicay), raltegravir (Isentress)
- co-receptor blockers – maraviroc (Celsentri)

Speak to your doctor and pharmacist to find out which strength of Descovy is right for you.

**General side effects**

In clinical trials Descovy was usually well tolerated. General side effects included the following:

- headache
- tiredness or lack of energy
- nausea
- diarrhea

These side effects are usually temporary.

**Uncommon side effects**

Fewer than 1% of participants in clinical trials experienced the following side effects:

- abdominal pain
- indigestion
- flatulence
- rash
- vomiting

These side effects were generally mild and temporary.

Further detailed information about Descovy, including drug interactions and warnings, will appear in a CATIE fact sheet that is in development.

**Access**

After Health Canada licenses a drug, physicians can prescribe it, but patients must pay for it themselves unless they have a private insurance plan that covers it. Such coverage may take weeks or months to take effect after licensure.
If left untreated, HIV infection leads to catastrophic disease that can affect one’s ability to work. HIV treatment is also expensive. Therefore, in Canada, provincial and territorial ministries of health heavily subsidize the cost of anti-HIV medications. Each ministry has a listing of drugs for which it is prepared to pay. These listings are called formularies.

In the months ahead, Gilead Sciences and provincial and territorial formularies will be negotiating the price of Descovy. Your pharmacist or doctor can tell you when Descovy is listed on your region’s formulary.

The cost of Descovy in Canada was not yet available at the time of writing.

—Sean R. Hosein

REFERENCES:

Disclaimer

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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