



## Community pharmacy and HIV

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**Community pharmacists are in a key position to raise awareness, provide education, and assist people living with human immunodeficiency virus (HIV). Pharmacists can help to facilitate the HIV treatment process by managing adherence and side effects and decreasing the stigma of HIV.**

One of the priority areas of *Seventh national HIV strategy 2014–2017* is to improve access to and uptake of antiretroviral therapy (ART) medicines. Community pharmacies will be able to dispense ART medicines to people living with HIV on or after 1 July 2015. Previously, these highly specialised medicines have been largely limited to supply through hospital and sexual health clinic pharmacies. This new arrangement will expand access to therapy for people living with HIV.<sup>1</sup>

As part of the health care team, pharmacists recognise the importance of confidentiality, empathy and non-discriminatory patient interaction and understand that the stronger the patient-pharmacist relationship, the better the person's expected health outcomes.<sup>2</sup>

HIV ART medicines are listed on the Pharmaceutical Benefits Schedule (PBS) through special arrangements under the provisions of section 100 of the *National Health Act 1953*. The special arrangements are called the Highly Specialised Drugs Program.<sup>3</sup>

This resource is designed to provide an introduction to HIV management by the pharmacist in a community pharmacy setting.

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# Community pharmacy and HIV Quick Facts

From 1 July 2015, a number of changes are being made to the prescribing and dispensing of HIV ART medicines that will see community pharmacies receiving more prescriptions for these medicines.

## Prescribing HIV ART medicines

The same PBS requirements for prescribing HIV ART will apply for eligible prescribers in public hospitals, private hospitals and the community. Currently, different arrangements apply in public and private hospitals.

PBS Authority [Streamlined] prescription requirements will apply from 1 July 2015 for all eligible prescribers. New PBS streamlined Authority codes [four digit numbers] will be available from 1 July 2015 for prescribers to use in circumstances where the intended use of the medicine complies with the PBS restrictions. These codes will be available from [www.pbs.gov.au](http://www.pbs.gov.au)

PBS quantities generally provide up to two months' treatment of HIV ART medicines at recommended doses.

Prescriptions dated 1 July 2015 or later on which the prescriber has not included the relevant Authority [Streamlined] code cannot be dispensed under the PBS.

The changes also remove the requirement for accredited prescribers to be hospital affiliated, and for prescriptions to include a public/private hospital provider number.

## Dispensing HIV ART medicines

Valid PBS prescriptions written on and from 1 July 2015, can be dispensed by public hospital pharmacies, private hospital pharmacies, community pharmacies, and dispensing doctors, irrespective of the source of the PBS prescription. Pharmacists claim for these PBS supplies in the normal manner.

Currently, restrictions apply to HIV ART prescriptions written in public hospital settings that prevent them being dispensed by community pharmacies. Prescriptions dated before 1 July 2015 must be dispensed under existing arrangements.

## Ordering HIV ART medicines

HIV ART medicines will be available from pharmaceutical wholesalers like other PBS medicines.

## Annotating HIV ART prescriptions under CTG

Prescribers cannot annotate HIV ART prescriptions under the (CTG) PBS arrangements for eligible Aboriginal and Torres Strait Islander people.

## Paying a PBS co-payment

People have to pay a PBS co-payment for each supply of HIV ART. Pharmacy dispensing software vendors will be given the appropriate information to upgrade their systems prior to 1 July 2015 to include the changed dispensing arrangements and ensure correct co-payments are charged.

## Further information

For further information, see [www.humanservices.gov.au](http://www.humanservices.gov.au)

## Glossary

<b>Acquired immune deficiency syndrome (AIDS)</b>	AIDS is caused by HIV. AIDS is defined by the development of opportunistic infections or specific malignancies
<b>Antiretroviral therapy (ART)</b>	A combination of three or more antiretroviral medicines given as treatment for HIV
<b>CD4 cells (or 'T' cells)</b>	A type of white blood cells that play a major role in protecting the body from infection. They provide the mechanism by which HIV replicates in the body
<b>Human immunodeficiency virus (HIV) medicine resistance</b>	The ability of HIV to mutate and reproduce itself in the presence of antiretroviral medicines. This can occur as a result of non-adherence to dosing schedules
<b>Pre-exposure prophylaxis (PrEP)</b>	Antiretroviral medicine given to an uninfected person who may be at risk of contracting HIV to lower the risk of HIV infection
<b>Post-exposure prophylaxis (PEP)</b>	Administration of HIV antiretroviral medicines within 72 hours of a high-risk exposure to HIV to lower the risk of infection
<b>Undetectable viral load</b>	Occurs when either no HIV is identified in a viral load test or it is below the limits of detection. A person with an undetectable viral load is unlikely to transmit HIV
<b>Viral load</b>	Viral load is the marker of viral activity and is measured using a quantitative test of the number of viral particles (number of HIV RNA copies per mL of blood) in the serum of a person with HIV

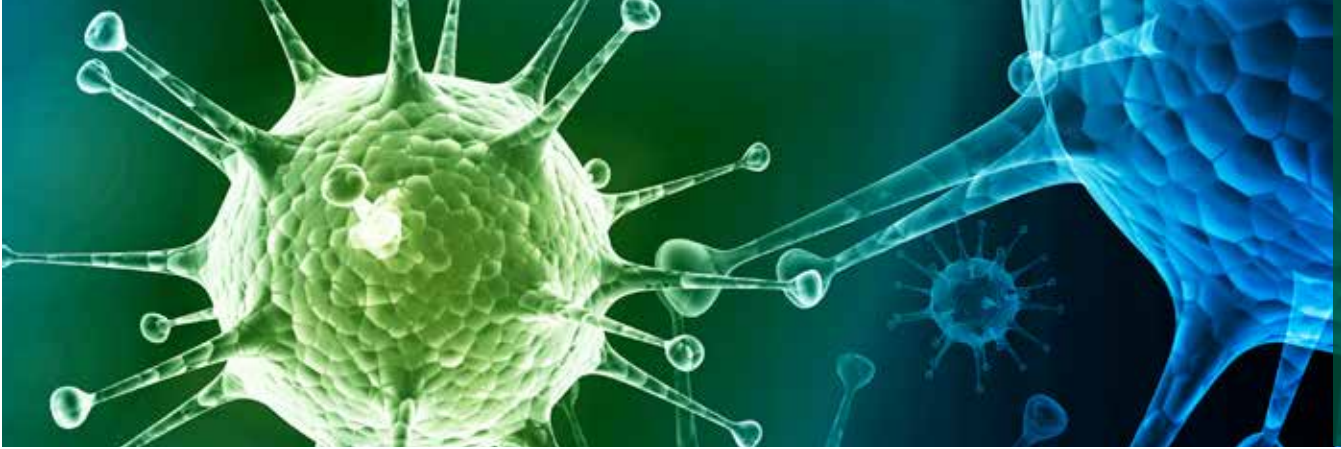
## Introduction

The management of HIV has changed significantly over the past 30 years. ART has reshaped the natural history of HIV and is now being offered early in the course of infection.

First introduced in the late 1980s, early antiretroviral medicines were associated with considerable side effects and toxicities. Monotherapy was found to be ineffective, leading to the rapid development of resistance. The development of the protease inhibitor class of medicines enabled combination therapy to be introduced in 1996, which saw a significant improvement in efficacy. Subsequent refinement of ART medicines has resulted in potent ART with limited and better tolerated side effects and simplified dosing regimens. Many agents are now formulated as dual or triple combinations, some with the addition of a pharmacokinetic enhancer. Once-daily regimens are prescribed for many people and are the preferred regimen for treatment initiation. Despite significant improvements in medicine tolerability, side effects may still occur necessitating monitoring for short-term side effects, longer-term toxicity and resistance.<sup>4</sup>

HIV is now a manageable chronic infection. It is timely that the management of HIV is normalised and dispensing moved into the community. From 1 July 2015, people living with HIV will be able to have their antiretroviral prescriptions dispensed by the pharmacy of their choice.

In the last 10 years, ART has undergone significant improvements. The newer medicines cause fewer toxicities and side effects and dosing has been simplified. With the introduction of combination products, many people are now taking a once-daily regimen.



## HIV in Australia

An estimated 26,800 Australians were living with HIV at the end of 2013.<sup>5</sup> There were 1,236 new diagnoses in 2013, of which 350 have been identified as new infections.<sup>5</sup> HIV ART medicines, subsidised through the PBS, are available to all Medicare-eligible people living with HIV, independent of their stage of disease.

In Australia, opportunistic infections that are associated with an AIDS diagnosis are usually only seen in people who have developed treatment-limiting drug resistance, have a severely impaired immune system, or have been diagnosed late in the course of their infection. This occurs due to previous treatment failure, actively avoiding treatment or very late diagnosis after infection. However, once these people commence treatment, many can achieve substantial recovery.

The *Seventh national HIV strategy 2014–2017* set a target of a 50% reduction in new infections and an increase of treatment uptake to 90%.<sup>1</sup> Achieving these targets requires a more active approach to HIV through:

- broadening of the access to, and simplifying requirements for, testing
- increasing the number of services and clinicians able to provide HIV care
- expanding dispensing to include community pharmacies.

The Commonwealth and all State and Territory Governments have endorsed the *Seventh national HIV strategy 2014–2017*.<sup>1</sup>

HIV ART medicines are effective provided they are taken as prescribed<sup>6</sup>:

- They require regular dosing.
- Resistance can develop rapidly if occasional doses are missed.
- 100% adherence should remain the goal, but 95% adherence may be effective.

Single fixed-dose combination regimens have greatly simplified HIV treatment.



# Pathogenesis

HIV, if left untreated, causes acquired immune deficiency syndrome (AIDS). HIV is a single-stranded ribonucleic acid (RNA) virus. It has an outer envelope that surrounds two copies of single-stranded RNA as well as a number of viral proteins.<sup>7,8</sup>

HIV replication commences when the virus envelope glycoprotein 120 (GP120) attaches to CD4 receptors expressed on the surface of CD4 lymphocytes. This is called binding. Fusion of the virion membrane and cell facilitates viral entry. Once inside the cell, the RNA is converted to deoxyribonucleic acid (DNA) via the enzyme, reverse transcriptase. The DNA then migrates to the cell nucleus and integrates, as proviral DNA, into the host cell DNA via the enzyme integrase.<sup>7</sup> It is this process of replication that classifies HIV as a retrovirus. Integrated viral DNA then accelerates the production of components of new virions, which assemble in the cytoplasm. New virions then bud off the cell in an immature state. As each virion matures, it goes through a process of proteolytic cleavage by the use of the enzyme protease. The mature virion then binds to the receptor on the CD4 and this cycle repeats (see Figure 1).

CD4 cells are a central and vital component of the human immune system.<sup>6</sup> They are produced when the immune system attempts to fight infections. When the immune system is activated and producing CD4 cells, it is also replicating and proliferating HIV (see Figure 1 and Table 1).

Table 1. Drug classes and their site of action on HIV life cycle

DRUG CLASS	ACTION	DRUG NAME
Binding inhibitors or entry inhibitors	Acts on host cell to block binding of HIV to the cell receptor	maraviroc
Fusion inhibitors	Prevents the virus entering the cell by blocking its fusion to the cell membrane	enfuvirtide
Nucleoside reverse transcriptase inhibitors (NRTIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs)	Inhibits reverse transcriptase by which RNA is converted to DNA	abacavir, emtricitabine, lamivudine, tenofovir, stavudine, didanosine, zidovudine, efavirenz, etravirine, nevirapine, rilpivirine
Integrase strand transfer inhibitors (INSTIs)	Prevents the integration of viral DNA into the host DNA in the cell nucleus by inhibiting HIV integrase	dolutegravir, elvitegravir/c, raltegravir
Protease inhibitors (PIs)	Inhibits protease in the final stage of viral assembly preventing viral maturation and replication	atazanavir/r, darunavir/r, lopinavir/r, fosamprenavir/r, tipranavir/r, saquinavir/r
Pharmacokinetic boosters/enhancers	Used with PIs or INSTIs to increase their performance	ritonavir (r), cobicistat (c)

Adapted from Aidsinfo (at: www.aidsinfo.nih.gov), AMH online  
 Note: /r indicates boosted with ritonavir and /c indicates boosted with cobicistat.

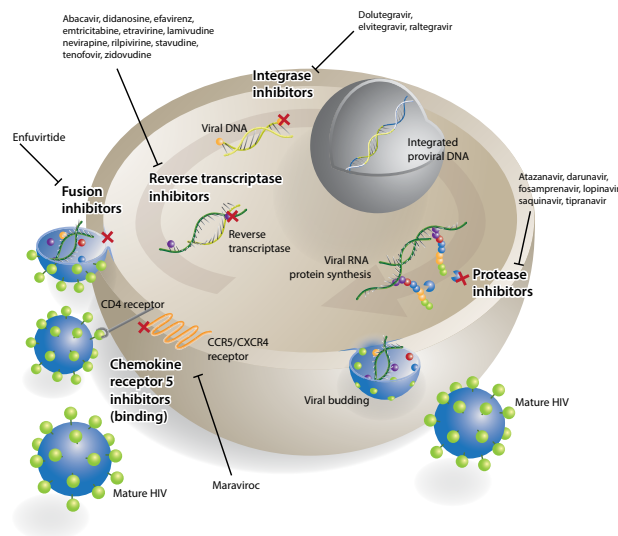


Figure 1. HIV viral life cycle depicting the maturation process and indicating where different classes of antiretroviral medicines act

# Acquisition of HIV

Following infection with HIV, there is a period of very high viraemia (viral load can be in excess of 1,000,000 HIV RNA copies/mL).<sup>7</sup> This is associated with immunosuppression as measured by a reduction in the CD4 lymphocyte count. The average CD4 cell count range for an adult is between 500 and 1,200 cells/mm<sup>3</sup> (microlitre) (see Figure 2).

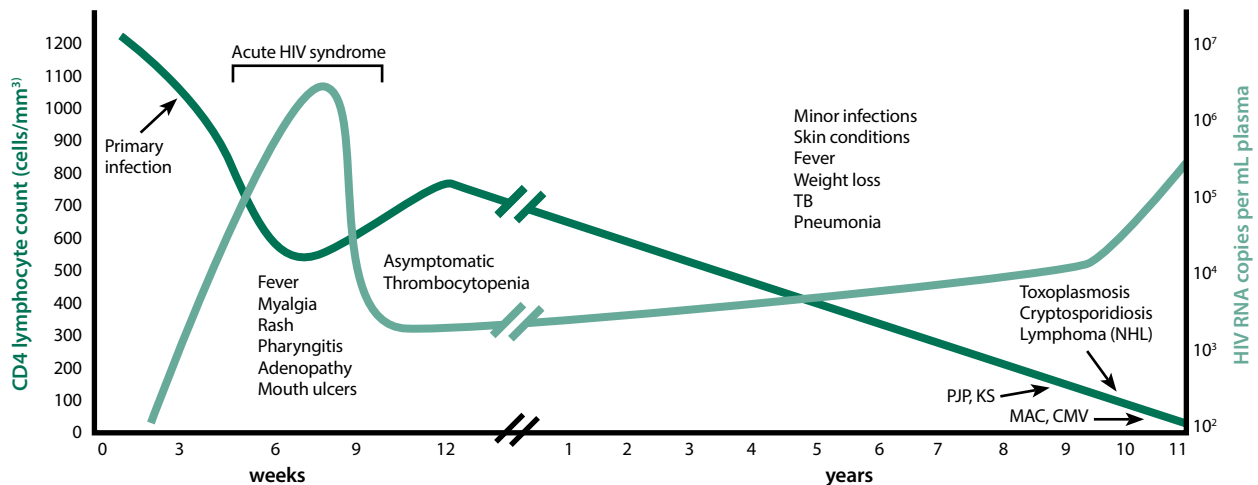
More than half of the people who contract HIV develop a mononucleosis-like HIV seroconversion illness characterised by fever, pharyngitis, lymphadenopathy, rash, splenomegaly and aseptic meningitis.<sup>7,8</sup> Other people living with HIV may either be asymptomatic or have subclinical illness.<sup>7</sup>

## Early HIV infection

Symptoms of acute HIV infection resolve as the immune system mounts a host immune response, partially controlling viral replication.<sup>7</sup> There is a rebound increase in CD4 cell count to near baseline levels and the person enters a period of clinical latency. Very high levels of viral replication decrease but replication continues, especially in lymphoid tissue. The plasma HIV RNA plateaus to a level of viraemia known as the virological 'set point' because HIV replicates inside the cell nucleus by inserting itself in the CD4 cell DNA. This process continues as new CD4 cells are produced to help fight HIV infection<sup>7,8</sup> (see Figure 2).

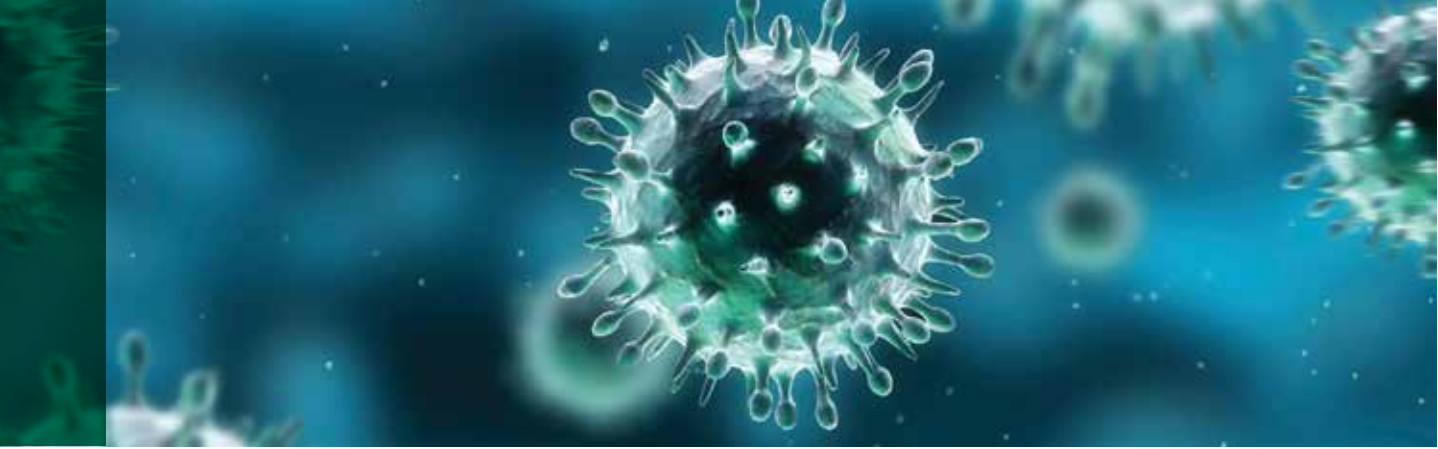
## Untreated HIV infection

If left untreated, the person experiences a gradual decline in CD4 cell count, with a median loss of 80 cells per year. Progression to AIDS, marked by the development of opportunistic infections or specific malignancies, occurs at a median of 10 years after initial infection with HIV. At this time, the CD4 cell count has usually fallen below 200 cells/mm<sup>3</sup> (microlitre) and the person is severely immunocompromised.<sup>7,8</sup>



MAC: mycobacterium avium complex CMV: cytomegalovirus KS: kaposi sarcoma PJP: pneumocystis jirovecii pneumonia TB: tuberculosis

Figure 2. CD4 and viral-load trajectory following HIV infection  
Adapted from ASHM antiretroviral guidelines at: [www.ashm.org.au](http://www.ashm.org.au)



## Viral load

Viral load is a quantitative test, which measures the number of viral particles in the serum of a person living with HIV. These tests are sensitive and measure down to about 20 copies/mL. If no HIV is identified in a viral load test, the sample is said to be undetectable, or below the limits of detection. A person with an undetectable viral load is unlikely to transmit HIV, although there can be a difference in viral load between serum, semen, vaginal fluid and cerebrospinal fluid in a small number of people.

Viral load is seen as the most accurate measure of viral activity. As shown in Figure 2, viral load increases dramatically when a person is first infected. Viral load at this time can be over one million copies/mL. A rise in viral load is usually identifiable before a drop in CD4 is observed. When this occurs, a person newly infected with HIV may transmit the virus before they realise they have contracted it. Clinicians will rely on viral load and resistance testing in making a decision to change a person's regimen.

### HIV transmission

An undetectable viral load reduces the risk of HIV transmission. However, it should be noted that semen and plasma viral load will vary in a small number of people, and viral load can rebound quite quickly if a person stops treatment, develops resistance, or is experiencing other infections, particularly sexually transmissible infections.

High viral load greatly increases the likelihood of transmission of HIV. To decrease HIV transmission, the viral load of people living with HIV must also be decreased. Therefore, the number of people living with HIV on treatment, who have an undetectable viral load, must be maximised.

Some people will not be able to achieve an undetectable viral load, and others may experience increases from time-to-time, even though their viral load is normally undetectable. For these reasons, people on treatment are encouraged to continue to use condoms with their HIV-negative partners to reduce the risk of transmission. A number of studies suggest that sexual transmission from a person with an undetectable HIV viral load is very low.<sup>9,10</sup>

HIV transmission can also be increased by poor adherence to ART causing an increase in the viral load. Rigid adherence to the ART medicine regimen should be discussed regularly with the person. Consider the impact on adherence of certain conditions such as depression and behaviours such as alcohol and substance use. Treatment of these issues may improve adherence as well as improving overall health and reduce the risk of transmission.<sup>11</sup>

### Treatment interruption

Viral load can also increase quite rapidly following an interruption in treatment. Some medicines have a narrow therapeutic index and need strict dosing to achieve and maintain a therapeutic level. Suboptimal adherence facilitates resistance. Short interruptions in treatment, such as forgetting to take medicine on a weekend away, or regular difficulties because of frequent international travel can all encourage resistance. Vomiting or diarrhoea can reduce the effectiveness of some medicines.

# Treatment

HIV is a chronic condition that is manageable with combination ART medicines. If combination ART medicines are started early, a person living with HIV should not experience HIV-related illnesses or AIDS. Eradication of HIV is not achievable with currently available antiretroviral agents and treatment remains lifelong.<sup>8</sup>

The primary goals of ART are to<sup>11</sup>:

- reduce HIV-associated morbidity and prolong the duration and quality of life
- restore and preserve immunological function
- suppress plasma HIV viral load to an undetectable level and maintain this level
- prevent HIV transmission.

The current understanding of HIV therapy is that the earlier treatment is commenced the less damage and immunocompromise HIV can cause. Many people now start HIV therapy before CD4 cells have been depleted. This is thought to provide protection to the immune system in the longer term. Also, once viral suppression is established, the person living with HIV is far less likely to transmit the virus through sexual contact or through sharing injecting equipment. This motivates many people with HIV, particularly people in relationships with HIV-negative partners, to start treatment to protect their partners.<sup>7,11</sup>

In Australia, treatment decisions are guided by the Australasian Society for HIV Medicine (ASHM) Australian commentary on the *US Department of Health and Human Services (DHHS) guidelines for the management of HIV-1 infected adults and adolescents*.<sup>11</sup> These guidelines are updated regularly as new evidence emerges and new medicines are registered by the Therapeutic Goods Administration (TGA). The guidelines allow for people to be initiated on HIV therapy at any CD4 level. Increasingly, treatment is started earlier after infection, when the CD4 cell level is in the normal range.<sup>11</sup> From time-to-time, the PBS may set some restrictions on person groups who can be prescribed subsidised therapy, i.e. for treatment-naïve or treatment-experienced people.

Treatment of HIV is most effective when different medicines, which act on these various stages of the viral lifecycle, are given in combination (*see Figure 1 and Table 1*). The person commencing therapy is started on a once-daily regimen, unless there is a clinical reason not to do so (such as identification of drug resistance or co-morbidity to one or more of the active components). As more combination products are developed, treatment-experienced people will likely move to fixed-dose combination regimens. Notwithstanding these changes, some people who are stable on multi-pill regimens may prefer to stay on these regimens even if alternatives are available.<sup>4</sup>

**Irrespective of formulation, current treatment is not a cure. People living with HIV must take their HIV medicines lifelong. Increasing people's access to medicine facilitates antiretroviral adherence.<sup>4</sup>**



# Combination ART for HIV

Each class of medicine in the combination ART, whether co-formulated or dosed separately, acts on a different part of the HIV life cycle. Commonly, two medicines are chosen from one class and a third from another. Each compound has a separate function. Some work directly on the virus while others act on the host cell, blocking the cell-surface receptors and therefore blocking entry of the virus.

Other medicines play a boosting role in a combination, and while they may not have a great impact on HIV directly, they alter pharmacokinetics resulting in increased exposure to the active compounds in the combination. This reduces pill burden, increases the medicine's half-life, increases the medicine's trough level and reduces the development of resistance because of the occasional missed dose<sup>4,7</sup> (see Appendix 1).

Understanding the mechanisms of ART helps explain why treatment adherence is crucial. People benefit from understanding why it is important to take their medicines regularly, as prescribed. Pharmacists have an important role in assisting people with this by counselling them about optimal use of each of their medicines.<sup>4</sup>

## People commencing therapy

People commencing treatment will usually be prescribed a combination of three medicines, which includes medicine from at least two different classes, usually dual NRTIs plus a medicine from another class.<sup>6,12</sup> The Guidelines recommend a regimen for a treatment-naïve person of two NRTIs in combination with a third active antiretroviral medicine from one of three drug classes: an NNRTI, a PI boosted with ritonavir, or an INSTI (see Table 1).<sup>11</sup> More frequently, treatment-naïve people are being initiated on a fixed-dose combination pill.

Before an initial regimen is selected, people undergo resistance testing, as resistant HIV can be transmitted from one person to another. If a person has acquired HIV, which is resistant to one or more medicines, it is essential to avoid taking a combination containing the medicines to which resistance has developed.

## Treatment-experienced people

People who have been on long-term treatment may have taken successive, more complex treatment regimens. These regimens, while life-saving, may have caused debilitating side effects including chronic diarrhoea, and toxicities such as the development of peripheral neuropathy, renal calculi, and fat redistribution resulting in lipodystrophy and/or lipoatrophy. The earlier medicines were also more susceptible to the development of resistance.

Many people have been living with HIV for more than twenty years. Some may be taking complex regimens in an attempt to avoid medicines to which they have developed resistance. It is not uncommon for these people to be on a regimen comprising five active antiretroviral medicines as well as treatment for other co-morbidities.<sup>4</sup>

## Developing HIV drug resistance

Resistance can occur quite rapidly in people living with HIV as the virus mutates easily. Some common resistance mutations are shared across some medicines in a class and others are drug specific. HIV has many sub-types and many virions carry slight mutations. As resistance develops, virions, which carry the resistance mutation, are able to replicate and resistant viruses can rapidly become the dominant virus type. Certain mutations render different medicines ineffective. While single fixed-dose combinations have many benefits, these are lost if the fixed-dose combination is no longer effective because the person is resistant to one or more of the component medicines. Resistance testing is conducted to help inform medicine selection.<sup>11</sup>

Many of the newer medicines have a longer half-life and so are more forgiving of an occasional missed or delayed dose. Pharmacists should explain why it is important to take medicines as prescribed and the need to maintain a therapeutic drug level. Adherence to dosing schedules can be greatly improved when people understand why this is being asked of them.<sup>4</sup>

The majority (approximately 85%) of people who will access a community pharmacy will be on an established treatment regimen. A much smaller number of people will be initiating therapy or changing their regimen each year.

For a person living with HIV, who is commencing on a new medicine, ensure they know:

- how the medicines should be taken
- when the medicines should be taken
- the importance of adherence
- any common side effects, less common side effects and particularly any dangerous side effects, and what action to take if any of these occur
- any drug-drug interactions which should be avoided or minimised.

To check for interactions with any other common medicines, including herbal and complementary therapies, over-the-counter (OTC) medicines and other drugs, refer to:

- ASHM Australian Commentary on the USA Guidelines, Interactions tables [www.arv.ashm.org.au/arv-guidelines/what-to-start](http://www.arv.ashm.org.au/arv-guidelines/what-to-start)
- The University of Liverpool, an active check of potential interactions [www.hiv-druginteractions.org](http://www.hiv-druginteractions.org)
- Canadian Immunodeficiency Clinic site [www.hivclinic.ca](http://www.hivclinic.ca)



## Counselling

Most people living with HIV in Australia have commenced treatment, have a suppressed viral load and their health is very stable. These people will have a good understanding of their treatment. However, all people living with HIV will need ongoing support to manage ART medicine adherence, side effects and resistance as well as maximise their health and wellbeing outcomes.

### Adherence

A major role for pharmacists is monitoring and supporting adherence. Adherence to HIV regimens is vital. Consistent and effective use of ART results in a sustained reduction in viral load and HIV transmission.<sup>11</sup> While 100% adherence is ideal, newer medicines are more forgiving of an occasional missed dose, 95% adherence may be effective. Maintaining adherence for the long term is essential as ART is lifelong. Avoiding the development of resistance is crucial. If resistance develops, alternative therapy regimens must be employed which are usually more complex, with a greater pill burden. It often involves medicines that are less well tolerated and can be more costly than initial therapy. Treatment failure through poor adherence is an unnecessary burden on the peoples' health and the health care system.

There are many reasons why people do not to take medicines as prescribed. Expanding access, so that people can have their medicines dispensed in the community, where opening hours are more flexible than in the hospital, removes one of the often-quoted barriers to access to these highly specialised and high-cost medicines.<sup>13</sup>

**Pharmacists will increasingly have a crucial role in reinforcing HIV treatment adherence and the taking of HIV antiretroviral medicines as prescribed. The decision to commence treatment is now relatively soon after diagnosis. This provides the person with fewer opportunities to discuss their treatment with their doctor before starting ART. Dose administration aids (DAAs) and reminders such as smart phone apps may help support adherence.**

### Starting therapy

Over time, it is highly likely that people starting HIV treatment will have their first prescription dispensed by a community pharmacist. It will be important that these people are provided with:

- a comprehensive introduction to the medicines they are being prescribed
- reinforcement on dosing and importance of taking the doses as and when prescribed, and what to do if adherence is difficult to maintain
- information about potential side effects and adverse events and what to do if these occur
- a review of their non-ART medicines so that possible drug-drug interactions can be considered.

Pharmacists may also want to refer the person to print or community support resources, listed at the back of this booklet, and encourage the person to return to the pharmacy if they have any difficulties.

To achieve 95% adherence to treatment

If taking a daily regimen:

- only miss 1 dose per month

If taking a twice-daily regimen:

- only miss 3 doses per month

## Changing therapy

If a person needs to change their regimen, and this is not simply moving to a co-formulation, it may mean there has been a problem with their previous medicines (e.g. development of resistance or an intolerable side effect). This can be a challenging and demoralising experience for the person living with HIV. It can indicate HIV reactivation and disease progression.

If resistance has developed due to poor adherence, the person may benefit from discussion about DAAs to help ensure strict adherence to the regimen.

Some people may become depressed and discouraged regarding treatment. There are support services available via the resources listed in the back of this publication, and the person may be referred to one of these.

If the treatment change has been made because of a viral load increase, then the person should be advised that until their viral load becomes undetectable, their risk of transmitting HIV will be increased.

## Treatment interruptions or drug holidays

These should be cautioned against where possible. If a person suggests he or she is going to stop treatment, refer them back to their doctor for discussion. Some people travelling to certain countries prefer to stop taking their medicines for fear of punishment, deportation or imprisonment for being found with the medicines or identified as HIV-positive. However, generally treatment breaks are mostly detrimental.

If a person is on a complex regimen, then a change in therapy, if possible, would be preferable to a break. If they are on multiple medicines for co-morbidities, it might be possible to review their non-ART medicines.

## Viral load and infectivity

A person with an undetectable viral load is unlikely to transmit HIV. There can be a difference in viral load in semen and some people seek testing to determine this. It can take a number of months after commencing treatment to have a suppressed viral load. People are far more likely to transmit HIV sexually and through sharing equipment used to inject drugs, while their viral load is detectable. People should be reminded to use condoms during this period and to never share injecting equipment.

## Pre-exposure prophylaxis (PrEP)

PrEP is the administration of antiretroviral medicine to an uninfected person who may be at risk of contracting HIV, to lower their risk of HIV infection. Some people may enquire about PrEP for their partners. PrEP is not currently a TGA-licensed indication, nor is it available in Australia on the PBS. People requesting PrEP should be referred to the treating clinician.<sup>11</sup>

## Post-exposure prophylaxis (PEP)

PEP is the administration of HIV ART medicines soon after a high-risk exposure to HIV, to lower the risk of infection. It must be administered within 72 hours of exposure and the sooner the better, i.e. within hours rather than days.<sup>11</sup> PEP is not available on the PBS.

PEP starter packs are available from hospital emergency departments, sexual health clinics and some high caseload GP clinics. Individuals requesting PEP should be referred to a hospital emergency department, HIV clinician or sexual health clinic.<sup>4</sup>



# ART and community pharmacy

HIV medicines have mainly been dispensed in public hospital pharmacies under the PBS section 100 Highly Specialised Drugs Program. From 1 July 2015, HIV section 100 medicines will be able to be dispensed in the community. Each pharmacist will need to plan ordering and supply arrangements with their people living with HIV.

This will largely be dependent on the individual pharmacist-person relationship which has the potential to be a long-term valued and valuable relationship. Many people living with HIV have co-morbidities, which require treatment and monitoring including the ongoing potential drug interactions. In making the decision to start treatment, the clinician discusses with the person<sup>7</sup>:

- their commitment to therapy
- their awareness of the importance of strict adherence to the regimen
- the potential for short- and long-term adverse effects
- the potential for drug-drug interactions and the need to discuss new medicines with a health professional.

The community pharmacist can provide adherence support each time the person visits the pharmacy. Depending on individual needs and the existing relationship with the person, pharmacists can offer a range of adherence aids and reminders to improve outcomes with therapy.

## Drug-drug interactions

A thorough review of all non-HIV medicines, including (but not limited to) complementary medicines and herbal preparations, is necessary to minimise side effects. This is particularly important when a new antiretroviral agent is added to an existing ART combination, as well as the addition of any other medicine.<sup>11</sup>

Detailed drug-drug interactions tables are found at [www.hiv-druginteractions.org](http://www.hiv-druginteractions.org). This site contains interactive drug interaction tables which allow interaction searching between ART medicines and other medicines including non-HIV medicines, recreational drugs and complementary medicines. Interactions tables are also available at [www.arv.ashm.org.au/arv-guidelines](http://www.arv.ashm.org.au/arv-guidelines) and [www.hivclinic.ca](http://www.hivclinic.ca). These tables complement drug interaction information contained in non-HIV specific sources. Side effects, toxicities, drug interactions and monitoring are listed in Appendix 2.

## Stigma

Fear of stigma and discrimination continue to be significant concerns for people living with HIV. While community pharmacists and their staff are subject to professional codes of conduct and privacy and confidentiality obligations, people living with HIV, particularly in close or small communities, are often concerned about disclosing their status. It is important to make sure that staff members are aware of their privacy and confidentiality obligations. Discrimination on the basis of HIV status, sexuality, sex or gender identification is unlawful.

Recent surveys of people living with HIV indicate that people with HIV welcome the introduction of community dispensing, but they also express a reticence to access HIV medicines in the community, citing concerns about not having access to a private space for discussions and the potential for accidental breaches in confidentiality.<sup>14</sup> Positive interactions in the pharmacy are likely to be rewarded by customer loyalty and word-of-mouth referrals.

While Aboriginal and Torres Strait Islander people are not over-represented in the Australian HIV data, they remain a priority population and additional care should be taken in protecting the confidentiality of Aboriginal and Torres Strait Islander people. Real and perceived stigma, particularly in small communities, is often raised by Aboriginal and Torres Strait Islander people as a barrier to access in the health care setting.<sup>7</sup>

Some staff members may have limited experience of interacting with people living with HIV and may be concerned about transmission issues. Staff should be assured that HIV is only transmitted through blood-to-blood and sexual contact. There is no risk of contracting HIV through social settings.

## Holding HIV ART medicines

Pharmacies do not have to hold a stock of HIV ART medicines. These medicines are high-cost and should be managed the same way as other high-cost medicines. The majority of pharmacies will not keep stock on hand and will order as and when required. Pharmacists should discuss with people the necessary timelines to avoid treatment interruptions.

# Contacts

## Support organisations

These support organisations are willing to be contacted by community pharmacists and people living with HIV.

## National organisations

### ASHM – Australasian Society for HIV Medicine

National body representing clinicians and health workers in the HIV and viral hepatitis fields. Representation, policy development and training, development of national HIV treatment guidelines, annual conference.

T: 02 8204 0700

E: [ashm@ashm.org.au](mailto:ashm@ashm.org.au)

[www.ashm.org.au](http://www.ashm.org.au)

### NAPWA – National Association of People Living with HIV/AIDS

National representative body for people living with HIV. HIV treatments advocacy, care and support (Centrelink, DSP, Medicare, PBS), education, international.

T: 02 8568 0300

E: [admin@napwaha.org.au](mailto:admin@napwaha.org.au)

[www.napwaha.org.au](http://www.napwaha.org.au)

### PozHet – Positive Heterosexuals

State-based support network for heterosexuals living with HIV and their families.

T: 1800 812 404

E: [pozhet@pozhet.org.au](mailto:pozhet@pozhet.org.au)

[www.pozhet.org.au](http://www.pozhet.org.au)

### MHAHS – Multicultural HIV/AIDS and Hepatitis C Service

Bilingual/bicultural support, education information and referral for people from non-English-speaking backgrounds.

T: 02 9515 1234

E: [info@mhahs.org.au](mailto:info@mhahs.org.au)

[www.mhahs.org.au](http://www.mhahs.org.au)

### AFAO – Australian Federation of AIDS Organisations

National peak organisation representing HIV partnership organisations Australia-wide. HIV prevention, health promotion, policy development, international work.

T: 02 9557 9399

[www.afao.org.au](http://www.afao.org.au)

### The Kirby Institute

National research centre based at University of NSW. HIV epidemiology (statistics, trends, national and state surveillance data), clinical trials in HIV, hepatitis and sexually-transmissible diseases.

T: 02 9385 0900

[www.kirby.unsw.edu.au](http://www.kirby.unsw.edu.au)

### Centre for Social Research in Health

National research centre based at University of NSW. Social research into HIV, hepatitis and related diseases. Social, sexual and related factors affecting HIV transmission, gay men's sexual practices.

T: 02 9385 6776

E: [csr@unsw.edu.au](mailto:csr@unsw.edu.au)

[www.csrh.arts.unsw.edu.au](http://www.csrh.arts.unsw.edu.au)

### Australian Capital Territory

#### AIDS Action Council of the ACT

T: 02 6257 2855

E: [support@aidsaction.org.au](mailto:support@aidsaction.org.au)

[www.aidsaction.org.au](http://www.aidsaction.org.au)

### New South Wales

#### PositiveLife NSW

T: 02 9206 2177 or 1800 245 677

[www.positivelife.org.au](http://www.positivelife.org.au)

#### ACON – AIDS Council of NSW

T: 02 9206 2000

E: [acon@acon.org.au](mailto:acon@acon.org.au)

[www.acon.org.au](http://www.acon.org.au)

#### NUAA – NSW Users and AIDS Association

T: 02 8354 7300

E: [nuaa@nuaa.org.au](mailto:nuaa@nuaa.org.au)

[www.nuaa.org.au](http://www.nuaa.org.au)

#### HALC – HIV/AIDS Legal Centre

T: 02 9206 2060

E: [halc@halc.org.au](mailto:halc@halc.org.au)

[www.halc.org.au](http://www.halc.org.au)

### Queensland

#### Queensland Positive People

T: 07 3013 5555 or 1800 636 241

[www.qpp.net.au](http://www.qpp.net.au)

## South Australia

### Positive Life SA

T: (08) 8293 3700

[www.hivsa.org.au](http://www.hivsa.org.au)

## Tasmania

### tasCAHRD – Tasmanian Council on AIDS, hepatitis and related diseases

T: 03 6234 1242 or 1800 005 900

[www.tascahrd.org.au](http://www.tascahrd.org.au)

## Victoria

### Positive Living Victoria

T: 03 9863 8733

[www.livingpositivevictoria.org.au](http://www.livingpositivevictoria.org.au)

## Western Australia

### WA AIDS Council

Tel: 08 9482 0000

E: [waac@waaidsonline.com](mailto:waac@waaidsonline.com)

[www.waaidsonline.com](http://www.waaidsonline.com)

### WA NAPWAH Representatives

E: [wanapwhareps@napwha.org.au](mailto:wanapwhareps@napwha.org.au)

## Key hospital and health centres

It is recommended that community pharmacists contact the person's previous supply hospital pharmacy should they have queries or concerns.

In addition the HIV specialist pharmacists in these organisations are willing to be contacted by community pharmacists to answer enquiries and offer advice.

NEW SOUTH WALES		
Pharmacy or health centre	Location	Telephone
Albion Centre Pharmacy	Surry Hills	02 9332 9650
Royal Prince Alfred Hospital	Camperdown	02 9515 8398
St Vincent's Hospital	Darlinghurst	02 8382 2594
Western Sydney Sexual Health Centre	Parramatta	02 9843 3135
VICTORIA		
Pharmacy or health centre	Location	Telephone
Alfred Health	Prahran	03 9076 2061
Melbourne Sexual Health Centre	Carlton	03 9341 6204
Monash Medical Centre	Clayton	03 9594 2360
QUEENSLAND		
Pharmacy or health centre	Location	Telephone
Royal Brisbane and Women's Hospital	Herston	07 3636 8111

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# Appendices

## Appendix 1. Summary of currently available HIV medicines in Australia

MECHANISM OF ACTION	MEDICINE NAMES AND ABBREVIATIONS		CO-FORMULATION AND BOOSTED MEDICINES					FIXED-DOSE COMBINATIONS			
			Combivir	Kivexa	Kaletra	Trizivir	Truvada	Atripla	Eviplera	Stribild	Triumeq
Reverse transcriptase inhibitors • Nucleoside reverse transcriptase inhibitors (NRTIs) • Nucleotide reverse transcriptase inhibitors (NtRTIs)	abacavir	ABC		×		×					×
	emtricitabine	FTC					×	×	×	×	
	lamivudine	3TC	×	×		×					×
	tenofovir	TDF					×	×	×	×	
	zidovudine	AZT	×			×					
	stavudine	d4T									
	didanosine	ddl									
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	efavirenz	EFV						×			
	etravirine	ETR									
	nevirapine	NVP									
	rilpivirine	RPV							×		
Protease inhibitors (PIs)	atazanavir/r	ATC									
	darunavir/c	DRV									
	fosamprenavir	FPV									
	lopinavir/r	LPV			×						
	tipranavir	TPV									
	saquinavir	SQV									
Binding inhibitor	maraviroc	MVC									
Fusion/entry inhibitor	enfuvirtide	T-20									
Integrase inhibitors (INSTIs)	dolutegravir	DTG									×
	elvitegravir	EVG								×	
	raltegravir	RAL									
Pharmacokinetic boosters	ritonavir	r			×						
	cobicistat	COBI								×	

Adapted from AMH online, eMIMS

Note: /r indicates boosted with ritonavir and /c indicates boosted with cobicistat.

## Appendix 2. Drug reactions, side effects and toxicities and special monitoring

DRUG CLASS	DRUGS IN CLASS	SIGNIFICANT TOXICITIES, INTERACTIONS AND SIDE EFFECTS	PRACTICE POINT
Nucleoside reverse transcriptase inhibitors (NRTIs)  Nucleotide reverse transcriptase inhibitors (NtRTIs)	Across class: enlarged, fatty liver and lactic acidosis are rare and seen less commonly with newer medicines		
	abacavir	<ul style="list-style-type: none"> <li>Hypersensitivity reaction</li> <li>Elevated risk of myocardial infarction (MI)</li> <li>Screen for HLAB5701 allele and do not use in those who test positive</li> </ul>	<ul style="list-style-type: none"> <li>If signs of hypersensitivity occur including flu-like symptoms, rash, diarrhoea, stop taking this medicine as symptoms will become worse with successive doses</li> </ul>
	emtricitabine	<ul style="list-style-type: none"> <li>Usually well tolerated</li> <li>In people with hepatitis B, can cause a hepatitis B flare when stopped</li> </ul>	<ul style="list-style-type: none"> <li>Check if person has hepatitis B</li> <li>Stop treatment immediately if lactic acidosis develops</li> </ul>
	lamivudine	<ul style="list-style-type: none"> <li>Usually well tolerated</li> <li>In people with hepatitis B, can cause a hepatitis B flare when stopped</li> </ul>	<ul style="list-style-type: none"> <li>Check if person has hepatitis B</li> </ul>
	tenofovir	<ul style="list-style-type: none"> <li>Usually well tolerated, but can cause acute kidney injury, proximal tubulopathy proteinuria</li> <li>Can exacerbate decrease in bone mineral density</li> <li>In people with hepatitis B, can cause a hepatitis B flare when stopped</li> </ul>	<ul style="list-style-type: none"> <li>Enquire about kidney function</li> <li>Check if person has hepatitis B</li> </ul>
	zidovudine	<ul style="list-style-type: none"> <li>Lipoatrophy, anaemia and neutropenia</li> <li>Flu-like symptoms</li> </ul>	<ul style="list-style-type: none"> <li>Report flu-like symptoms. Nausea and headaches are common on initiation</li> </ul>
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	<ul style="list-style-type: none"> <li>Across class: mild rash is common</li> <li>Severe rash can occur and needs medical attention</li> </ul>		
	efavirenz	<ul style="list-style-type: none"> <li>Central nervous system (CNS) adverse events include vivid dreams, insomnia</li> <li>Potential for teratogenicity but used after first 8 weeks of pregnancy</li> </ul>	<ul style="list-style-type: none"> <li>CNS side effects should dissipate with time but may persist in some people therefore always ask</li> <li>Take on empty stomach to reduce incidence of side effects</li> </ul>
	etravirine	<ul style="list-style-type: none"> <li>Rash and increased cholesterol. Skin or hypersensitivity, rarely peripheral neuropathy</li> </ul>	<ul style="list-style-type: none"> <li>Caution new people to watch for rash</li> </ul>
	nevirapine	<ul style="list-style-type: none"> <li>Can cause fatal hepatotoxicity early in treatment and potentially fatal hypersensitivity skin reactions</li> <li>More common in women and at high CD4 cell count</li> </ul>	<ul style="list-style-type: none"> <li>When starting therapy, take half a dose for 2 weeks then increase to full dose</li> <li>Watch for signs of rash during this time</li> </ul>
	rilpivirine	<ul style="list-style-type: none"> <li>Must take with food and an acid stomach environment. Do not dose with antacids or H2 antagonists and not to be co-administered with proton pump inhibitors (PPIs).</li> </ul>	<ul style="list-style-type: none"> <li>Must take with a substantial meal including solid foods for adequate absorption</li> </ul>
Protease inhibitors (PI) Boosted to give higher trough concentration, longer half-life and reduce pill burden.	<ul style="list-style-type: none"> <li>Across class: increased cholesterol, triglycerides and blood glucose. Gastrointestinal (GI) side effects include nausea and diarrhoea vomiting. Lipodystrophy, reduced bone mineral density, bleeding in people with bleeding disorders and rash especially with sulfur allergies.</li> </ul>		
	atazanavir	<ul style="list-style-type: none"> <li>Do not use with proton pump inhibitors (PPIs) and dose separately from H2 antagonists and antacids.</li> <li>Associated with increased risk of kidney stones and gallstones and unconjugated hyperbilirubinaemia</li> </ul>	<ul style="list-style-type: none"> <li>Alert person to possibility of slight yellowing of the eyes – this is normal and not dangerous</li> <li>Take with food to reduce possible gastrointestinal (GI) side effects</li> <li>Do not take with proton pump inhibitors (PPIs) and H2 antagonists no sooner than 12 hours after dose</li> </ul>
	darunavir	<ul style="list-style-type: none"> <li>People with sulfur allergy should be alerted to the potential for rash</li> </ul>	<ul style="list-style-type: none"> <li>Take with food to reduce possible gastrointestinal (GI) side effects</li> </ul>
	lopinavir	<ul style="list-style-type: none"> <li>Diarrhoea is most common</li> </ul>	<ul style="list-style-type: none"> <li>Take with food to reduce possible gastrointestinal (GI) side effects</li> </ul>
Binding inhibitors	maraviroc	<ul style="list-style-type: none"> <li>Hepatotoxicity, may be preceded by severe rash, systemic allergic reaction fever, eosinophilia, or elevated IgE. Other adverse events include upper respiratory tract infections (URTI), cough, pyrexia, rash, and dizziness. Heart problems particularly in those with history of heart disease</li> </ul>	<ul style="list-style-type: none"> <li>Many potential drug interactions therefore check co-administered medications carefully</li> </ul>
Fusion inhibitors	enfuvirtide	<ul style="list-style-type: none"> <li>Injection side effects most common</li> <li>Hypersensitivity possible</li> </ul>	<ul style="list-style-type: none"> <li>Stop taking and notify doctor immediately if a rash, fever and chills appear, feel dizzy or faint or have difficulty breathing</li> <li>Do not take again</li> </ul>
Integrase inhibitors (INSTIs)	dolutegravir	<ul style="list-style-type: none"> <li>Increase in creatinine, but this is an artefact and not associated with renal damage, flu-like symptoms. Do not take with antacid</li> </ul>	<ul style="list-style-type: none"> <li>Blocks creatinine secretion in the distal renal tubule by blocking the OCT4 pump on the basal membrane. It is not symptomatic of renal damage</li> </ul>
	elvitegravir	<ul style="list-style-type: none"> <li>Flu-like symptoms and elevated liver enzymes</li> </ul>	<ul style="list-style-type: none"> <li>Take with food</li> <li>Do not take with antacid</li> </ul>
	raltegravir	<ul style="list-style-type: none"> <li>Flu-like symptoms</li> <li>Rarely anaemia and neutropenia elevated ALT, AST and hyperbilirubinaemia, creatinine</li> <li>Resistance develops rapidly</li> </ul>	<ul style="list-style-type: none"> <li>Do not take with antacid</li> </ul>
Pharmacokinetic boosters	ritonavir (r)	<ul style="list-style-type: none"> <li>Considerable side effects at therapeutic doses but these are less significant when used as a booster</li> <li>A very potent CYP3A4 inhibitor and can cause many significant drug interactions</li> </ul>	<ul style="list-style-type: none"> <li>Take with meals</li> <li>Swallow tablets whole; do not break, chew or crush</li> </ul>
	cobicistat (c)	<ul style="list-style-type: none"> <li>Gastrointestinal (GI) effects</li> <li>Increased cholesterol, triglycerides and serum creatinine and decreased creatinine clearance</li> </ul>	<ul style="list-style-type: none"> <li>Not currently available as separate medicine</li> </ul>

Adapted from [www.hivdruginteractions.org](http://www.hivdruginteractions.org), ASHM antiretroviral guidelines, Immunodeficiency Clinic drug interaction tables and Positively Aware 19th Annual Drug Guide. This is not a complete summary and goes to source drugs only.

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