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anti-hiv drugs

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Revised by Rob Dawson
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The booklet has been written to help you decide what questions to ask your doctor about any course of treatment you might be considering. We don't intend for it to replace discussion with your doctor about your treatment.

This booklet is a starting point for anyone who wants to know about treatments for HIV and AIDS. It provides basic information about the drugs that fight HIV - known as antiretroviral drugs - and deals briefly with dosing, side-effects, drug interactions and drug resistance.

Information contained in this booklet has been reviewed by a panel of medical experts. For full details of side-effects and drug interactions, see the Product Information Leaflets which are produced by the drug manufacturers.

This information was correct at the time of going to press (January 2007). The booklet includes information on drugs which have been licensed in the UK or European Union.

contents

HIV and anti-HIV drugs 1

HIV is a virus which attacks the immune system - the body's defence system against infection and illness. If you have HIV, you can take drugs to reduce the level of HIV in your body. By reducing the amount of HIV in your body, you can slow or prevent damage to your immune system. These drugs are not a cure, but they can help you stay well and extend your life. Anti-HIV drugs are known as antiretroviral drugs.

How antiretroviral drugs work

HIV mainly infects cells in the immune system called CD4 cells. Over many years of HIV infection, the number of CD4 cells drops gradually but continually and the immune system is weakened. If nothing is done to slow or halt this destruction of the immune system, a condition called AIDS (Acquired Immune Deficiency Syndrome) follows as your immune system is no longer able to fight infections. Antiretroviral drugs work by interrupting this process.

The aim of treatment

An untreated person with HIV may have thousands or even millions of HIV particles in every millilitre of blood. The aim of treatment is to reduce the amount of HIV to very low levels - below 50 copies per millilitre of blood,

although some HIV treatment centres are now using tests that can measure as low as 40 copies per millilitre.

To provide you with the best chance of reducing the amount of HIV in your blood to very low levels, your doctor may recommend that you take a powerful combination of at least three antiretroviral drugs. Once your viral load - the amount of HIV in your blood - has dropped, your immune system should begin to recover and your ability to fight infections is likely to improve.

When to take treatment

There are many opinions about the best time to start taking antiretroviral therapy but there is no general rule that applies to everyone. Some people take treatment early on, before much damage is done to the immune system; others start later, when blood tests show they are likely to become sick in the near future. Some people wait until they are sick before taking antiretrovirals.

Your decision about when to start therapy should be made in consultation with your doctor. If you are getting persistent 'minor' infections, or if you have had an AIDS-defining illness, (e.g. PCP, a form of pneumonia), your immune system may already be seriously weakened. In this situation, your doctor

will strongly advise you to consider taking antiretrovirals.

If you have established HIV infection but have no symptoms, current guidelines recommend beginning therapy before your CD4 count falls below 200.

If your CD4 count is between 200 and 350 it is recommended that you consider starting therapy. In such circumstances you should use your recent viral load measurements and the number of CD4 cells you have been losing to guide your decision.

The final decision about when to begin treatment rests with you. Social factors such as family, plans to start a family, relationships, work and travel may influence your decision.

For more information, see the booklet *hiv therapy* in this booklet series.

Sticking to your drug routine

Taking antiretroviral therapy is a long-term commitment. Once you start the drugs, it is recommended that you continue treatment for the rest of your life.

It is very important not to miss doses and to take the drugs exactly as prescribed. If you miss doses, or you do not take the drugs as you are supposed to, the HIV in your body is more likely to develop resistance to the drugs. This will reduce their long-term effectiveness.

If you are having difficulty sticking to your drug routine, discuss alternative combinations that may be easier to take with your doctor. There are many tips and aids which may improve your ability to take your drugs as required. For more information, speak to your healthcare team, or visit NAM's website **aidsmap.com**.

Further information can also be found in the booklets a*dherence* and *resistance* that form part of this series and are produced by NAM.

Regular check-ups

If you have HIV, you should see a doctor regularly for a check-up. Most people with HIV attend GUM clinics or specialist HIV clinics which have doctors and other health professionals trained in HIV and AIDS. Even if you do not want to take treatments at this stage, regular blood tests will tell you how the disease is progressing.

If you are entitled to free NHS care, antiretroviral drugs provided through NHS HIV clinics and GUM clinics are free.

Monitoring

Before you start on antiretrovirals, or before you switch to a new combination, you should have a number of blood tests. Viral load and CD4 tests will tell you how advanced your HIV disease is. Once you have begun treatment, tests to measure liver function and fat and sugar levels in the blood may be conducted to assess the effects of the drugs on the normal workings of your body. Your doctor may also test to see if the HIV has developed resistance to any of the antiretroviral drugs. Some clinics also do a genetic test (called HLA*B5701) to see if you may be more likely to develop an allergic reaction to one of the anti-HIV medicines ('abacavir hypersensitivity reaction'). The accuracy of this test seems to be highest in people of white ethnicity.

Once you are on a new combination, a viral load and CD4 count will be done within the first month of treatment. This is to check that the drugs are working. Testing is generally performed every three months, although some doctors may perform tests more regularly to begin with and less often once you are well established on treatment and doing well.

For more information, see the booklet *viral load & CD4* that forms part of this series and is produced by NAM.

Pregnancy

Combinations of antiretrovirals are now commonly used during pregnancy as an effective means of preventing the transmission of HIV from a mother to her baby. Although the long-term effects on the child are not yet clear, the benefits of treatment in greatly reducing the chances of them being infected are believed to outweigh any potential risks. Generally, anti-HIV drugs are not recommended during the first three months of pregnancy unless the woman is already on treatment.

As a woman's health improves on antiretrovirals, her fertility may also increase. It is recommended that women considering pregnancy, or women who may conceive, discuss their treatment options with their doctor before conceiving. One reason for this is that some anti-HIV medicines (e.g. efavirenz, *Sustiva*) are not generally recommended for women who are planning a pregnancy. You should tell your HIV doctor or another member of your healthcare team immediately if you become pregnant. The contraceptive pill is less effective in women on many of the anti-HIV drugs due to drug interactions.

There is no evidence that a father's treatment increases the risk of birth defects.

For more information, see the booklets *hiv and children* and *hiv and women* that form part of this series and are produced by NAM.

Side-effects

It is very common for people to experience side-effects to antiretroviral therapy, especially during the first few weeks of treatment. Your doctor can prescribe a number of drugs to help you cope with this initial period.

Common side-effects of many medications include headache, nausea, diarrhoea, and tiredness. Report side-effects, especially rash and fever, to your doctor promptly.

In this booklet, we have listed as common side-effects anything which affected more than 1% of people in clinical trials of a drug, and which are therefore likely to be side-effects of the drug.

There may be other side-effects which can develop after taking mediction for a number of years. These are called long-term side-effects. Your doctor will monitor your progress once you have started treatment to see if these are occurring.

Drug interactions

Taking two or more different drugs together may result in an alteration in the effectiveness (or toxicity) of one or more of the drugs being taken. Some prescription drugs and some drugs which you buy over the counter at the pharmacist should not be taken in combination with certain antiretrovirals. This booklet lists the key drug interactions for antiretroviral drugs.

Some antiretroviral drugs lower or increase levels of other antiretroviral drugs. Some antiretroviral drugs interact with other medicines commonly used in the treatment of HIV.

Some drug combinations are contraindicated - which means you definitely should not take them together. Reasons for this include serious toxicity and interactions which make one or both drugs ineffective.

Other interactions are less serious. Levels of one or both drugs in your blood may be affected and dosing adjustments may be required.

Some drug interactions may mean that you have a greater chance of developing certain side-effects such as peripheral neuropathy.

Less is known about interactions with recreational drugs. However, if you use recreational drugs, it is sensible to discuss this with your doctor, HIV pharmacist or other healthcare provider. Protease inhibitors are the class of antiretrovirals most likely to interact with recreational drugs, though interactions with both NRTIs and NNRTIs and recreational drugs have been described.

Antiretrovirals can also interact with herbal and alternative treatments. It is known that the herbal antidepressant St John's wort lowers blood levels of both NNRTIs and protease inhibitors. Garlic capsules stop the protease inhibitor saquinavir (*Invirase*) from working properly and it is thought that they could have a similar effect on other protease inhibitors as well. Test tube studies have recently indicated that African potato and *Sutherlandia*, two herbs widely used to treat HIV in Africa, interfere with the body's ability to process protease inhibitors and NNRTIs.

Interactions can even happen with medicines that are not taken by mouth. For example, ritonavir (*Norvir*) can interact with inhalers and nasal sprays containing fluticasone (e.g. *Flixotide, Seretide*, and *Flixonase*) causing serious side-effects.

To help increase the chances of all your drugs working effectively and to minimise the possibility of side-effects, make sure you tell your clinic doctor and HIV pharmacist about **all** the medicines that you are taking. Also check before taking anything new (whether you buy it yourself or have it prescribed by a doctor or dentist).

What's in a name?

Pharmaceutical drugs are given several names:

- First, a research name based on its chemical make-up or manufacturer, e.g. DMP266.
- Second, a generic name which is common to all pharmaceuticals with the same chemical make-up, e.g. efavirenz.
- Third, a brand name for a formulation which belongs to a particular company. A brand name starts with a capital letter and is generally written in italics, e.g. *Sustiva*.

This booklet lists all three names at the start of a drug entry. The most common name for each drug is used in the text.

Types of antiretroviral drugs

There are five main types of antiretroviral drugs:

- nucleoside analogue reverse transcriptase inhibitors (NRTIs), which target an HIV protein called reverse transcriptase.
- nucleotide analogue reverse transcriptase inhibitors (NtRTIs), which target reverse transcriptase in a similar way to NRTIs.
- non-nucleoside reverse transcriptase inhibitors (NNRTIs), which also target reverse transcriptase, but in a different way to NRTIs and NtRTIs.
- protease inhibitors (PIs), which target an HIV protein called protease.
- fusion inhibitors, which target the point where HIV binds onto cells of the immune system.

Each class of drug attacks HIV in a different way. Generally drugs from two (or sometimes three) classes are combined to ensure a powerful attack on HIV.

12 Where antiretrovirals block HIV

fusion
Fusion inhibitors work here by targeting the point where HIV locks onto an immune cell.

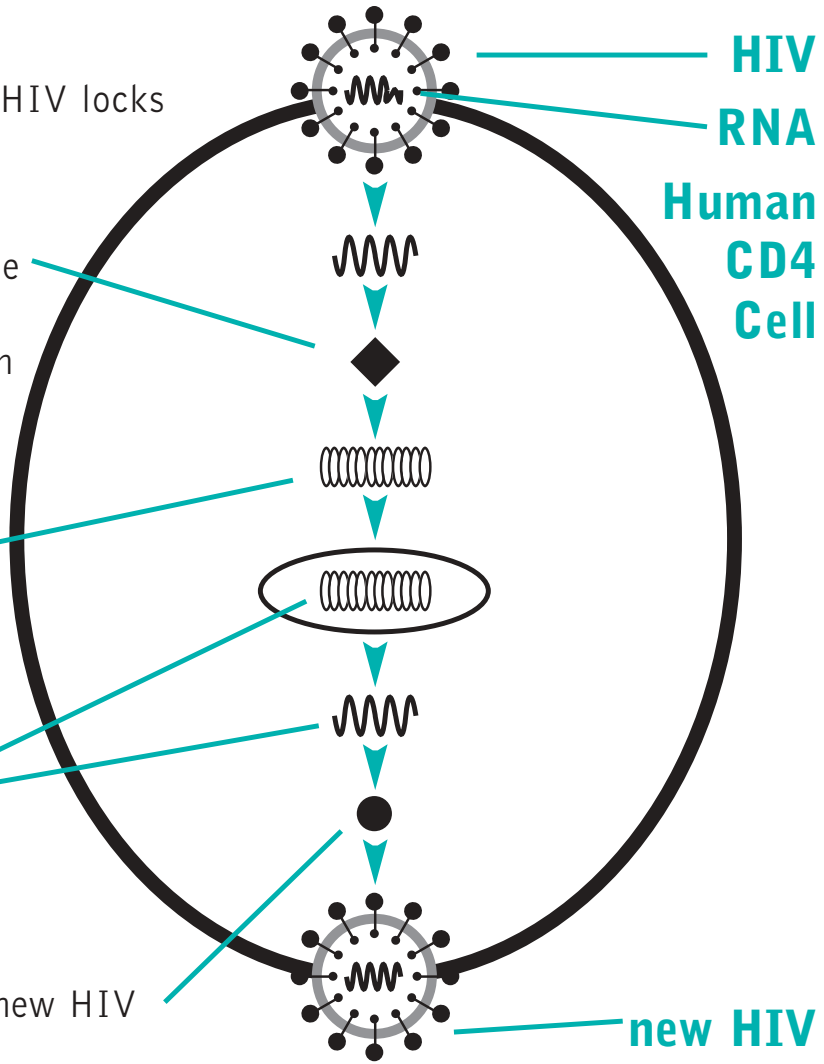
reverse transcription (reverse transcriptase)
Non-nucleoside reverse transcriptase inhibitors, nucleoside analogue reverse transcriptase inhibitors and nucleotide analogue reverse transcriptase inhibitors work here. When HIV has entered the cell, it uses reverse transcriptase to convert itself into viral DNA.

viral DNA
When HIV has entered the cell it uses reverse transcriptase to convert itself into viral DNA.

integration
Viral DNA is inserted into human DNA in the nucleus.

transcription and translation
New viral material.

viral assembly
Protease inhibitors work here. Protease is used to make new HIV from viral material made in the nucleus.



Nucleoside analogue reverse transcriptase inhibitors (NRTIs)

NRTIs are normally the basis or 'backbone' of any anti-HIV drug combination. NRTIs may also be called nukes. The NRTIs are:

- 3TC, lamivudine, *Epivir*
- abacavir, *Ziagen*
- AZT, zidovudine, *Retrovir*
- *Combivir*, (3TC and AZT)
- *Kivexa* (abacavir and 3TC)
- *Trizivir,* (3TC, AZT and abacavir)
- d4T, stavudine, *Zerit*
- ddI, didanosine, *Videx, Videx EC*
- FTC, emtricitabine, *Emtriva*

Common dual combinations of NRTIs that are used as a part of three or four drug combinations are: AZT/3TC (often given as a combined pill called *Combivir* and 3TC/abacavir (often given in a combined pill called *Kivexa*). Combinations that should be avoided are: d4T/AZT and d4T/ddI. The combination of ddI with the nucleotide analogue tenofovir should only be taken in exceptional circumstances and avoided whenever possible.

The nucleoside analogue FTC (emtricitabine) is often used in

combination with the nucleotide analogue tenofovir (often given in a combined pill called *Truvada*).

Trizivir is a combination tablet containing three nucleoside analogues (AZT, 3TC, abacavir).

Nucleotide analogue reverse transcriptase inhibitors (NtRTIs)

Nucleotide analogues also work against reverse transcriptase, and are usually used in place of an NRTI in a three-drug combination. One nucleotide analogue is approved in the UK:

- tenofovir, *Viread*.

Tenofovir is also available in a combination tablet with the nucleoside analogue FTC (emtricitabine, *Emtriva*) called *Truvada*.

Non-nucleoside reverse transcriptase inhibitors (NNRTIs)

An NNRTI is often taken with two NRTIs, or an NRTI and tenofovir, as first line HIV therapy. NNRTIs may also be called 'non-nukes'.

Two NNRTIs are currently approved for use in the UK:

- efavirenz, *Sustiva*
- nevirapine, *Viramune*

Protease inhibitors (PIs)

The protease inhibitors in current use are:

- atazanavir, *Reyataz*
- fosamprenavir, *Telzir*
- indinavir, *Crixivan*
- lopinavir/ritonavir, *Kaletra*
- nelfinavir, *Viracept*
- ritonavir, *Norvir*
- saquinavir, *Invirase*
- tipranavir, *Aptivus*

People who choose to take a combination containing a protease inhibitor often take a protease inhibitor 'boosted' by a small dose of ritonavir, or an NRTI and tenofovir, as well as taking two NRTIs. Common 'boosted' protease inhibitors are: lopinavir/ritonavir (the only boosted protease inhibitor combination medicine), fosamprenavir/ritonavir, saquinavir/ritonavir, atazanavir/ritonavir, indinavir/ritonavir and tipranavir/ritonavir. Darunavir/ritonavir will be licensed in the early spring of 2007 and until then it will only be available on expanded access schemes.

Other combinations may include one or two protease inhibitors, one NNRTI, and one or two NRTIs. If a person's initial combination has not worked, some doctors may recommend a combination of four or more antiretrovirals.

Fusion inhibitors

Fusion inhibitors stop HIV from binding to and entering the human cell. One fusion inhibitor called T20 (enfuvirtide, *Fuzeon*) has been approved and is given by a subcutaneous injection (similar to the way diabetics inject insulin). It is only available to people who have been extensively pre-treated with other anti-HIV drugs and have very limited treatment options available to them.

- T-20, enfuvirtide, *Fuzeon*

3TC

Names: 3TC, lamivudine, *Epivir*

Approved dosage: 300mg daily, either as one white 150mg tablet twice a day or two white 150mg tablets once a day or one larger grey 300mg tablet once a day. The dose may be altered if you have impaired kidney function. Also available in a combined form with AZT called *Combivir* and in a combined form with AZT and abacavir called *Trizivir*. 3TC and abacavir are also available in a combined formulation called *Kivexa*. *Combivir* and *Trizivir* are both taken as one tablet twice a day and *Kivexa* is taken as one tablet once a day.

Children: approved for use in children. Liquid suspension available.

Tips on taking it: take with or without food.

Common side-effects: nausea, vomiting, abdominal pain, diarrhoea, headache, muscle pains, cough, nasal symptoms, fever, tiredness, rash, hair loss and difficulty sleeping.

Rare side-effects include: blood disorders, peripheral neuropathy and liver problems.

Resistance to 3TC: may affect your response to abacavir. Drug-resistant 3TC may continue to have an antiviral effect.

People who have virus resistant to 3TC are unlikely to respond to FTC.

Key drug interactions: few significant drug interactions. Any drug that causes neutropenia may increase side-effects. 3TC should not be taken with intravenous foscarnet or, theoretically, ganciclovir.

abacavir

Names: abacavir, *Ziagen*

Approved dosage: 600mg daily, either as one 300mg yellow tablet twice daily or two 300mg tablets once a day. Also available in a combined form with AZT and 3TC (*Trizivir*, taken as one tablet twice daily). Abacavir and 3TC are also available in a combined formulation called *Kivexa*. The combined *Kivexa* pill contains 600mg of abacavir and 300mg of 3TC and the dose is one tablet taken once daily.

Children: liquid formulation available.

Tips on taking it:
take with or without food.

Common side-effects: nausea and vomiting, diarrhoea, headaches, high temperature, fatigue and loss of appetite.

Special warning: An allergic reaction (often involving fever and rash) occurs in approximately 5% of people taking abacavir, usually within four weeks of

starting the drug. See your doctor immediately if you develop a rash, fever, shortness of breath or abdominal pain while on abacavir. You should not re-try abacavir, or take *Trizivir* or *Kivexa* if you have had an allergic reaction to abacavir previously. Many clinics now conduct a genetic test to see if a person is likely to have an allergic reaction to abacavir.

Rare side-effects include: inflammation of the pancreas.

Resistance to abacavir: may affect your response to AZT, 3TC, ddI and possibly tenofovir.

Key drug interactions: no significant drug interactions yet identified.

Brain: abacavir may cross the blood-brain barrier and may be effective against HIV in the brain.

Kivexa

Abacavir and 3TC are available in a combined form called *Kivexa*. The dosage of *Kivexa* is one orange tablet (600mg abacavir and 300mg 3TC) once a day. See the entries for abacavir and 3TC for side-effects and further information.

AZT

Names: AZT, zidovudine, *Retrovir*

Approved dosage: one white and blue 250mg capsule taken twice a day.

A 100mg capsule is available for dose variations.

Children: approved for use in children. Liquid formulation available.

Tips on taking it: take with or after food to reduce nausea. Anti-nausea drugs may be used up-front in the first few weeks.

Common side-effects: nausea, dizziness, vomiting, abdominal pain, diarrhoea, muscle aches, headache, blood disorders and breathing problems.

Rare side-effects include: liver problems and insomnia.

Resistance to AZT: is likely to cause resistance to d4T and possibly also to abacavir and tenofovir.

Key drug interactions: other drugs (e.g. hydroxyurea, ganciclovir) that cause blood disorders (i.e. anemia) may worsen side-effects. Do not take with d4T. Drug levels may be affected if methadone, phenytoin, or probenecid are taken with AZT. Doses of clarithromycin and AZT should be taken one hour apart.

Brain: AZT is effective against HIV in the brain and the central nervous system.

Combivir

AZT is also available in a combined form with 3TC called *Combivir*. Dosage of *Combivir* is one white tablet (150mg 3TC and 300mg AZT) twice a day. See

the entries for AZT and 3TC for side-effects and further information.

Trizivir

AZT is also available in a combined form with 3TC and abacavir called *Trizivir*. Dosage of *Trizivir* is one green tablet (300mg AZT, 150mg 3TC and 300mg abacavir) taken twice a day. See the entries for AZT, 3TC and abacavir for side-effects and further information.

d4T

Names: d4T, stavudine, *Zerit*, *Zerit PRC*

Approved dosage: for people over 60kg (9 1/2 stone): one dark orange 40mg capsule twice a day; for people under 60kg: usually one light and dark orange 30mg capsule twice a day. Note: people with impaired kidney function or peripheral neuropathy may take 15 or 20mg twice a day. d4T is available as 40mg, 30mg, 20mg and 15mg capsules.

Zerit PRC is approved for once-daily dosing but is not available in the UK. The dose for people weighing over 60kg is 100mg, and for people weighing less than 60kg, 75mg a day.

Children: approved for use in children. d4T comes in a powder form which is made into a liquid.

Tips on taking it: although the product information advises taking d4T on an empty stomach, this does not affect absorption of the drug and it is possible to take with or without food. However, taking it with food reduces nausea.

Common side-effects: peripheral neuropathy, headache, nausea, diarrhoea or constipation, lipodystrophy, fatigue, depression and rash.

Rare side-effects include: pancreatitis and liver problems.

Resistance to d4T: likely to cause resistance to AZT.

Key drug interactions: do not take with AZT or ddI. Drugs that may cause peripheral neuropathy or pancreatitis (e.g. ddI) may increase the risk of these side-effects.

Brain: d4T crosses the blood-brain barrier and may be effective against HIV in the brain.

ddI (*Videx*)

ddI is available in two formulations, as a tablet and capsule. Advice on taking ddI differs depending upon which formulation you are taking, so it is very important to check that you are following the correct advice.

Names: ddI, didanosine, *Videx*

Approved dosage: for people over 60kg (9 1/2 stone): two white, orange-flavoured 200mg tablets once daily; for people under 60kg: one large white, orange-flavoured 200mg tablet plus two large white, orange flavoured 25mg tablets once daily. Note: people who have kidney or liver abnormalities may be advised by their doctor to take a lower dose.

Children: approved for use in children. Liquid formulation available (not licensed in the UK).

Tips on taking it: take on an empty stomach to maximise the amount of ddI that gets into your blood. Take ddI tablets or liquid at least two hours after eating and wait another half an hour before eating again. During this fasting period avoid fruit juices (except clear apple juice), fizzy drinks and milk. Smoking may also reduce the absorption of ddI. Crush and dissolve ddI tablets in ice-cold water or clear apple juice. If you take a dose first thing in the morning, dissolve your dose the night before and leave in the fridge. Pill-crushers are available from pharmacies.

Common side-effects: diarrhoea, peripheral neuropathy, rash, fatigue, nausea, vomiting and abdominal pain.

Rare side-effects include: pancreatitis (greater risk if you have high alcohol consumption) and liver problems.

Resistance to ddI: low risk of resistance to ddC, 3TC and abacavir.

Key drug interactions: ddI tablets should be taken at least two hours apart from any medicines which carry the warning 'not to be taken at the same time of day as indigestion remedies', as the effectiveness of these other medicines may be reduced. Examples of drugs which should not be taken at the same time as ddI tablets are atazanavir, itraconazole, ketoconazole, indinavir, ciprofloxacin, valganciclovir, tetracycline antibiotics and delavirdine (an NNRTI, not licensed in the UK). Do not take with allopurinol or intravenous pentamidine. Drugs such as H2 blockers, omeprazole, rifampicin, and rifabutin may increase the risk of pancreatitis. ddI tablets should not be taken at the same time of day as some other medications. For example, ddI tablets and protease inhibitors must be taken at least one hour apart. Tenofovir increases ddI levels and they should only be taken in combination with ddI if no other options are available. If you do need to take ddI and tenofovir, you should be very closely monitored by your clinic. In this case the ddI dose will usually be

reduced (250mg for weight >60kg, 200mg for weight <60kg) and the ddI and tenofovir can be taken together, with or without food.

When taken with hydroxyurea, the amount of active ddI in cells increases. Hydroxyurea may therefore both improve the effectiveness of ddI and increase the risk of side-effects, but is not licensed for use in this way (and is not generally recommended).

ddI EC(*Videx EC*)

Names: ddI EC capsules, didanosine enteric coated, *Videx EC*

Approved dosage: for people over 60kg (9 1/2 stone): one 400mg white capsule once a day, or one 200mg capsule twice a day; for people under 60kg: one 250mg capsule once a day or one 125mg capsule twice daily. Note: people who have kidney or liver abnormalities may be advised by their doctor to take a lower dose.

Children: ddI EC is approved for use in children.

Tips on taking it: take with water on an empty stomach to maximise the amount of ddI EC that gets into your blood. Take ddI EC capsules at least two hours before and at least two hours after food. Some people find taking the capsules

before bedtime may be most convenient. During this fasting period avoid all liquids except water. It is okay to take ddI EC at the same time as other antiretrovirals, including indinavir, so long as they do not need to be taken with food. ddI EC does not interact with medicines that should not be taken at the same time as indigestion remedies.

Common side-effects: diarrhoea, peripheral neuropathy, rash, fatigue, nausea, vomiting and abdominal pain.

Rare side-effects include: pancreatitis and liver problems.

Resistance to ddI: low risk of resistance to 3TC and abacavir.

FTC (emtricitabine, *Emtriva*)

Names: FTC, emtricitabine, *Emtriva*

Approved dosage: one blue and white 200mg capsule once a day. Note: people who have kidney abnormalities may be advised by their doctor to take a lower dose.

Children: approved for use by children aged four months and over.

Tips on taking it: can be taken with or without food.

Common side-effects: headache, diarrhoea, nausea, increased creatine kinase in the blood leading to muscle pain and weakness, dizziness, difficulty

sleeping, problems with digestion, rash, changes in skin colour, changes in the blood and disturbance of function of the liver, kidney and pancreas.

Rare side-effects include: reduced kidney and liver function, lactic acidosis.

Resistance to FTC: unlikely to be beneficial for people who are already resistant to 3TC or abacavir.

Truvada

FTC (emtricitabine) is also available in a combined pill with the nucleotide analogue, tenofovir. The FTC/tenofovir pill is called *Truvada* . The dose is one blue tablet (200mg FTC and 300mg tenofovir) once a day. For side-effects see the entries for FTC and tenofovir.

28 Non-nucleoside reverse transcriptase inhibitors (NNRTIs)

efavirenz

Names: efavirenz, *Sustiva*

Approved dosage: one dark yellow 600mg tablet once a day or three dark yellow 200mg capsules once a day.

Children: approved for use in children aged three years and above, who weigh more than 13kg. Oral solution available (but note that the dose of the solution is different from the dose of the tablets or capsules).

Tips on taking it: recommended to take on an empty stomach. Avoid taking it with a high fat meal which may increase absorption. If efavirenz causes confusion or dizziness, take before going to bed.

Common side-effects: dizziness, headache, sleep disturbances, abdominal pain, diarrhoea, nausea, vomiting, rash and psychological effects (most common during the first four weeks of treatment and include feeling 'out of sorts', confusion, abnormal dreams, disturbance in attention, and depression).

Rare side-effects include: Stevens-Johnson Syndrome (very rare), disturbance in liver function tests, aches and pains, and psychological symptoms including paranoia and suicidal thoughts.

Resistance to efavirenz: is likely to cause resistance to delavirdine (an NNRTI that is not licensed for use in the UK) and nevirapine.

Key drug interactions: alters blood levels of protease inhibitors. May interfere with oral contraceptives. Do not take efavirenz with unboosted hard gel saquinavir (i.e. without ritonavir), St John's wort, clarithromycin, terfenadine, astemizole, cisapride, triazolam, rifampicin and midazolam. Drug levels may be affected if taken with *Viagra*, *Cialis*, *Levitra*, *Zyban* or rifabutin.

Brain: efavirenz crosses the blood-brain barrier and has some action against HIV in the brain and the central nervous system.

Pregnancy: efavirenz is not recommended during pregnancy or in women planning pregnancy.

nevirapine

Names: nevirapine, *Viramune*

Approved dosage: one white 200mg tablet once a day for the first two weeks and then one 200mg tablet twice a day thereafter. Men should not start treatment with nevirapine if their CD4 cell count is above 400, women should not start treatment with nevirapine if their CD4 cell count is above 250 as this increases the risk of potentially dangerous side-effects.

Experimental dosage: two white 200mg tablets once a day. This is not normally recommended within the first two months of taking nevirapine.

Children: syrup available.

Tips on taking it:
take with or without food.

Common side-effects: headache, rash, fatigue, liver problems, muscle pain and nausea.

Rare side-effects include:
Stevens-Johnson Syndrome.

Resistance to nevirapine: is very likely to cause resistance to delavirdine (an NNRTI that is not licensed in the UK) and efavirenz.

Key drug interactions: drug levels may be affected if nevirapine is taken with a number of drugs including atazanavir, indinavir, lopinavir/ritonavir, ketoconazole, *Cialis*, *Viagra*, *Levitra*. Nevirapine may reduce the effectiveness of oral contraceptives. Drugs that may worsen side-effects are clarithromycin, and erythromycin. Do not take with St John's wort.

Brain: nevirapine crosses the blood-brain barrier and has some action against HIV in the brain and central nervous system.

tenofovir

Names: tenofovir, *Viread*

Approved dosage: One blue, almond shaped film-coated 300mg tablet daily. Dose may be adjusted if kidney function is impaired.

Tips on taking it: take with food, to increase absorption.

Common side-effects: dizziness, diarrhoea, nausea, vomiting, flatulence and changes in blood phosphates.

Rare side-effects include: pancreatitis and rash. Longer-term side-effects of tenofovir are not yet established, however there are some reports of kidney toxicities (particularly in people who are on other medicines that can affect the kidneys, or those who have had previous kidney problems). Creatinine monitoring advised to spot kidney damage, especially in patients with impaired kidney function.

Resistance to tenofovir: may cause resistance to ddI.

Key drug interactions: tenofovir increases levels of ddI.

Truvada

Tenofovir is also available in a combined pill with the nucleoside analogue, FTC (emtricitabine). The tenofovir/FTC pill is

called *Truvada*. The dose is one blue tablet (300mg tenofovir and 200mg FTC) once a day. For side-effects and further information, see the entries for FTC and tenofovir.

atazanavir

Names: atazanavir, *Reyataz*

Approved dosage: 300mg (two light and dark blue 150mg capsules) plus one cream 100mg ritonavir capsule taken together once a day. If the combination also contains efavirenz or nevirapine the dose is 400mg (two turquoise 200mg capsules) plus one 100mg ritonavir capsule taken together once a day.

Tips on taking it: take with a snack to improve absorption.

Common side-effects: peripheral neuropathy, headache, insomnia, jaundice, vomiting, diarrhoea, abdominal pain, nausea, indigestion, rash, lipodystrophy, tiredness.

Rare side-effects include: abnormal liver function and pancreatitis.

Resistance to atazanavir: there is conflicting evidence. Early studies suggested that atazanavir would be effective in people resistant to other protease inhibitors. However, more recent evidence shows that as many as 40% of people who had previously used a protease inhibitor would have reduced sensitivity to the drug. This is one of the reasons why it is recommended to boost atazanavir levels with ritonavir.

Key drug interactions: when taken with efavirenz or tenofovir, levels of atazanavir drop. However, adding 100mg of ritonavir counters this. Take ddI tablets at least two hours before or one hour after atazanavir (not necessary if taking *Videx EC* capsules). Doses of the anti-TB drug rifabutin should be reduced by 75%. Reduce doses of clarithromycin by half if taken at the same time as atazanavir. Reduce doses of *Cialis, Viagra*, or *Levitra* by half. Don't take with St John's wort. Don't take antacids within four hours of atazanavir. Don't take lansoprazole, omeprazole, rifampicin, phenytoin, carbamazepine, or simvastatin with atazanavir.

fosamprenavir

Names: fosamprenavir, *Telzir*

Note: fosamprenavir is a pro-drug of amprenavir, which means that it is converted into amprenavir in the body.

Approved dosage: one pink 700mg tablet with one cream 100mg ritonavir capsule twice daily.

Tips on taking it:
take with or without food.

Common side-effects: diarrhoea, increased blood fats, nausea, vomiting, pain in the stomach, loose stools, rash, headache, feeling dizzy, tiredness, changes in liver and pancreas function.

Rare side-effects include: changes in cholesterol levels,
Stevens Johnson Syndrome

Resistance to fosmaprenavir: is likely to cause resistance to ritonavir, and possibly also to saquinavir, indinavir and nelfinavir.

Key drug interactions: astemizole, terfenadine, pimozide, cisapride, ergot derivatives, rifampicin, amiodarone, quinidine, flecainide, propafenone, bepridil and St John's wort. Dose adjustments may be required when fosamprenavir is taken with lidocaine, rifabutin, clarithromycin, dapsone, erythromycin, ketoconazole, itraconazole, halofantrine, carbamazepine, phenytoin, phenobarbital, atorvastatin, lovastatin, simvastatin, *Viagra, Cialis, Levitra, Zyban*, efavirenz, nevirapine, methadone, oestrogens, progestogens, fluticasone propionate, budesonide, desipramine, nortriptyline, benzodiazepines, midazolam, triazolam and clozapine. If you are taking the contraceptive pill, it is recommended that you use an alternative method (e.g. a condom) to prevent pregnancy while you are taking fosamprenavir. The use of fosamprenavir and the contraceptive pill at the same time may result in a decrease of the effect of the oral contraceptive.

indinavir

Names: indinavir, *Crixivan*

Approved dosage: 800mg (two cream 400mg capsules) every eight hours.

Experimental dosage: with ritonavir: 400mg of both drugs twice daily. Alternatively, two 400mg capsules of indinavir and 100mg of ritonavir twice a day, or two 400mg capsules of indinavir and 200mg of ritonavir (other doses have been used in conjunction with drug level monitoring studies).

Tips on taking it: when indinavir is taken without ritonavir it should ideally be taken on an empty stomach (avoiding food for two hours before and one hour after each dose). Alternatively it can be taken with a light, low-fat snack, e.g. 30g cereal with 100g skimmed milk or a tea or coffee with sugar and skimmed milk plus one biscuit, or two small slices of toast with low-fat spread and 15g of jam per slice. For more suggestions, see NAM's *nutrition* booklet, or discuss your options with an HIV dietitian. If indinavir is taken with ritonavir, there are no food restrictions. Drink 1.5 litres of water or a non-caffeinated drink in addition to your usual fluid intake, to reduce the risk of kidney stones. Indinavir must be stored with a desiccant to keep the capsules dry. Can

be kept in a dosette box without a desiccant for up to three days.

Common side-effects: headache, dizziness, nausea, vomiting, diarrhoea, rash, kidney stones, fatigue, alerted taste, abdominal pain, sleep disturbance, flatulence, dry mouth, acid regurgitation, jaundice and muscle pain.

Rare side-effects include: diabetes and liver abnormalities.

Resistance to indinavir: causes resistance to ritonavir, and is likely to cause resistance to saquinavir, nelfinavir and fosamprenavir.

Key drug interactions: do not take indinavir with St John's wort, terfenadine, astemizole, cisapride, alprazolam, pimozide, rifampicin, amiodarone, quinidine and ergot alkaloids. Careful monitoring and dose adjustments may be needed if indinavir is taken with drugs including: rifabutin, ketoconazole, the NNRTIs, *Viagra, Cialis, Levitra* and simvastatin. Large doses of vitamin C have been shown to reduce indinavir concentrations in the blood.

lopinavir/ritonavir (*Kaletra*)

Names: lopinavir/ritonavir, ABT-378/r, *Kaletra*

Note: *Kaletra* is available in two formulations, hard tablets and soft capsules. Advice on how to take *Kaletra* varies depending on which you take.

Approved dosage: The tablets contain 200mg lopinavir and 50mg ritonavir so two yellow tablets are required twice daily. There is a, as yet unapproved, once-daily dose of *Kaletra* hard tablets consisting of four tablets a day. The dose of the capsules in 400mg lopinavir plus 100mg ritonavir (three orange 133.3mg/33.3mg capsules) twice daily. The dose is increased to four capsules when taken with efavirenz or nevirapine.

Children: approved for children over two years. Liquid formulation available.

Tips on taking it: The soft-gel capsules need to be taken with food and should be kept in the fridge. However they can be stored at room temperature (below 25 degrees C) for up to six weeks. The hard tablets do not require refrigeration and can be taken with or without food, but must not be broken, chewed or crushed.

Common side-effects: diarrhoea, insomnia, headache, nausea, vomiting,

abdominal pain, abnormal stools, indigestion, flatulence, rash, feeling weak and changes in blood fats and sugars. It is possible that lipodystrophy, a side-effect of other protease inhibitors, will also affect lopinavir/ritonavir users.

Rare side-effects include: muscle pain and abnormal kidney or liver function.

Resistance to lopinavir/ritonavir: likely cross-resistance with indinavir and ritonavir and, to some extent, amprenavir. High level resistance to other protease inhibitors may reduce the effectiveness of lopinavir/ritonavir, but lopinavir/ritonavir appears effective against virus resistant to other protease inhibitors.

Key drug interactions: due to the presence of ritonavir, avoid all drugs which negatively interact with ritonavir (see ritonavir entry). Efavirenz and nevirapine reduce levels of lopinavir/ritonavir and dose adjustments are recommended. Lopinavir/ritonavir reduces levels of amprenavir. Do not take with St John's wort. Monitoring and dose adjustment may be necessary when lopinavir/ritonavir is taken in conjunction with amiodarone, bepredil, quinidine, systemic lidocaine, warfarin, calcium channel blockers, *Viagra*, *Cialis*, *Levitra*, *Zyban*, tacrolimus, cyclosporin, methadone, rifabutin,

rifampicin, oral contraceptives, ketoconazole and itraconazole.

nelfinavir

Names: nelfinavir, *Viracept*

Approved dosage: five blue 250mg tablets twice a day, or three blue 250mg tablets three times a day.

Children: nelfinavir is approved for use in children. Available in powder form.

Tips on taking it: it is very important that you take nelfinavir with food to increase absorption.

Common side-effects: diarrhoea, nausea, flatulence, rash and metabolic abnormalities.

Rare side-effects include: jaundice and diabetes.

Resistance to nelfinavir: is likely to cause resistance to saquinavir and may cause resistance to ritonavir and indinavir.

Key drug interactions: careful monitoring and dose adjustments may be needed if nelfinavir is taken with drugs including: oral contraceptives, rifabutin, methadone, carbamazapine, phenytoin, *Viagra, Cialis, Zyban*, *Levitra* and some lipid-lowering drugs. Do not take nelfinavir with terfenadine, rifampicin, astemizole, cisapride, pimozide, amiodarone, quinidine, midazole, triazolam, simvastatin, ergot alkaloids or St John's wort.

ritonavir

Names: ritonavir, *Norvir*

Approved dosage: six 100mg cream capsules twice a day. Alternatively, 7.5ml of ritonavir liquid twice daily. Start on a low dose and increase over 14 days to minimise side-effects.

Ritonavir is also used in small doses (usually 100mg or 200mg once or twice daily) to 'boost' other protease inhibitors. It has been approved for use in this way in the following doses: ritonavir/fosamprenavir 100/700mg twice daily; ritonavir/atazanavir 100/300mg once daily; ritonavir/saquinavir 100mg/1000mg, twice daily; ritonavir/tipranavir 200/500mg twice daily.

Experimental dosage: ritonavir/saquinavir 400/400mg twice daily; ritonavir/indinavir 400/400mg or 200/800mg or 100/800mg twice daily.

Children: ritonavir is not formally approved for use in children, although it can be made available.

Tips on taking it: take with food to reduce nausea. If taking the liquid, try mixing it with a milk-based nutritional supplement. Do not mix with water, fizzy drinks or fruit juice. To disguise the taste, suck ice cubes or icy fruit juice before and after your dose. Alternatively,

follow ritonavir with chocolate, mango, peanut butter, salty crisps or other food with strong flavour. *Norvir* capsules should be stored in a fridge, but can be kept at room temperature (below 25 degrees C) for up to 30 days. Ritonavir liquid should always be stored at room temperature.

Common side-effects: diarrhoea, stomach pain, nausea, vomiting, weakness, taste abnormalities, loss of appetite, numbness around the mouth, lipodystrophy and metabolic abnormalities.

Rare side-effects:
kidney problems, diabetes.

Resistance to ritonavir: causes resistance to indinavir and is likely to mean some resistance to nelfinavir, saquinavir and amprenavir.

Key drug interactions: ritonavir interacts with many other medications. Consult your doctor or HIV pharmacist before taking any other drugs with ritonavir (including inhalers, medicines bought from a high street chemist, herbal preparations and recreational drugs). Do not take ritonavir with piroxicam, dextropropoxyphene, pethidine; amiodarone, encainide, flecainide, propafenone, quinidine, bupropion (*Zyban*), astemizole, terfenadine,

clozapine, pimozide, alprazolam, clorazepate, diazepam, estazolam, bepridil, cisapride; fluorazepam, midazolam, triazolam, zolpidem, *Viagra*, *Cialis, Levitra* or St John's wort.

saquinavir (*Invirase*)

Names: saquinavir (hard gel), *Invirase*

Approved dosage: two orange 500mg tablets (or five yellow and green 200mg capsules) together with one 100mg capsule of ritonavir twice a day.

Children: *Invirase* is not approved for use by children.

Tips on taking it: take *Invirase* within two hours of a full meal to increase absorption.

Common side-effects: fatigue, anaemia, nausea, vomiting, lipodystrophy and metabolic disorders.

Rare side-effects include: diabetes and Stevens-Johnson Syndrome.

Resistance to saquinavir: may mean resistance to nelfinavir, indinavir and ritonavir.

Key drug interactions: do not take with rifampicin, rifabutin, astemizole, terfenadine, cisapride or the herbal anti-depressant St John's wort. Careful monitoring and dose adjustments may be needed if taking saquinavir with many other drugs including: NNRTIs, methadone, anti-arrhythmics, some

anti-depressants, some anti-convulsants, some lipid-lowering drugs, dapsone, ergotamine, dihydroergotamine, dexamethasone, *Viagra*, *Cialis* and *Levitra*. Do not take with garlic supplements.

tipranavir

Names: tipranavir, *Aptivus*

Approved dosage: approved dosage: two 250 mg pink capsules together with 200 mg (two 100 mg cream capsules) ritonavir, twice daily.

Tips on taking it: to be taken with food.

Common side-effects: diarrhoea, nausea, vomiting, abdominal pain, flatulence, tiredness, headache and rash.

Rare side-effects: diabetes and kidney problems.

Resistance to tipranavir: test tube studies report that resistance to tipranavir is slow to develop, and that there is no clear pattern of cross-resistance to currently available PIs.

Key drug interactions: rifampicin, cisapride pimozide, sertindole, triazolam, ergot derivatives, astemizole, terfenadine, simvastatin, lovastatin, amioradone, bepridil, flecainide, propafenone, quinidine and St John's wort. Take special care with *Viagra*, *Cialis* and *Levitra,* disulfiram, fluticasone, atorvastatin and

metronidazole. Tipranavir may also interact with other types of medicines, which may lead to a loss of effectiveness of these medicines. These include the morphine-substitute methadone and oral contraceptives. If you are using oral contraceptives to prevent pregnancy you should use an additional or different type of contraception. If you are taking enteric-coated ddI, it should be taken at least two hours apart from tipranavir.

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T-20

Names: T-20, enfuvirtide, *Fuzeon*

Approved dosage: 90mg (given as a 1ml injection under the skin) twice a day. The drug has to be made up from powder.

Tips on taking it: extensive support and advice is available to people prescribed T-20. Doses can be prepared within 24 hours of use, so two doses can be prepared together. T-20 can be injected into the thigh, arm or abdomen. A different injection site should be used each day to reduce problems with injection site reactions.

Common side-effects: injection site reaction, possibly involving an itchy rash, swollen red or puffy skin, hardening of the skin, or cysts, diarrhoea, nausea, sinusitis, skin problems, influenza, ear infection, appetite decreased, anorexia, anxiety, nightmare, irritability, peripheral neuropathy, conjunctivitis, vertigo, nasal congestion, pancreatitis, gastro-oesophageal reflux disease, muscle pain, influenza like illness, weakness. Bacterial pneumonia and lymphadenopathy (swollen glands) also occur more frequently.

Rare side-effects: abscesses at the injection site and rare hypersensitivity reaction involving difficulty breathing,

fever, chills, skin rash and low blood-pressure.

Resistance to T-20: test-tube studies suggest that resistance to T-20 does not cause resistance to the experimental entry inhibitor T-1249. People who are resistant to T-20 may still get some benefit from it.

Key drug interactions: no significant interactions recorded.

Immune-based therapies

In addition to antiretroviral therapies to combat HIV, treatments aimed at strengthening the immune system are currently being studied.

Interleukin-2 (IL-2) is a naturally occurring chemical in the immune system which stimulates CD4 cell production. A clinical trial called STALWART, which is investigating the long-term effects of interleukin-2 given with or without anti-HIV drugs on CD4 cell count, is underway in many centres in the UK. For details ask your health care team or visit NAM's website **aidsmap.com**.

Summary

- Anti-HIV drugs prevent HIV from damaging your immune system, and so prevent ill health and prolong survival.
- The best time to begin anti-HIV drugs is not known. Decisions are guided mainly by the CD4 count and any symptoms that you may have. It is currently recommended that treatment starts before the CD4 count falls below 200.
- Combinations of at least three anti-HIV drugs provide the best chance of reducing the amount of HIV in your blood to very low levels.
- Taking your anti-HIV drugs as prescribed is extremely important, as this will prolong the benefit you will get from them, and reduce the risk of resistance to the drugs developing.
- Tell a member of your HIV care team (doctor, nurse or pharmacist) if you are having problems with your anti-HIV drugs. Make sure that they know about any other medicines you are taking (including those bought from a chemist, herbal preparations and recreational drugs).
- Five classes of antiretroviral drugs are now available in the UK and other classes are currently being investigated.

Glossary

adherence The act of taking treatment exactly as prescribed, i.e. at the right times, with or without food as needed.

antiretroviral A medicine that acts against retroviruses such as HIV.

CD4 A molecule on the surface of some white blood cells onto which HIV can bind. The CD4 cell count roughly reflects the state of the immune system.

diagnosis Description of the causes of a patient's medical problems.

disease progression The worsening of a disease.

immune system The body's mechanisms for fighting infection and getting rid of cells that are not working properly.

lipodystrophy A disruption in the way the body produces, uses and stores fat.

NNRTI Non-nucleoside reverse transcriptase inhibitor, the family of antiretrovirals which includes efavirenz and nevirapine.

NRTI Nucleoside reverse transcriptase inhibitor, the family of antiretrovirals that includes 3TC, AZT, ddI, d4T, abacavir, and FTC.

opportunistic infection Specific infections which cause disease in someone with a damaged immune system.

protease inhibitor Family of antiretrovirals which target the protease enzyme. Includes fosamprenavir, indinavir, lopinavir, ritonavir, saquinavir, nelfinavir, atazanavir, and tipranavir.

regimen A drug or treatment combination and the way it is taken.

resistance A drug-resistant HIV-strain is one which is less susceptible to the effects of one or more anti-HIV drugs.

undetectable viral load A level of viral load too low to be picked up by the particular viral load test being used.

viral load Measurement of the amount of virus in a sample. HIV viral load in the blood is checked to see if treatments are working.

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drug chart

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