Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Viracept is and what it is used for
2. Before you take Viracept
3. How to take Viracept
4. Possible side effects
5. How to store Viracept
6. Further information

1. WHAT VIRACEPT IS AND WHAT IT IS USED FOR

What Viracept is
Viracept contains a medicine called nelfinavir, which is a ‘protease inhibitor’. This belongs to a group of medicines called ‘anti-retrovirals’.

What Viracept is used for
Viracept is used with other ‘anti-retroviral’ medicines to:
- Work against the Human Immunodeficiency Virus (HIV). It helps to reduce the number of HIV particles in your blood.
- Increase the number of some cells in your blood that help fight infection. These are called CD4 white blood cells. They are particularly reduced in numbers when you have HIV infection. This can lead to an increased risk of many types of infections.

Viracept is not a cure for HIV infection. You may continue to get infections or other illnesses due to your HIV. Treatment with Viracept does not stop you giving HIV to others through contact with blood or sexual contact. Therefore you must keep taking appropriate precautions to avoid giving the virus to others when you are taking Viracept.

2. BEFORE YOU TAKE VIRACEPT

Do not take Viracept if:
- You are allergic to nelfinavir or to any of the other ingredients (listed in Section 6 ‘Further information’).
- You are taking any of the medicines listed in the first part of Section 2 ‘Taking other medicines’, ‘Do not take Viracept’.

Do not take Viracept if any of the above apply to you.

Take special care with Viracept
Check with your doctor or pharmacist before taking Viracept if:
- You have kidney problems.
- You have high blood sugar (diabetes).
• You have a rare blood problem which runs in families called ‘haemophilia’.
• You have liver disease caused by hepatitis B or C. Your doctor may wish to carry out regular blood tests.

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Viracept.

**Patients with liver disease**
Patients with chronic hepatitis B or C and treated with anti-retroviral agents are at increased risk for severe and potentially fatal liver adverse events and may require blood tests for control of liver function. Speak with your doctor if you have a history of liver disease.

**Body fat**
Combination anti-retroviral therapy may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck (‘buffalo hump’). The cause and long-term health effects of these conditions are not known at this time. Contact your doctor if you notice changes in body fat.

**Signs of previous infections**
In some patients with advanced HIV infection and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body’s immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

**Bone disease (osteonecrosis)**
Some patients taking combination anti-retroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination anti-retroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor immediately.

**Taking other medicines**
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Viracept can affect the way some other medicines work. Also some other medicines can affect the way Viracept works.

**Do not take Viracept** and tell your doctor or pharmacist if you are taking any of the following medicines:
• Medicines made from ergot such as cabergoline, ergotamine or lisuride (for Parkinson’s disease or migraine)
• Herbal preparations containing St. John’s Wort (for depression or improving your mood)
• Rifampicin (for tuberculosis (TB))
• Terfenadine or astemizole (for allergy)
• Pimozide (used for mental health problems)
• Amiodarone or quinidine (for an uneven heart beat)
• Phenobarbital or carbamazepine (for fits or epilepsy)
• Triazolam or oral midazolam taken by mouth (for anxiety or to help you sleep)
• Cisapride (for heart burn or problems with your digestive system)
• Omeprazole (for ulcers in your stomach or gut)
• Alfuzosin (for benign prostatic hyperplasia (BPH))
• Sildenafil (for pulmonary arterial hypertension (PAH))
• Simvastatin or lovastatin (for lowering blood cholesterol)
Do not take Viracept and tell your doctor or pharmacist if any of these apply to you. If you are not sure, talk to your doctor or pharmacist before taking Viracept.

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Any other medicines for HIV infection such as ritonavir, indinavir, saquinavir and delavirdine, amprenavir, efavirenz or nevirapine
- Oral contraceptives (the pill). Viracept can stop the pill from working, so you should use other contraception methods (such as condoms) while you are taking Viracept.
- Calcium channel blockers such as bepridil (for heart problems)
- Immunosuppressant medicines such as tacrolimus or ciclosporin
- Medicines that lower stomach acid such as lansoprazole
- Fluticasone (for hay fever)
- Phenytoin (for fits or epilepsy)
- Methadone (for drug dependence)
- Sildenafil (for getting or keeping an erection)
- Tadalafil (for pulmonary arterial hypertension (PAH), or for getting or keeping an erection)
- Vardenafil (for pulmonary arterial hypertension (PAH), or for getting or keeping an erection)
- Ketoconazole, itraconazole or fluconazole (for fungal infections)
- Rifabutin, erythromycin or clarithromycin (for bacterial infections)
- Midazolam given by injection or diazepam (for anxiety or to help you sleep)
- Fluoxetine, paroxetine, imipramine, amitriptyline or trazodone (for depression)
- Atorvastatin or other statins (for lowering blood cholesterol)
- Salmeterol (for asthma or chronic obstructive pulmonary disease (COPD)
- Warfarin (for lowering the chance of blood clots in your body)
- Colchicine (for gout-flares or Mediterranean fever)
- Bosentan (for pulmonary arterial hypertension (PAH))

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Viracept.

Taking Viracept with food and drink
Take Viracept with a meal. This helps your body to get the full benefit from your medicine.

Pregnancy, contraception and breast-feeding
- Talk to your doctor before you take Viracept if you are pregnant or planning to become pregnant.
- Do not breast-feed while taking Viracept because HIV may be passed to the baby.
- Viracept can stop oral contraceptives (the pill) from working, so you should use other contraception methods (such as condoms) while you are taking Viracept.
- Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Viracept is not likely to affect you being able to drive or use any tools or machines.

3. HOW TO TAKE VIRACEPT

Always take Viracept exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. The usual doses are described below. Follow the instructions carefully to get the most benefit from Viracept.

The Viracept tablets must be taken by mouth. They should be swallowed whole and taken with a meal. For adults or children unable to take tablets, Viracept tablets may be put into water and taken as follows:
- Put the tablets in a half cup of water and stir with a spoon.
• Once the tablet is dispersed, mix the cloudy bluish liquid thoroughly and take immediately.
• Rinse the glass with a half cup of water and swallow the rinse to ensure all of the dose is taken.

Acidic food or juice (such as orange juice, apple juice or apple sauce) are not recommended to be taken with Viracept because together they may have a bitter taste.

Alternatively, Viracept 50 mg/g oral powder may be taken instead. If you want to take the powder instead please see the Package Leaflet for Viracept 50 mg/g oral powder.

Taking this medicine
• Take Viracept with a meal. This helps your body to get the full benefit from your medicine.
• Take all your doses at the right time each day. This helps make your medicine work as well as it can.
• Do not stop taking this medicine without talking to your doctor first.

How much to take

Adults and children older than 13 years

Viracept tablets can be taken either two or three times a day with a meal. Table 1 below shows the usual doses.

<table>
<thead>
<tr>
<th>How often you take it</th>
<th>Number of tablets</th>
<th>How much you take each time (in milligrams)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two times a day</td>
<td>5</td>
<td>1250 mg</td>
</tr>
<tr>
<td>Three times a day</td>
<td>3</td>
<td>750 mg</td>
</tr>
</tbody>
</table>

Children aged 3 to 13 years

For children aged 3 to 13 years, the recommended dose of Viracept tablets is based on their body weight. Carefully monitor the increase in weight of your child to ensure the appropriate total daily dose is taken.
• When your child weighs 18 kg or more, you may provide the tablets either two or three times a day.
• When your child weighs 18 kg or less, you must provide the tablets three times a day.

The different ways are shown in separate tables below.

• Table 2: if you give the medicine two times a day (for children who weigh 18 kg or more), you will give 50-55 mg nelfinavir each time for each kg of body weight.
• Table 3: if you give the medicine three times a day, you will give 25-35 mg nelfinavir each time for each kg of body weight, except for children who weigh from 10.5 to 12 kg, from 12 to 14 kg and from 18 to 22 kg. These children will be given a different number of tablets with each meal. The table also shows the recommended total number of Viracept tablets that children will be given each day based on their weight.
Table 2

<table>
<thead>
<tr>
<th>Body weight of your child</th>
<th>Number of tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 to 22 kg</td>
<td>4</td>
</tr>
<tr>
<td>over 22 kg</td>
<td>5</td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
<th>Body weight of your child</th>
<th>Recommended number of tablets given at each meal</th>
<th>Total number of tablets per day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of tablets at breakfast</td>
<td>Number of tablets at lunch</td>
</tr>
<tr>
<td>7.5 to 8.5 kg</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>8.5 to 10.5 kg</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>10.5 to 12 kg*</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>12 to 14 kg*</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>14 to 16 kg</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>16 to 18 kg</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>18 to 22 kg*</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>over 22 kg</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

* Children with these weights will be given an uneven number of tablets during the day. Your doctor should monitor the number of HIV particles and the number of CD4 white blood cells in your child’s blood to assure the medicine works as well as it can.

If you take more Viracept than you should

If you take more Viracept than you should, talk to a doctor or pharmacist or go to a hospital straight away. Take the medicine pack with you. Among other things, very large doses of Viracept might cause problems with your heart rhythm.

If you forget to take Viracept

If you forget to take a dose, take it as soon as you remember it.
- However if it is nearly time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Viracept

Do not stop taking this medicine without talking to your doctor first. Take all your doses at the right time each day. This helps make your medicine work as well as it can.

4. **POSSIBLE SIDE EFFECTS**

Like all medicines, Viracept can have side effects, although not everybody gets them. The following side effects may happen with this medicine.

**Contact your doctor straight away if you notice any of the following side effects:**

- **Allergic reactions.** The signs may include difficulty in breathing, fever, itching, swelling of the face and skin rashes that can sometimes form blisters.
• **Increased bleeding if you have haemophilia.** If you have haemophilia type A or B, in rare cases your bleeding may increase.
• **Bone disease (osteonecrosis).** The signs may include joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. Some patients taking combination anti-retroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone).
• **Infection.** In some patients with advanced HIV infection and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body’s immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

If you notice any of the above, contact your doctor straight away.

**Other possible side effects, where you should talk to your doctor**

If you get any of the side effects on this list, or if you notice any side effects not listed in this leaflet, please tell your doctor.

**Very common (affect more than 1 in 10 people):**
• Diarrhoea.

**Common (affect less than 1 in 10 people):**
• Rash.
• Wind.
• Feeling sick.
• Low numbers of a type of white blood cell that fights infections (neutrophils).
• Abnormal results from blood tests that measure how well your liver or muscles are working.

**Uncommon (affect less than 1 in 100 people):**
• Being sick.
• Pancreatitis. The signs include severe pains in your stomach that spread to your back.
• Combination anti-retroviral therapy may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck (‘buffalo hump’). The cause and long-term health effects of these conditions are not known at this time.

**Rare (affect less than 1 in 1000 people):**
• Yellow skin or eyes. This could be a sign of a liver problem such as hepatitis or jaundice.
• A severe form of rash (erythema multiforme).
• Swelling of your belly (abdomen).
• High blood sugar (diabetes) or diabetes get worse.
• There have been rare reports of muscle pain, tenderness or weakness, particularly with combination anti-retroviral therapy including protease inhibitors and nucleoside analogues. On rare occasions these muscle problems have been serious causing muscle degeneration (rhabdomyolysis).

**Other side effects which have also been reported:**
• Combination anti-retroviral therapy may also cause raised lactic acid and sugar in the blood, hyperlipaemia (increased fats in the blood) and resistance to insulin.
• Low numbers of red blood cells (anaemia).
• Lung disease (pneumonia).
• Cases of diabetes mellitus or increased blood sugar levels have been reported in patients receiving this treatment or another protease inhibitor.
Side effects in children
About 400 children (aged from 0 to 13 years) received Viracept in clinical trials. The side effects seen in children are similar to those seen in adults. The most commonly reported side effect in children is diarrhoea. The side effects only rarely resulted into having to stop taking Viracept.

5. HOW TO STORE VIRACEPT
- Keep out of the reach and sight of children.
- Do not use after the expiry date stated on the label and carton.
- Do not store above 30°C.
- Store in the original container.

6. FURTHER INFORMATION
What Viracept contains
- The active substance in Viracept is nelfinavir. Each tablet contains 250 mg of nelfinavir.
- The other ingredients are calcium silicate, crospovidone, magnesium stearate, indigo carmine (E132), as powder, hypromellose and glycerol triacetate.

What Viracept looks like and contents of the pack
Viracept film-coated tablets is supplied in plastic bottles with plastic child resistant lid. Each bottle contains either 270 or 300 tablets. Not all pack sizes may be marketed.

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Manufacturer
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This leaflet was last approved in June 2012.

Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu/. There are also links to other websites about rare diseases and treatments.