

APTIVUS®

Soft Capsules

Tipranavir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Aptivus.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using Aptivus against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet with your medicine.

You may need to read it again.

What Aptivus is used for

Aptivus is used in the treatment of the infection caused by the Human Immunodeficiency Virus (HIV-1). HIV-1 is the main virus responsible for the development of Acquired Immunodeficiency Syndrome (AIDS).

Aptivus contains the active ingredient Tipranavir. Tipranavir belongs to a group of antiretroviral medicines called protease inhibitors.

Tipranavir helps control HIV infection by inhibiting or interfering with the protease enzyme that the HIV virus needs to multiply.

Aptivus does not cure or prevent HIV-1 infection or AIDS, but it does hinder the growth of HIV-1.

Aptivus is prescribed for use in combination with low-dose ritonavir and other antiretrovirals.

When these medicines are taken with Aptivus, the growth of HIV-1 is hindered more effectively.

Aptivus has not been shown to reduce the incidence or frequency of the illnesses caused by AIDS. It is important for you to continue seeing your doctor regularly.

Aptivus does not reduce the risk of or prevent transmission of HIV-1 to others through sexual contact or blood contamination.

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Aptivus if you have the rare inherited condition of fructose intolerance.

Aptivus soft capsules contain approximately 50 mg sorbitol per maximum recommended daily dose.

Do not take Aptivus if you have moderate to severe liver problems.

Do not take Aptivus if you are taking certain other medicines which include:

- vardenafil - used to treat erectile dysfunction
- amiodarone, bepridil, flecainide, propafenone, quinidine - used to treat irregular heartbeats (antiarrhythmics)
- astemizole, terfenadine - used to treat allergic conditions such as hay fever (antihistamines)
- dihydroergotamine, ergonovine, ergotamine, methylergonovine - used to treat migraine (ergot derivatives)
- cisapride - used to treat stomach reflux or gastroparesis
- pimozide, sertindole, quetiapine - used to treat chronic psychotic disorders
- midazolam - used as a sedative during medical procedures
- triazolam - used to treat sleeping problems
- alfuzosin, sildenafil - when used to treat pulmonary arterial hypertension

Before you take Aptivus

When you must not take it

Do not take Aptivus if you have an allergy to:

- any medicine containing tipranavir
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- lovastatin, simvastatin - used to lower cholesterol
- rifampicin (an antibiotic)
- herbal medicines derived from St John's Wort (*Hypericum perforatum*)
- colchicine (used to treat gout), if you have liver or kidney problems.

Do not give this medicine to children younger than 2 years of age.

Safety and effectiveness in children younger than 2 years of age have not been established.

Do not take this medicine after the expiry date printed on the carton or bottle or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Aptivus, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

It is essential that your doctor knows your medical history before prescribing Aptivus.

Tell your doctor if you have, or have had, any of the following conditions:

- liver problem/disease or hepatitis
- haemophilia or other medical condition where the risk of bleeding is increased e.g. trauma, surgery, taking antiplatelet agents or anticoagulants
- diabetes mellitus
- high blood levels of cholesterol or triglycerides
- allergy to sulfonamides (sulfa medicines)
- fits or convulsions (epilepsy)
- problems with alcohol dependency.

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Breastfeeding is not recommended for a HIV infected woman as there is a risk of passing the HIV-1 virus to your baby.

If you have not told your doctor about any of the above, tell him/her before you start taking Aptivus.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:

- other anti-HIV medicines
- cobicistat and cobicistat containing products
- anti-Hepatitis C medicines
- antacids
- antibiotics (e.g. clarithromycin, disulfiram/metronidazole, rifabutin, rifampicin)
- anticoagulants (e.g. warfarin), antiplatelet agents or medicine used to prevent blood clots (e.g. aspirin)
- antidepressants (e.g. desipramine, trazadone, fluoxetine, paroxetine, sertraline)
- antifungals (e.g. fluconazole, itraconazole, ketoconazole, voriconazole)
- anti-gouts (e.g. colchicine)
- anticonvulsants (e.g. carbamazepine, phenobarbital, phenytoin)
- cholesterol lowering medicines (e.g. atorvastatin, lovastatin,

simvastatin, rosuvastatin, pravastatin)

- medicines used to treat Type 2 diabetes (e.g. glibenclamide, glimepiride, glipizide, pioglitazone, repaglinide, tolbutamide)
- disulfiram
- fluticasone propionate
- omeprazole
- bosentan, a medicine used to treat hypertension
- salmeterol, a medicine used for asthma
- valaciclovir, a medicine used to treat herpes
- immunosuppressants (e.g. ciclosporin, sirolimus, tacrolimus)
- medicines used to treat erectile dysfunction (e.g. sildenafil, tadalafil, vardenafil)
- loperamide
- methadone
- oral contraceptives
- oestrogens for hormone replacement (ethinyl estradiol)
- pethidine
- herbal medicines derived from St John's Wort (*Hypericum perforatum*)
- buprenorphine/naloxone
- bupropion
- theophylline
- vitamin E supplements.

These medicines may be affected by Aptivus, or may affect how well it works. You may need different amounts of the medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

As Aptivus may reduce the effectiveness of oral contraceptives, talk to your doctor about alternative methods of contraception.

How to take Aptivus

It is essential that you take Aptivus with low-dose ritonavir.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton or bottle, ask your doctor or pharmacist for help.

How much to take

The recommended dose for adults is two Aptivus soft capsules together with 200 mg of ritonavir, twice daily (i.e. at regular 12-hour intervals at about the same time each day - morning and night).

The recommended dose of Aptivus and ritonavir for children 2 years of age or older will be determined by your doctor based on the weight and size of your child. Your doctor or pharmacist will be able to help you determine how and at what time you should give Aptivus to your child.

How to take it

Aptivus capsules should be swallowed whole with a full glass of water.

Do not chew the capsules.

Aptivus taken with low-dose ritonavir should be taken with food.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is

important to keep taking your medicine even if you feel well.

If you forget to take it

It is important to take Aptivus as directed.

If you miss a dose, take it as soon as you remember. However, if you remember when it is almost time for your next dose, take only your usual dose at that time.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, talk to your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at your nearest hospital if you think that you or anyone else may have taken too much Aptivus. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Aptivus

Things you must do

Contact your doctor if you experience any symptoms of liver problems, such as loss of appetite, nausea, vomiting, jaundice (yellowing of the skin and/or eyes), dark coloured urine, pale coloured stools, pain/ache or sensitivity to touch in your right abdominal area (below your ribs).

These could be signs of serious liver dysfunction which your doctor will need to monitor closely and may require stopping treatment with Aptivus.

Patients taking Aptivus (with ritonavir) may develop severe liver disease that can be life-threatening. The chance of developing liver problems is increased if you have chronic hepatitis B or C infection.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Aptivus.

Tell all doctors, dentists and pharmacists who treat you that you are taking Aptivus.

If you are taking oral contraceptives (to prevent pregnancy), you should use additional or different type of contraception.

Aptivus may reduce the effectiveness of oral contraceptives.

If you become pregnant while taking Aptivus tell your doctor immediately.

Contact your doctor immediately if you notice any unusual or unexplained bleeding.

There have been reports of bleeding episodes in people with haemophilia while taking protease inhibitors.

Bleeding in the brain, which can lead to permanent disability or death, has occurred in patients treated with Aptivus in clinical trials. A majority of the patients (experiencing bleeding in the brain) also had other medical conditions or were receiving other medications that may have caused or contributed to bleeding in the brain.

If you have diabetes, tell your doctor if you notice symptoms of high blood glucose levels.

There have been some reports of diabetes and increased blood glucose (hyperglycaemia) in people treated with protease inhibitors. In some of these people this led to ketoacidosis, a serious condition resulting from poorly controlled blood glucose. Some people required adjustments to their diabetes medicines, while others needed new diabetes medicines.

If you have had a previous opportunistic infection, and you notice symptoms of inflammation occurring when you first start taking Aptivus, tell your doctor immediately.

Symptoms of inflammation include redness, swelling, heat and pain. These symptoms have been reported in some patients who have previously had an infection when combination antiretroviral therapy was started.

Contact your doctor if you experience any symptoms of an overactive thyroid gland, such as rapid heart rate, tremors and increased sweating.

Autoimmune problems such as overactive or enlarged thyroid gland (goitre) have been reported in some patients.

If you are taking 'statin' medicines to lower your cholesterol level (including atorvastatin), and you notice any muscle pain or weakness not caused by exercise, tell your doctor immediately.

Severe muscle pain and weakness have occurred in people taking protease inhibitors together with cholesterol-lowering medicines called 'statins'.

Things you must not do

Do not give Aptivus to anyone else, even if they have the same condition as you.

Do not stop taking Aptivus or change the dose without first checking with your doctor.

Aptivus helps control your HIV infection but does not cure it. Therefore, Aptivus must be taken every day as your doctor prescribed it.

Things to be careful of

Be careful driving or operating machinery until you know how Aptivus affects you.

Aptivus may cause dizziness, drowsiness or tiredness in some people. Make sure you know how

you react to Aptivus before you drive or operate machinery.

Aptivus soft capsules contain small amounts of alcohol (approximately 7% or 100 mg per capsule).

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Aptivus.

It may be difficult to tell whether side effects are the result of taking Aptivus, effects of the HIV disease or side effects of other medicines you may be taking. For this reason, it is very important to inform your doctor of any change in your condition. Your doctor may need to change your dose or advise you to stop taking Aptivus.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

The commonly reported side effects in adults are:

- diarrhoea, loose stools, nausea, vomiting, stomach pain, stomach fullness, flatulence, indigestion
- decreased appetite
- fever
- headache
- rash - some patients who developed rash also had joint pain or stiffness, throat tightness, or generalised itching
- tiredness
- changes in blood chemistry including increases in blood lipid (cholesterol and triglycerides) levels and abnormal liver function tests.

Less frequently reported side effects in adults include:

- reduction in red/white blood cells or blood platelets
- heartburn, dehydration, weight loss
- diabetes, increased blood level of glucose or pancreas enzymes (such as amylase, lipase), pancreatitis
- flu-like symptoms, generally feeling unwell, cough, breathing difficulties
- dizziness, sleepiness
- trouble sleeping, other sleep disorders
- muscle cramp or pain
- numbness or weakness of the arms and legs
- bronchitis
- depression
- kidney and liver problems.

The most frequently reported side effects in children are similar to those described in adults. The frequency of most side effects tends to be lower in children.

Contact your doctor immediately if you experience rash and/or any signs of hypersensitivity reactions.

Hypersensitivity (allergic) reactions may appear in the form of:

- anaphylaxis (sudden life-threatening allergic reaction) - sudden signs of rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- rash accompanied by other side effects such as fever, blisters, mouth sores, conjunctivitis, facial swelling, muscle or joint aches, swollen lymph glands, or tiredness.

Cases of hepatitis and severe life-threatening liver dysfunction (such as liver failure) have been reported in patients being treated with Aptivus.

Contact your doctor immediately if you experience any symptoms of liver problems, such as loss of appetite, nausea, vomiting, jaundice (yellowing of the skin and/or eyes), dark coloured urine, pale coloured stools, pain/ache or sensitivity to touch in your right abdominal area (below your ribs).

In some patients, combination antiretroviral 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 and other internal organs
- breast enlargement
- fatty lumps on the back of the neck.

In patients with haemophilia type A and B, there have been reports of increased bleeding while taking protease inhibitors.

Bleeding in the brain has been reported rarely.

Tell your doctor as soon as possible if you experience any side effects during or after taking Aptivus, so that these may be properly treated.

Other side effects not listed above may also occur in some patients.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Aptivus.

After taking Aptivus

Storage

Keep your bottles of Aptivus soft capsules in the refrigerator where the temperature stays between 2°C and 8°C. Do not freeze the capsules.

After opening the bottle, the capsules may be stored below 25°C but must be used within 60 days. You should write the date of opening the bottle on the bottle label or outer carton.

Any capsules remaining after 60 days should be returned to your pharmacist for disposal.

Do not store Aptivus or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat or dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Aptivus is the brand name of your medicine.

Aptivus soft capsules are pink, oblong, soft gelatin capsules with a black imprint of "TPV 250".

The capsules are supplied in a plastic bottle containing 120 capsules.

Ingredients

Each capsule contains 250 mg tipranavir (active ingredient).

The other ingredients are:

- PEG-35 castor oil
- ethanol absolute
- glyceryl caprylate/caprate
- propylene glycol
- purified water
- trometamol
- nitrogen
- propyl gallate.

The capsule shell consists of:

- gelatin
- iron oxide red CI77491
- propylene glycol

- purified water
- Sorbitol Special Glycerin Blend (sorbitol, 1, 4-sorbitan, mannitol and glycerin)
- titanium dioxide CI77891
- black printing ink containing: SDA 35 alcohol, propylene glycol, iron oxide black CI77499, polyvinyl acetate phthalate, purified water, isopropyl alcohol, macrogol 400 and ammonia solution concentrated 28%.

Supplier

Aptivus soft capsules are supplied in Australia by:

BOEHRINGER INGELHEIM PTY LIMITED
ABN 52 000 452 308
78 Waterloo Road
North Ryde NSW 2113

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Aptivus soft capsules

- Bottles AUST R 118104