

AGENERASE(TM) Oral Solution

amprenavir

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start Agenerase oral solution.

This leaflet answers some common questions about Agenerase. It does not contain all of 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 taking Agenerase against the expected benefits it will have for you.

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

Keep this leaflet with the oral solution.

You may need to read it again.

What Agenerase oral solution is used for

Agenerase oral solution contains amprenavir which belongs to a group of antiretroviral medicines called protease inhibitors.

Agenerase is used together with other antiretroviral medicines to slow down the progression of human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (eg AIDS-related Complex or ARC).

Agenerase does not cure AIDS or kill the HIV virus, but prevents further damage to the immune system by stopping production of new viruses.

Agenerase does not reduce the risk of passing the infection to others. You will still be able to pass on the HIV virus by sexual activity or by contamination with infected blood. You should still use proper precautions to prevent this.

While taking Agenerase and/or any other therapy for HIV disease, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with the doctor who is looking after you.

Agenerase oral solution is not addictive.

Ask your doctor if you have any questions about why Agenerase oral solution has been prescribed for you.

Before you take Agenerase

When you must not take it

- * **Do not take Agenerase if you have ever had an allergic or hypersensitivity reaction to amprenavir or any of the ingredients listed at the end of this leaflet.**

If you develop any of the symptoms of allergy or hypersensitivity, tell your doctor

immediately. If an allergy or hypersensitivity is diagnosed then your doctor may stop your Agenerase treatment.

- * **Do not take Agenerase if you are pregnant, trying to become pregnant or breastfeeding.**

Your doctor will discuss the risks and benefits of using Agenerase if you are pregnant or breastfeeding.

- * **There are some medicines that must not be taken with Agenerase. These medicines include:**

- * **astemizole and terfenadine, which are used to treat hayfever**
- * **rifampicin which is used to treat tuberculosis**
- * **midazolam and triazolam which are used to induce sedation**
- * **dihydroergotamine and ergotamine which are used to treat migraine**
- * **cisapride which is used to treat gastric reflux**
- * **disulfiram which is used as an aid to reduce chronic excessive alcoholic consumption**
- * **metronidazole which is an antibiotic used to treat certain infections. Metronidazole is also contained in combination products used to treat peptic ulcers**
- * **pimozide which is used to treat chronic psychotic**

disorders

- * **Do not give Agenerase oral solution to infants and children below the age of 4 years and patients with kidney and liver failure.**
- * **Do not give Agenerase to anyone else, even though their symptoms may sound similar to yours.**
- * **Do not give Agenerase oral solution with ritonavir oral solution.**
- * **Do not take Agenerase oral solution after the expiry or "use by" date (EXP) printed on the bottle.**

If you're not sure whether you should be taking Agenerase oral solution, talk to your doctor.

Before you start to take it

You must tell your doctor if:

- * you are allergic to foods, dyes, preservatives or any other medicines (eg sulfonamide).
- * you had a previous allergic reaction to Agenerase (amprenavir) containing products.
- * you have, or have ever had, kidney or liver problems, for example jaundice, hepatitis, virus affecting the liver, enlarged liver or liver scarring (cirrhosis) or if you have any risk factors for liver problems, e.g. excessive alcohol intake, intravenous drug use with shared equipment, iron or copper storage disorders.
- * you have any other illness, for example diabetes mellitus or haemophilia, including those that you think are not related to HIV infection.

Taking other medicines

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

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking Agenerase oral solution with other medicines.

Some of the medicines that can interact with amprenavir include: terfenadine, astemizole, cisapride, triazolam, midazolam, ergot derivatives, rifampicin, methadone, lopinavir/rotonavir (Kaletra) and rifabutin.

There are also some medicines in the following groups that may interact with Agenerase: antibiotics, antifungals, benzodiazepines, calcium channel blockers, cholesterol lowering agents, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, anticonvulsants, tricyclic antidepressants, anti-arrhythmics and steroids.

Other medicines that may interact with Agenerase include clozapine, carbamazepine, cimetidine, loratadine, pimozide, St John's Wort (*Hypericum perforatum*), and warfarin.

If you are taking sildenafil for impotence, coadministration with Agenerase may increase the side effects of sildenafil including hypotension, visual changes and persistent painful erection (priapism).

If you are taking the contraceptive pill, it is recommended that you use an additional reliable barrier method to prevent pregnancy, while you are taking Agenerase. This is because Agenerase may interact with the hormones in the pill and reduce its effect.

If you need to take an antacid for indigestion, or are taking the drug didanosine, which contains an antacid, you are advised to take it more than an hour before or after Agenerase, otherwise the effects of Agenerase may be reduced.

Agenerase oral solution contains propylene glycol. This can produce alcohol-like effects (ie dizziness) when taken or given with drugs that reduce the body's

ability to break down alcohol (ie disulfiram and metronidazole).

How to take Agenerase oral solution

Your doctor will tell you how much Agenerase oral solution to take and how often to take it. You will also find this information on the label of your medicine.

Do not take extra oral solution. Do not take the oral solution more often than you have been told.

How much to take

The normal adult dose is 1400 mg twice a day. Your doctor may prescribe a different dosage.

If you are giving Agenerase oral solution to a child, follow the doctor's instructions.

How to take it

A 20 mL measuring cup is provided, to help you measure out the correct amount of oral solution for each dose. Ensure that you rinse the cup and swallow the entire contents to make sure that you get the total dose.

Agenerase can be taken with or without food.

How long to take it

Because your medicine helps to control your condition, but does not cure it, you will need to take the oral solution every day. Do not stop taking your medicine without first talking to your doctor.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126), or go to the accident and emergency unit at your nearest hospital, if you think you or anyone else may have taken too much Agenerase oral solution. Do this even if there are no signs of discomfort or poisoning.

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

While you are taking Agenerase oral solution

Things you must do

Tell your doctor or pharmacist that you are taking Agenerase oral solution if you are about to be started on any other medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking Agenerase oral solution, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Agenerase oral solution to treat any other complaints unless your doctor says to.

Because Agenerase oral solution contains vitamin E, you should not take additional vitamin E supplements.

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking Agenerase oral solution, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, Agenerase oral solution can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and may need medical attention.

Common side effects associated with Agenerase treatment include:

- * Nausea & vomiting.
- * Diarrhoea.
- * Flatulence.

Other side effects that have been reported include:

- * Tingling of your lips and mouth.
- * Skin rash
- * Headache.
- * Fatigue

Occasionally the skin rash may be severe and as a result your doctor may decide that you have to stop taking this medicine.

Changes in fat distribution have been reported in association with combination antiretroviral therapy.

These may include:

- * Loss of body fat from areas such as legs, arms and face
- * Increased fat appearing in areas such as abdomen (belly) and other internal organs, breasts and the back of the neck

Your doctor will test your blood regularly for any abnormalities. Increases in liver enzymes and blood fats have been reported in patients taking Agenerase.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (eg pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV. If you become concerned about any new symptoms, or any changes in your health after starting HIV treatment, please discuss with your doctor immediately.

Some people may get other side effects while taking Agenerase oral solution. If you are concerned, talk to your doctor or pharmacist.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking Agenerase oral solution

Storage

Keep the oral solution where children cannot reach it.

Keep Agenerase oral solution in a cool place where it stays below 25 degrees C.

Disposal

If your doctor tells you to stop taking Agenerase oral solution, or the oral solution has passed its expiry date, ask your pharmacist what to do with any oral solution left over.

Product description

What Agenerase oral solution looks like.

Agenerase oral solution is a clear, pale yellow to yellow solution with grape flavouring.

Agenerase oral solution is supplied in plastic bottles containing 240 mL.

Ingredients

Agenerase oral solution contains 15 mg/mL of amprenavir. Your oral solution also contains the following inactive ingredients:

d-alpha tocopheryl polyethylene glycol 1000 succinate (TPGS), macrogol 400, propylene glycol, acesulfame potassium, saccharin sodium, sodium chloride, artificial grape bubblegum flavour, natural peppermint flavour, menthol, citric acid anhydrous, sodium citrate dihydrate and purified water.

Agenerase oral solution does not contain gluten.

Manufacturer

Your Agenerase oral solution is supplied by:

GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia
Victoria, 3155
Australia.

Licensed from
Vertex Pharmaceuticals Inc.
Cambridge, MA 02139

Further Information

Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your illness and its treatment from other sources, for example from books in public libraries.

Counselling is also available from your local AIDS council.

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The information provided applies only to: Agenerase(TM) oral solution.
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