

# **AGENERASE™ SOLUTION**

**Amprenavir 15mg/mL**

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## **What is in this leaflet?**

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Please read this leaflet carefully before you start taking Agenerase.

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 risks and benefits. Your doctor has weighed the risks of you taking Agenerase against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

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## **What Agenerase is used for**

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

Agenerase does not cure AIDS or HIV infection, but slows production of human immunodeficiency virus. In this way it stops ongoing damage to the body's immune system, which fights infection.

Agenerase does not reduce your risk of passing HIV infection to others. You will still be able to pass on the HIV virus by sexual activity or by passing on blood or bodily secretions which carry the HIV virus. You should continue to take all appropriate precautions.

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 your doctor.

The long-term risks and benefits of taking Agenerase are not known.

Your doctor may have prescribed Agenerase for another reason. Ask your doctor if you have any questions about why Agenerase has been prescribed for you.

Agenerase is not addictive.

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## **Before you take Agenerase**

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### ***When you must not take it***

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

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting.

Do not take Agenerase with the following medicines: pimozone (Orap™), cisapride (Prepulsid™), triazolam (Halcion™), Hypam™, midazolam (Hypnovel™), ergotamine (Cafergol™) or rifampicin (Rifadin™, Rifinah™).

Do not take Agenerase if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should. Your doctor should discuss with you the risks and benefits of using Agenerase liquid if you are pregnant or breastfeeding. It is not recommended that women with HIV/AIDS breastfeed their babies to help avoid giving the babies HIV. Agenerase liquid contains propylene glycol which is not recommended in pregnancy.

### ***Before you start to take it***

#### **You must tell your doctor if you:**

have or have had liver disease  
have or have had kidney disease  
have Chinese or Japanese ancestry or your body processes some medicines slowly  
Some people including Chinese and Japanese people may process an ingredient (propylene glycol) slowly, therefore the dose might need to be changed. See also under “Side effects”, below.  
are taking any other medicines or herbal remedies, including from a pharmacy, supermarket or health food shop – see below for further details  
have haemophilia  
are allergic to foods, dyes, preservatives or any other medicines.

### ***Taking other medicines***

Agenerase does not mix with a number of other medicines well. Even herbal remedies and vitamins may not mix well with Agenerase. Check all other medicines, herbal remedies and vitamins with your doctor or pharmacist before taking with Agenerase.

The following medicines should be avoided with Agenerase:

pimozide (Orap<sup>TM</sup>),  
cisapride (Prepulsid<sup>TM</sup>),  
triazolam (Halcion<sup>TM</sup>, Hypam<sup>TM</sup>),  
midazolam (Hypnovel<sup>TM</sup>),  
ergotamine (Cafergot<sup>TM</sup>)  
rifampicin (Rifadin<sup>TM</sup>, Rifinah<sup>TM</sup>).

Check with your doctor or pharmacist before taking any of the following medicines or remedies while you are taking Agenerase:

St Johns Wort also known as *hypericum perforatum*, a herbal remedy for depression and other conditions  
Vitamin E  
Lovastatin  
Simvastatin (Zocor<sup>TM</sup>, Lipex<sup>TM</sup>)  
Atorvastatin (Lipitor<sup>TM</sup>)  
Bepidil  
Amiodarone (Cordarone<sup>TM</sup>)  
Lidocaine (lignocaine, except when just applied to the skin)  
Tricyclic antidepressants e.g. amitriptyline (Amitrip<sup>TM</sup>), nortriptyline (Allegron<sup>TM</sup>, Norpress<sup>TM</sup>), trimipramine (Tripress<sup>TM</sup>), imipramine (Tofranil<sup>TM</sup>), doxepin (Anten<sup>TM</sup>), dothiepin (Dopress<sup>TM</sup>), clomipramine (Anafranil<sup>TM</sup>, Clopress<sup>TM</sup>)  
Quinidine  
Warfarin (Marevan<sup>TM</sup>, Coumadin<sup>TM</sup>)  
Contraceptive tablets (“the pill”)  
Rifabutin (Mycobutin<sup>TM</sup>)  
Ritonavir (Norvir<sup>TM</sup>)  
Efavirenz (Stocrin<sup>TM</sup>)  
Nevirapine (Viramune<sup>TM</sup>)  
Delavirdine  
Sildenafil (Viagra<sup>TM</sup>)  
Dapsone  
Erythromycin (Eromycin<sup>TM</sup>, Emycin<sup>TM</sup>, ERA<sup>TM</sup>, EES<sup>TM</sup>)  
Alprazolam (Xanax<sup>TM</sup>), diazepam (D-pam<sup>TM</sup>, Propam<sup>TM</sup>)  
Itraconazole (Sporanox<sup>TM</sup>)  
Diltiazem (Cardizem<sup>TM</sup>, Dilzem<sup>TM</sup>), nifedipine, nifedipine (Adalat<sup>TM</sup>, Nyefax<sup>TM</sup>), and nimodipine

Methadone (Biodone™, Pallidone™)  
Phenobarbital, phenytoin (Dilantin™), carbamazepine (Tegretol™, Teril™) dexamethasone  
Clozapine (Clozaril™, Clopine™), cimetidine (Tagamet™) and loratadine (Claratyne™, Lora  
tabs™)  
Antacids (tablets or mixtures for indigestion)  
Metronidazole (Flagyl™, Trichozole™)  
Other medicines containing propylene glycol as an inactive ingredient  
Alcoholic drinks or medicines or foods containing alcohol  
Disulfiram (Antabuse™)

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

### ***Use in children***

Agenerase is not for use in children under 4 years old.

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## **How to take Agenerase**

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Your doctor will tell you how much Agenerase to take and how often to take it. You will also find this information on the label of your medicine. This may be different from the usual doses given below. Follow the instructions of your doctor.

Do not take or give extra Agenerase liquid. Do not take the liquid more often than you have been told.

### ***How much to take***

#### **Adults and adolescents from 13 years old, over 50kg in weight**

The usual dosage of Agenerase liquid is 93.3mL twice a day.

#### **Children 4-12 years and adults or adolescents less than 50kg**

The usual dose of Agenerase liquid is 22.5mg (1.5mL)/kg body weight twice a day, or 17mg(1.1mL)/kg three times a day, but never more than 2800mg (186.6mL) total per day. Your doctor or pharmacist will work it out for you. Note: If changing from Agenerase liquid to Agenerase capsules, or from the capsules to the liquid, your dose will change. Talk to your doctor if you make this change.

### ***When to take it***

Your doctor or pharmacist will be able to tell you when you should take your Agenerase liquid. It doesn't matter if it is taken with food 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 liquid 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.

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## **If you take too much (overdose)**

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**Immediately telephone your doctor or Poisons Information Centre (0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too much Agenerase liquid. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

Keep telephone numbers for these places handy.  
If you are not sure what to do, contact your doctor or pharmacist.

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## **While you are taking Agenerase**

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### ***Things you must do***

Tell your doctor or pharmacist that you are taking Agenerase liquid if you are about to be started on any new medicines. Check with your doctor or pharmacist before you start taking medicines or remedies you buy from a pharmacy, health food shop or supermarket.

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.

Remember to have your blood tests as the doctor advises.

### ***Things you must not do***

Do not stop taking Agenerase, 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 to treat any other complaints unless your doctor says to.

### ***Things to be careful of***

Be careful driving or operating machinery until you know how Agenerase liquid affect you.  
Agenerase can cause tiredness.

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## **Side Effects**

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

Like other medicines, Agenerase can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention. Some of these symptoms may occur as part of HIV infection, AIDS or AIDS-related Complex or may be from taking other medicines at the same time as Agenerase.

**If you think you are having an allergic reaction to Agenerase, TELL YOUR DOCTOR IMMEDIATELY or go to the accident and emergency department at your nearest hospital. Symptoms usually include some or all of the following:**

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

**If you have any of the following symptoms soon after starting to take your medicine, do not take any more Agenerase and tell your doctor immediately or go to the accident and emergency department at your nearest hospital.**

Severe skin rash and ulcers in the mouth and on the genitals

**This is a very rare side effect that needs prompt medical attention.**

Common side effects include:

- Nausea
- Diarrhoea
- Flatulence (wind)

Vomiting

Check with your doctor if these side effects are bothering you.

Less common side effects include:

Numbness or tingling of the mouth or around the mouth

Skin rash – usually in the second week of treatment and goes within two weeks without stopping

Agenerase (see above for severe skin rash)

Headache

Tiredness

Fat redistribution

Changes in blood tests

Check with your doctor if these side effects are bothering you.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Side-effects may depend on whether you take Agenerase alone, or also have taken other antiretroviral medication(s).

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

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## **After taking Agenerase liquid**

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### ***Storage***

Keep this medicine where young children cannot reach it.

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

Keep Agenerase liquid in a cool, dry place where it stays below 25°C. Do not store the liquid, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your Agenerase liquid in its pack until it is time to take it. Keep the lid screwed on tight.

### ***Disposal***

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

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## **Product description**

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### ***What Agenerase liquid looks like***

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

Agenerase Solution is packed in white bottles, each bottle contains 240mL.

### ***Ingredients***

Agenerase contains the active ingredient amprenavir 15mg/mL.

Agenerase solution also contains the following inactive ingredients:

- Propylene glycol
- Macrogol 400

- d-alpha Tocopheryl polyethylene glycol 1000 succinate
- Acesulfame potassium
- Saccharin sodium
- Sodium chloride
- Artificial grape bubblegum flavour
- Natural peppermint flavour
- Menthol
- Anhydrous citric acid
- Sodium citrate dihydrate
- Purified water.

Agenerase does not contain gluten, lactose or sucrose.

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## **Manufacturer**

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Your Agenerase solution is distributed by:

„ laxoSmithKline NZ Ltd  
Quay Tower  
Cnr Albert and Customs St  
Private Bag 106600  
Downtown Auckland  
New Zealand

Ph (09) 367-2900  
Fax (09) 367-2910

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## **Further Information**

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Agenerase is only available if prescribed by a doctor.

This is not all the information that is available on Agenerase. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. 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 disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away. You may need to read it again.

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

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