

# RESCRIPTOR\*

*delavirdine mesylate*

## Consumer Medicine Information

### What is in this leaflet

Please read this leaflet carefully before you start taking RESSCRIPTOR. This leaflet answers some common questions about RESSCRIPTOR.

It does not contain all 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 RESSCRIPTOR 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 medicine.**

You may need to read it again.

It is important to remember that RESSCRIPTOR tablets are a PRESCRIPTION ONLY MEDICINE.

You should use RESSCRIPTOR tablets as directed by your physician.

### What RESSCRIPTOR is used for

RESCRIPTOR is used in combination with other anti-HIV medicines in the treatment of HIV-1 virus infection.

You should be aware that RESSCRIPTOR is not a cure for HIV or AIDS and that appropriate precautions should be taken to prevent transmission.

Your doctor may have prescribed RESSCRIPTOR Tablets for another reason.

**Ask your doctor if you have any questions about why RESSCRIPTOR Tablets have been prescribed for you.**

This medicine is only available with a doctor's prescription.

### Before you take RESSCRIPTOR

#### **When you must not use it**

**Do not take RESSCRIPTOR if you have an allergy to:**

- \* any medicine containing delavirdine mesylate
- \* any of the ingredients listed at the end of this leaflet
- \* any other similar medicines

Some of the symptoms of an allergic reaction may include 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 RESSCRIPTOR if you are also taking the following medicines:**

- \* midazolam, alprazolam or triazolam medicines used to help you sleep and treat stress-related disorders
- \* cisapride, a medicine used to treat stomach reflux
- \* pimozide, a medicine used to treat psychosis
- \* ergotamine, dihydroergotamine

and methysergide medicines used to treat migraine headaches

**Do not take this medicine after the expiry date printed on the pack 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 this medicine, 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.

**Tell your doctor if you suffer from any liver or kidney disorders.**

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

RESCRIPTOR is not recommended in pregnancy. Your doctor can discuss with you the risks and benefits involved if you do need to take RESSCRIPTOR during your pregnancy.

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

RESCRIPTOR is not recommended in breastfeeding mothers.

**RESCRIPTOR is not recommended for children under 12 years of age or for elderly patients.**

#### **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.**

Other medicines may interfere with RESCRIPTOR or be interfered with by RESCRIPTOR.

**These are some medicines that SHOULD NOT BE TAKEN with RESCRIPTOR:**

- \* midazolam, or triazolam medicines used to help you sleep
- \* alprazolam, a medicine used to treat stress-related disorders
- \* cisapride, a medicine used to treat stomach reflux
- \* pimozide, a medicine used to treat psychosis
- \* ergotamine, dihydroergotamine and methysergide medicines used to treat migraine headaches

There are some medicines that may still be taken with RESCRIPTOR but may require close supervision by your doctor. These include:

- \* simvastatin, atorvastatin and pravastatin, medicines used to lower cholesterol levels
- \* ethinyl oestradiol, an active ingredient used in oral contraceptives
- \* rifampicin, clarithromycin, rifabutin, medicines used to treat bacterial infections and MAC (*Mycobacterium avium* complex)
- \* indinavir, ritonavir, saquinavir, nelfinavir, amprenavir, lopinavir, medicines used to treat viral infections
- \* fluconazole, ketonazole, medicines used to treat fungal infection
- \* cyclosporin and tacrolimus, medicines used to suppress the immune system
- \* cimetidine, famotidine, nizatidine, ranitidine, some medicines used to treat heartburn, indigestion or reflux
- \* omeprazole, lansoprazole, pantoprazole, medicines used to treat stomach ulcers or reflux
- \* St John's Wort (*hypericum perforatum*), an ingredient used

in some herbal medicines to treat depression

- \* phenytoin, phenobarbital, carbamazepine, medicines used to treat epilepsy
- \* warfarin and other similar medicines used to prevent blood clotting
- \* Bepridil, quinidine and amiodarone, medicines used to treat an irregular heart beat
- \* some calcium channel blocking medicines, used to treat high blood pressure and for chest pains associated with heart disease
- \* sildenafil, a medicine used to treat impotence in men

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

**If you have not told your doctor about any of these medicines, do so before you use RESCRIPTOR.**

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

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## How to take RESCRIPTOR

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**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 bottle, ask your doctor or pharmacist for help.**

### **How much to take**

The recommended daily dose of RESCRIPTOR is four (100 mg) tablets three times a day.

### **How to take it**

These tablets should be taken by mouth in combination with other anti-HIV medicines. Your doctor will tell you the dosage for the other anti-HIV medicines and whether or not you should take them at a different time to RESCRIPTOR.

If you find it difficult to swallow whole RESCRIPTOR Tablets, these can be dissolved in at least 100 mL of water. Allow to stand for a few minutes and then stir until a uniform solution occurs. The solution should be consumed promptly. The glass should be rinsed and the rinse swallowed to ensure the entire dose is consumed.

RESCRIPTOR Tablets may be taken with or without food.

If you also take didanosine ensure you take your RESCRIPTOR dose either one hour before or after your didanosine dose.

### **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**

**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, and then go back to taking your medicine as you would normally.**

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

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask 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 or the Poisons Information Centre in Australia (telephone 13 11 26) or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much RESCRIPTOR. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## **While you are using RESCRIPTOR**

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**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking RESCRIPTOR.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**Continue to use safe sexual practices while taking RESCRIPTOR. RESCRIPTOR has not been shown to decrease the chance of giving HIV to your partner.**

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

**Do not take RESCRIPTOR to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking your medicine or lower the dosage without**

**checking with your doctor.**

**Do not take any other medication unless your doctor is aware of it.**

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## **Side effects**

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

This medicine helps most people with HIV-1 virus infection but, like all other medicines, it may cause some unwanted side effects in some people. Most of the time, these are not serious. You may need medical attention if you get some of the side effects.

**Frequently it is difficult to tell whether side effects are the result of taking RESCRIPTOR, 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 want to change your dose or advise you to stop taking RESCRIPTOR.**

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

**Tell your doctor or pharmacist as soon as possible if you have any of the following side effects or other effects that you think may be related to RESCRIPTOR.**

- \* allergic reaction
- \* skin rash and/or itching
- \* nausea
- \* headache
- \* fatigue
- \* abdominal pain
- \* diarrhoea
- \* decreased appetite
- \* depression
- \* fever
- \* mouth blisters
- \* inflamed eyes
- \* muscle or joint pains
- \* yellowing of the skin and eyes and dark coloured urine
- \* redistribution of body fat

This is not a complete list of all the possible side effects. Other side effects not listed above may occur in some patients.

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you develop a severe skin rash or skin rash together with:**

- \* fever
- \* blistering
- \* lesions or blisters in the mouth
- \* discharge with itching of the eyes and crusty eyelids
- \* swelling
- \* muscle or joint aches
- \* generally feeling unwell

This is a very serious side effect.

You may need urgent medical attention or hospitalisation. Side effects such as this are rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

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## **After using RESCRIPTOR**

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### ***Storage***

**Keep your RESCRIPTOR tablets in their original bottle until it is time to take them.**

**Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.**

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

Heat and dampness can destroy your medicine.

**Keep your RESCRIPTOR tablets where children cannot reach them.**

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, return any unused tablets to your pharmacy.**

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## **Product Description**

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### ***What RESCRIPTOR looks like***

RESCRIPTOR Tablets are white, capsule-shaped and marked with "U 3761" and packed in a plastic bottle containing 360 tablets.

### ***Ingredients***

#### **Active Ingredients**

The active ingredient in RESCRIPTOR is delavirdine mesylate. Each tablet contains 100 mg of delavirdine mesylate.

#### **Inactive Ingredients**

RESCRIPTOR also contains microcrystalline cellulose, lactose, croscarmellose sodium, silicon dioxide, magnesium stearate, carnauba wax and Opadry YS-1-7000E.

### ***Identification***

RESCRIPTOR can be identified by the Australian Register Number, AUST R 60345 which appears on the label of the bottle.

### ***Supplier***

RESCRIPTOR is supplied in Australia by:

Pfizer Pty Limited  
ABN 5000 8422 348  
38-42 Wharf Road  
WEST RYDE NSW 2114  
Australia

Toll Free number: 1800 675 229