

# STOCRIN<sup>®</sup> TABLET

Efavirenz (200mg and 600mg)

## What is in this leaflet

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Please read this leaflet carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information in the previous leaflet may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

## What *STOCRIN* is used for

Stocrin contains an active ingredient efavirenz. Your doctor has prescribed *STOCRIN* for you because you have HIV infection. *STOCRIN* taken in combination with other antiretroviral medicines reduces the amount of the virus in the blood.

## How *STOCRIN* works

*STOCRIN* is a member of a class of antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). It is an antiretroviral medicine that fights HIV infection by reducing the amount of virus in blood.

## Before you take *STOCRIN*

### -When you must not take it

Do not take *STOCRIN* if you know you are allergic to any of the ingredients in *STOCRIN* tablets. *STOCRIN* should not be taken with some other medicines. (See *Taking other medicines*)

### -Before you start take it

Inform your doctor about any past or present medical problems, including liver disease (for example, chronic hepatitis B or C) or allergies, seizures, mental illness, or substance or alcohol abuse. Also inform your doctor about any medications, vitamins, or nutritional supplements including St. John's wort (*Hypericum perforatum*) that you are currently taking or intend to take.

Inform your doctor if you are breast-feeding a baby, pregnant, or intend to become pregnant. Tell your doctor if you are taking a medicine that contains efavirenz. *STOCRIN* should not be taken together with other medicines that contain efavirenz. Tell your doctor if you have a higher risk of Torsade de Pointes. QTc Prolongation has been observed with the use of efavirenz. Your doctor may give you an alternative antiretroviral.

## Use in pregnancy and breast-feeding

Women should notify their physician if they become pregnant while taking *STOCRIN*.

If you could get pregnant while receiving *STOCRIN*, a reliable form of barrier contraception should always be used with other methods of contraception including oral (pill) or other hormonal contraceptives (e.g., implants, injection). Efavirenz, may remain in your blood for a time after therapy is stopped. Therefore, you should continue to use contraceptive measures, for 12 weeks after you stop taking *STOCRIN*.

Inform your doctor immediately if you are pregnant or intend to become pregnant. If you are pregnant, you should take *STOCRIN* only if you and your doctor decide it is clearly needed.

Malformations have been seen in fetuses from animals treated with *STOCRIN*. The animals in this study were given doses of *STOCRIN* similar to those used in humans. Malformations have also been seen in newborns of

women treated with *STOCRIN* during pregnancy; therefore, pregnancy should be avoided in women taking *STOCRIN*.

It is recommended that HIV-infected women should not breast-feed their infants because of the possibility that your baby can be infected with HIV through your breast milk. Talk with your doctor about the best way to feed your baby.

## Use in children

*STOCRIN* tablets have not been studied in children below 3 years of age or who weigh less than 13 kg. *STOCRIN* tablets can be given to children 3 years of age and older who are able to swallow tablets.

*STOCRIN* must be taken with other medicines that act against the HIV virus. If *STOCRIN* is started because your current treatment has not prevented the virus multiplying, another medicine you have not taken before must be started at the same time.

You should know that *STOCRIN* is not a cure for HIV infection and that you may continue to develop infections or other illnesses associated with HIV disease. You must remain under the care of your doctor while taking *STOCRIN*.

In some patients with advanced HIV infections (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur when combination antiretroviral treatment is started. In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur. Tell your doctor immediately if you notice any symptoms of infection or inflammation.

Treatment with *STOCRIN* has not been shown to reduce the risk of passing on HIV infection to others through sexual contact or blood contamination. This product has been prescribed only for you. You should not give it to

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others.

## -Taking other medicines

Medicines that should not be administered concurrently when taken with *STOCRIN* include astemizole, cisapride, terfenadine, midazolam, triazolam, pimozide, bepridil, and ergot derivatives. Taking these medicines with *STOCRIN* could create the potential for serious and/or life-threatening side-effects.

The generally recommended dose of *STOCRIN* must not be taken with the generally recommended dose of voriconazole, a medicine that is used to treat fungal infections. *STOCRIN* may make voriconazole less likely to work. Also, voriconazole may make side effects from *STOCRIN* more likely.

Do not take *STOCRIN* with St. John's wort (*Hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's wort, as it may decrease the effect of *STOCRIN* or other HIV-related medicines.

*STOCRIN* may be taken with many of the medicines commonly used in people with HIV-infection. These include the protease inhibitors and nucleoside analogue reverse transcriptase inhibitors (NRTIs). The optimal dose of indinavir, when given in combination with efavirenz, is not known. The dose of atazanavir must be adjusted when taken with *STOCRIN* and ritonavir. The dose of darunavir may be adjusted when taken with *STOCRIN* and ritonavir. Use of *STOCRIN* with saquinavir and simeprevir is not recommended.

A dose increase of lopinavir/ritonavir may be required when given in combination with *STOCRIN*.

If you are treated with telaprevir (a medicine to treat hepatitis C) while taking *STOCRIN*, your doctor may need to adjust your dose of telaprevir.

If you are taking the antibiotic clarithromycin, your doctor may consider giving you an alternative antibiotic. If you are taking rifampin, your doctor will prescribe a higher dose of *STOCRIN*.

If you are taking methadone, your doctor may need to adjust your dosage of methadone after you start taking *STOCRIN*.

If you are treated with sertraline when you start taking *STOCRIN*, your doctor may need to adjust your dose of sertraline.

If you are treated with bupropion when you start taking *STOCRIN*, your doctor may need to adjust your dose of bupropion.

*STOCRIN* may make itraconazole (used to treat fungal infections) less likely to work. Inform your doctor if you are taking itraconazole.

If you are treated with atorvastatin, pravastatin, or simvastatin (lipid-lowering medicines, also called statins) when you start taking *STOCRIN*, your doctor may need to adjust your dose of the statin.

If you are treated with an immunosuppressant (such as cyclosporine, tacrolimus or sirolimus) when you start or stop taking

*STOCRIN*, your doctor will closely monitor your plasma levels of the immunosuppressant and may need to adjust its dose.

*STOCRIN* may make carbamazepine (used to prevent seizures) less likely to work. Also, carbamazepine may make *STOCRIN* less likely to work. Inform your doctor if you are taking carbamazepine.

If you are treated with diltiazem or similar medicines (called calcium channel blockers) when you start taking *STOCRIN*, your doctor may need to

adjust your dose of the calcium channel blocker.

If you are treated with warfarin or acenocoumarol (medicines used to reduce clotting of the blood) when you start taking *STOCRIN*, your doctor may need to adjust your dose of these medicines.

If you are treated with atovaquone/proguanil or artemether/lumefantrine (medicines to treat malaria), *STOCRIN* may reduce the amount of atovaquone/proguanil or artemether/lumefantrine in your blood. Your doctor may need to adjust your dose of these medicines.

If you are treated with medicines with known risk of Torsade de Pointes: QTc prolongation has been observed with the use of efavirenz. Your doctor may need to consider giving you different medicine.

You should always inform your doctor about all medicines you are taking or plan to take, including those obtained without a prescription, herbal products, or dietary supplements. *STOCRIN* should not be taken together with other medicines that contain efavirenz.

## **How to take *STOCRIN***

### -How much to take

The dose for adults and children weighing greater than or equal to 40 kg is 600 mg once daily for the tablets.

The dose for children weighing 40 kg or less is calculated by body weight and is taken once daily as shown in the table below.

Body Weight (kg)	STOCRIN Tablets Dose (mg)
13 to < 15	200
15 to < 20	250
20 to < 25	300
25 to < 32.5	350
32.5 to < 40	400
≥ 40	600

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Your doctor or pharmacist will give you instructions for proper dosage.

## -When to take it

*STOCRIN* tablets may be taken with or without food. *STOCRIN* must be taken every day. *STOCRIN* should never be used alone to treat HIV. *STOCRIN* must always be taken in combination with other anti-HIV medications.

## -How long to take it

It is important that you take *STOCRIN* exactly as your doctor prescribes. You should not stop taking it without first consulting your doctor.

## -If you forget to take it

Try not to miss a dose. If you do miss a dose, take the next dose as soon as possible, but do not double the next dose. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.

When your *STOCRIN* supply starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The virus may then become harder to treat.

## -If you take too much (overdose)

If you take too much *STOCRIN* consult your doctor or clinic.

## **While you are taking *STOCRIN***

### -Things you must do

Take the medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *STOCRIN*.

Tell your doctor immediately if you

become pregnant while taking this medication.

### -Things you must not do

Do not stop taking this medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *STOCRIN* to anyone else, even if they have the same symptoms or conditions as you.

### -Things to be careful of

#### **Can I drive or operate machinery while using *STOCRIN*?**

Dizziness, impaired concentration, and drowsiness have been reported during treatment with *STOCRIN*. If you experience these symptoms you should avoid potentially hazardous tasks such as driving or operating machinery.

#### **Side effects**

Any medicine may have unintended or undesirable effects, so-called side effects. *STOCRIN* has been shown to be generally well tolerated. The most frequently reported adverse reactions associated with *STOCRIN* in combination with other anti-HIV medications include rash, nausea, dizziness, headache, and fatigue.

The most notable unwanted effects are skin rash and nervous system symptoms that include dizziness, insomnia, somnolence (drowsiness), impaired concentration, and abnormal dreaming.

You should consult your doctor if you have a rash, since some rashes may be serious; however, most cases of rash disappear without any change to your treatment with *STOCRIN*. Rash was more common in children than in adults treated with *STOCRIN*.

The nervous system symptoms tend to occur when treatment is first started, but

generally decrease in the first few weeks. If you are affected your doctor may suggest that you take *STOCRIN* at bedtime and on an empty stomach. Rarely, some patients have more serious symptoms that may affect mood or the ability to think clearly. These include depression, suicidal thoughts, angry behavior, strange thoughts, and catatonia (condition in which the patient is rendered motionless and speechless for a period). Some patients have actually committed suicide. These problems tend to occur more often in those who have a history of mental illness. Always notify your doctor if you have these symptoms or any side effects while taking *STOCRIN*.

Rarely, disturbances of coordination and balance, seizures, itching, stomach ache, blurred vision, breast enlargement in men, liver failure, inflammation of the pancreas, increased fat appearing in areas such as the neck, breasts, abdomen, and back, flushing, tremors, and ringing in the ears have been reported in patients receiving *STOCRIN*.

Other side effects may occur with *STOCRIN*. Your doctor or pharmacist has a more complete list of side effects. Inform your doctor promptly about these or any other undesirable effects, especially if not mentioned in this leaflet. If the condition persists or worsens, seek medical attention.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npa.moh.gov.my](http://npa.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI)

#### **How can I learn more about *STOCRIN* and my condition?**

Not all the information about the medicine is printed here. If you have any additional questions, ask your

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doctor or pharmacist who have more detailed information about *STOCRIN* and HIV infection.

## Storage and disposal of *STOCRIN*

### -Storage

*STOCRIN* should be stored below 30°C (86°F). Protect from moisture and light.

Keep out of the reach and sight of the children.

### -Disposal

Do not use this medicine after the month and year shown by the numbers following expiry date on the container. You may obtain further information from your doctor or pharmacist, who has more detailed information.

## Product description

### -What it looks like

#### ***STOCRIN TABLET 200MG:***

Yellow, round shaped tablet with '223' on one side and plain on the other. It is supplied in bottles of 90 tablets.

#### ***STOCRIN TABLET 600MG:***

Yellow, modified capsular-shaped tablets, debossed with "225" on one side and plain on the other. . It is supplied in bottles of 30 tablets.

### -Ingredient

Active ingredients:

Each *STOCRIN* contains 200mg or 600mg of efavirenz as the active ingredient.

Inactive ingredients:

*STOCRIN* 200mg or 600mg tablets also contain the following other ingredients. Tablet core: croscarmellose sodium, microcrystalline cellulose, sodium lauryl sulfate, hydroxypropyl cellulose, lactose monohydrate, and magnesium stearate. The film coating contains as excipients: hypromellose (E464), titanium dioxide (E171), macrogol 400, and carnauba wax. In addition, the 200 mg and 600mg tablet

contains yellow iron oxide (E172).

### -MAL numbers:

*STOCRIN TABLET 200MG:*

MAL14055020ACRZ

*STOCRIN TABLETS 600MG:*

MAL14035016ACRZ

## Manufacturer

Zhejiang Huahai Pharmaceutical Co., Ltd  
Xunqiao Linhai Zhejiang,  
317024 China.

## Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.  
Lot No. B-22-1 & B-22-2, Level 22  
The Ascent, Paradigm No. 1  
Jalan SS 7/26A, Kelana Jaya  
47301 Petaling Jaya  
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