

STOCRIN[®]

efavirenz

50 mg, 200 mg & 600 mg tablets

What is in this leaflet

This leaflet answers some common questions about STOCRIN. 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 STOCRIN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor, pharmacist or treatments officer at your local AIDS Council.

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

What STOCRIN is used for

STOCRIN is used to help treat HIV (Human Immunodeficiency Virus) infection. It is used in combination with other appropriate medicines used to treat the HIV virus. Examples include protease inhibitors such as indinavir (CRIXIVAN[®]) and nelfinavir (Viracept*). They also include nucleoside analogue reverse transcriptase inhibitors (NRTIs) such as zidovudine (AZT, Retrovir*) or lamivudine (3TC*).

STOCRIN belongs to a group of medicines called non-nucleoside reverse transcriptase inhibitors. It works by interrupting the formation of new HIV particles in already infected cells. When HIV is attacked by STOCRIN, the virus is not able to reproduce normally. This helps reduce the amount of virus in the blood. Although STOCRIN helps reduce the amount of virus in the blood and thus increases the CD4 count, it has not yet been shown to improve survival or slow the progression of the disease.

You may continue to develop infections or other illnesses associated with HIV disease while you are taking STOCRIN.

Before you take STOCRIN

When you must not take it

Do not take STOCRIN if:

- you have an allergy to STOCRIN or any of the ingredients listed at the end of this leaflet
- the packaging is torn or shows signs of tampering
- you are pregnant or are planning to become pregnant (if you are please inform your doctor immediately)
- you are breast-feeding or plan to breast-feed.
You should not breast-feed if you are taking STOCRIN because of the possibility that your baby can be infected with HIV through your breast milk. Talk to your doctor about the best way to feed your baby.
- the expiry date on the pack has passed.
If you take this medicine after the expiry date has passed, it may not work.

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

STOCRIN tablets have not been studied in children below 3 years of age or those 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.

Before you start to take it

Tell your doctor if:

1. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
2. you have any medical conditions, especially the following:
 - liver disease, including chronic hepatitis B or C
 - high cholesterol
3. you are breast-feeding a baby, pregnant, or intend to become pregnant
4. you are taking any other medicine that contains efavirenz. STOCRIN should not be taken together with ATRIPLA or other medicines that contain efavirenz
5. 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.

If you have not told your doctor about any of the above, tell them before you take any STOCRIN.

Taking other medicines

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

Some medicines should not be taken with STOCRIN as they may cause a life-threatening interaction. These include:

- terfenadine and astemizole, antihistamines used for hay fever and other allergic conditions
- cisapride, used to treat stomach reflux
- triazolam (e.g Halcion*), used to treat anxiety, depression or for sleeplessness
- midazolam (e.g Hypnovel*), used as a sedative before surgical procedures
- ergot derivatives used for treatment of migraine and during labour/childbirth
- pimozide, used to treat psychiatric conditions
- bepridil, used to treat angina.

Do not take STOCRIN with elbasvir/grazoprevir as it may decrease the effect of elbasvir/grazoprevir.

Do not take STOCRIN with St. John's wort (*Hypericum perforatum*), 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 drugs.

STOCRIN should not be taken together with ATRIPLA or other medicines that contain efavirenz. 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. An increased dose of voriconazole may be taken at the same time as a reduced dose of efavirenz, but you must check with your doctor first.

Some other medicines and STOCRIN may interfere with each other

These include:

- saquinavir (e.g Invirase*), protease inhibitor used to treat HIV infection
- simeprevir, a protease inhibitor used to treat hepatitis C

- sofosbuvir/velpatasvir, a medicine used to treat hepatitis C
- sofosbuvir/velpatasvir/voxilaprevir, a medicine used to treat hepatitis C
- atazanavir, a protease inhibitor
- lopinavir/ritonavir, protease inhibitors
- telaprevir, a medicine used to treat hepatitis C
- clarithromycin, an antibiotic used to treat bacterial infections
- rifampicin and rifabutin (e.g Mycobutin*) antibiotics used to treat TB and infections caused by MAC
- atovaquone/proguanil (e.g Malarone) or artemether/lumefantrine, medicines used to treat malaria
- warfarin and acenocoumarol, medicines used to prevent blood clots
- ethinyl oestradiol, used in some oral contraceptives
- methadone, used to treat opioid dependence
- sertraline, an antidepressant
- bupropion, a medicine used to help you stop smoking
- itraconazole, used to treat fungal infections
- atorvastatin, pravastatin, or simvastatin (lipid-lowering medicines, also called statins)
- carbamazepine (used to prevent seizures)
- diltiazem or similar medicines (called calcium channel blockers), used to treat angina pectoris and hypertension.
- medicines affecting the immune system (eg cyclosporine, tacrolimus or sirolimus).

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

STOCRIN is taken in combination with other medicines commonly used to help treat HIV-infection. These include the protease inhibitors and nucleoside analogue reverse transcriptase inhibitors (NRTIs). The optimal dose of indinavir, when given in combination with STOCRIN, 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 is not recommended. A dose increase of lopinavir/ritonavir may be required when given in combination with STOCRIN.

Use of STOCRIN with simprevir or sofosbuvir/velpatasvir or sofosbuvir/velpatasvir/voxilaprevir is not recommended.

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.

Make sure your doctor and pharmacist know about all of the medicines, including herbal products and dietary supplements, you are taking, as they have more information on medicines to be careful with or avoid while taking STOCRIN.

How to take STOCRIN

How much to take

Take STOCRIN only when prescribed by your doctor. Your doctor will tell you how many tablets you need to take each day.

For adults and children weighing more than 40 kg, the normal dose is 600 mg once daily (that is three 200 mg tablets, or one 600 mg tablet, once a day). It is important that you are started and continue on this dose.

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

Follow all directions given to you by your doctor 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 to take it

Swallow STOCRIN with a glass of water or other liquid.

It does not matter if you take STOCRIN with or without food.

When to take it

Your doctor may ask you to take STOCRIN at bedtime to avoid or reduce certain adverse effects, such as dizziness and sleepiness.

How long to take it

STOCRIN helps control your HIV infection but does not cure it. Therefore STOCRIN must be taken every day. Continue taking STOCRIN for as long as your doctor prescribes.

Do not stop taking STOCRIN or change the dose without first checking with your doctor. Do not let yourself run out of medicine over weekends or on holidays.

If you have a break in therapy or reduce your dose temporarily, the virus may develop resistance and therefore STOCRIN may no longer be effective. If, for any reason, your therapy with STOCRIN is interrupted or stopped, tell your doctor.

If you forget to take it

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

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much STOCRIN. Do this even if

there are no signs of discomfort or poisoning.

While you are using STOCRIN

Things you must do

Report any changes in your condition to your doctor immediately. This is to make sure that any infections which occur due to your low immunity (called opportunistic infections) are treated promptly. Continue to use safer sexual practices.

In some patients with advanced HIV infection (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 infection, 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.

STOCRIN has not been shown to decrease the chance of transmitting HIV to others through sexual contact or blood contamination.

Women should not get pregnant during treatment with STOCRIN and for 12 weeks thereafter. 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.

If you become pregnant while taking STOCRIN, tell your doctor immediately.

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

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

Things you must not do

Do not stop taking STOCRIN or change the dose without first checking with your doctor. Do not let yourself run out of medicine over weekends or on holidays.

If you have a break in therapy or reduce your dose temporarily, the virus may develop resistance and therefore STOCRIN may no longer be effective. If, for any reason your therapy with STOCRIN is interrupted or stopped, tell your doctor.

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

Things to be careful of

Be careful driving or operating machinery until you know how STOCRIN affects you. STOCRIN may cause dizziness, sleepiness or affect concentration in some people, especially after the first one or two days. Make sure you know how you react to STOCRIN before you drive a car or operate machinery.

Adverse Effects

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

STOCRIN helps most people with HIV infection, but it may have unwanted adverse effects. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Frequently it is difficult to tell whether adverse effects are the result of taking STOCRIN, effects of the HIV disease or adverse 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 STOCRIN.

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

Tell your doctor if you notice any of the following and they worry you:

- skin rash
- nausea
- dizziness
- headache
- fatigue
- insomnia (sleeplessness)
- drowsiness
- unable to concentrate
- abnormal dreaming

These are the more common adverse effects of STOCRIN. They generally resolve after the first few weeks. Taking STOCRIN at night may help to reduce some of these adverse effects.

Tell your doctor immediately or go to accident and emergency at your nearest hospital if you develop any of the following:

- any severe skin reaction
- pinkish, itchy swellings on the skin, also called hives or nettlerash
- seizures (have a "fit" or convulsion)

Because these adverse effects are serious, you may need urgent medical attention.

Rarely, some patients have more serious symptoms that may affect mood or the ability to think clearly. These include depression, suicidal thoughts, angry behaviour, 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.

Other rarely reported adverse effects include stomach ache, blurred vision, breast enlargement in men, liver failure, inflammation of the pancreas, disturbances of co-ordination and balance, increased fat appearing in areas such as the neck, breasts, abdomen and back, flushing, tremors, and ringing in the ears.

Other adverse effects not listed above may also occur in some patients. The long-term effects of STOCRIN are unknown at this time. Tell your doctor if you notice any other effects.

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

After using STOCRIN

Storage

Keep your tablets in the original container until it is time to take them.

If you take the tablets out of the container they may not keep well, as they are affected by moisture.

Keep STOCRIN in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it 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 the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

STOCRIN tablets come in three strengths:

- 50 mg - yellow round shaped tablet with 113 engraved on one side and plain on the other.
- 200 mg - yellow round shaped tablet with 223 engraved on one side and plain on the other.
- 600 mg - yellow modified capsular shaped tablet with 225 engraved on one side and plain on the other.

A bottle of STOCRIN 50 mg tablets contains 30 tablets.

A bottle of STOCRIN 200 mg tablets contains 90 tablets.

A bottle of STOCRIN 600 mg tablets contains 30 tablets.

Ingredients

Active ingredient:

- efavirenz

Inactive ingredients:

- Croscarmellose sodium
- Microcrystalline cellulose
- Sodium lauryl sulphate
- Hydroxypropyl cellulose
- Lactose monohydrate
- Magnesium stearate
- Hypromellose (E464)
- Titanium dioxide (E171)
- Macrogol 400
- Carnauba wax

- Yellow iron oxide

The tablets are not printed with ink.

STOCRIN does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

STOCRIN is marketed in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99 851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

This leaflet was prepared in April 2018.

CPPI-MK0831-MF-022018

Copyright © 2014 Merck Sharp & Dohme Corp., a subsidiary Merck & Co., Inc., Whitehouse Station, NJ, USA.
All rights reserved

* Trademarks