

STOCRIN®

Efavirenz

Consumer Medicine Information

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 (NNRTIs). 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**
- **the expiry date on the pack has passed.**
If you take this medicine after the expiry date has passed, it may not work.
- **you are breast feeding or plan to breast feed**
It is possible that your baby can be infected with HIV through your breast milk.

Talk to your doctor about the best way to feed your baby.

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

Do not give STOCRIN to children under 3 years of age or those who weigh less than 13 kg.

The safety and effectiveness of STOCRIN in these children have not been adequately established.

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 or have had any medical conditions, especially the following:**
 - liver disease, including hepatitis B or C
 - high cholesterol
 - mental illness
 - seizures or fits
3. **you consume large amounts of alcohol or use recreational drugs**
4. **you are pregnant or intend to become pregnant**
If there is a need to take STOCRIN when you are pregnant, your doctor will discuss the possible risks and benefits to you and the unborn baby.
5. **you are taking a medicine that contains efavirenz (e.g. ATRIPLA).**
STOCRIN should not be taken together with ATRIPLA or other medicines that contain efavirenz.
6. **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, herbal products, or dietary supplements, including those 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 allergic conditions, including hayfever
- 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
- some medicines used to treat migraine, including Cafergot*, Cafergot S*, Ergodryl*, Ergodryl Mono*, Dihydergot*, Migral*.
- pimozone (not available in Australia)
- bepridil (not available in Australia)
- STOCRIN should not be taken together with ATRIPLA or other medicines that contain efavirenz.

In addition, STOCRIN should not be taken with St. John's wort (*Hypericum perforatum*), a herbal product sold as a dietary supplement, or products containing St. John's wort as it may decrease the effect of STOCRIN.

STOCRIN should not be taken with voriconazole.

Some medicines and STOCRIN may interfere with each other.

These include:-

- saquinavir (e.g. Invirase), amprenavir (e.g. Agenerase) and lopinavir/ritonavir (e.g. Kaletra)

protease inhibitors used to treat HIV infection

- telaprevir, simeprevir and boceprevir, medicines used to treat hepatitis C
- clarithromycin (e.g. Klacid), an antibiotic used to treat bacterial infections
- rifampicin (e.g. Rifadin, Rimycin) 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
- phenobarbitone, phenytoin and carbamazepine, medicines used to treat epilepsy and/or convulsions
- methadone, a medicine used to treat opioid drug dependency
- sertraline used to treat depression, obsessive compulsive disorder and panic disorder
- bupropion, a medicine used to help you stop smoking
- medicines affecting the immune system (e.g. ciclosporin, tacrolimus or sirolimus). Your doctor might want to do some additional tests.
- itraconazole
- diltiazem or similar medicines (calcium channel blockers)
- atorvastatin, pravastatin or simvastatin (lipid lowering medicines, also called statins)
- 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.

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 such as indinavir (Crixivan*) and nelfinavir (Viracept*). They also include nucleoside analogue reverse transcriptase inhibitors (NRTIs) such as zidovudine (AZT, Retrovir*) or lamivudine (3TC). The optimal dose of indinavir, when given in combination with efavirenz, is not known.

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 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.

Make sure your doctor and pharmacist know about all of the medicines 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 or how much solution you need to take each day.

For adults and children weighing more than 40 kg, the normal dose is 600 mg once a day or 24 mL of the solution once a day. It is important that you are started and continue on this dose.

For children and teenagers 3 to 17 years old, the dose depends on body weight. Your child's doctor will decide the dose.

Please note that the dose of STOCRIN oral solution in mg of efavirenz is not the same as for STOCRIN tablets.

Carefully follow all directions given to you by your doctor.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle or box, ask your doctor or pharmacist for help.

How to take it

Swallow STOCRIN with a glass of water.

Measure the dose of STOCRIN oral solution using the syringe supplied in the box.

Follow the instructions on the leaflet inside the box.

Take STOCRIN on an empty stomach, preferably just before bedtime.

If you take STOCRIN with food, this can increase the risk of side effects.

When to take it

Take STOCRIN at about the same time each day.

Taking your tablets or solution at the same time each day is important because keeping a constant level of STOCRIN in your body helps prevent resistance. Resistance means that the medicine may lose its effectiveness over time.

Your doctor may ask you to take STOCRIN at bedtime to avoid or reduce certain side 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 tablet or solution 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 or solution, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) 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 safe sexual practices.

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

Women taking STOCRIN should avoid pregnancy during treatment and for 12 weeks after they've stopped taking treatment. Use barrier contraception even if you are using other methods (eg. oral contraceptive pill or other hormonal contraceptives).

If you become pregnant while taking STOCRIN or in the 12 weeks after you've stopped taking it, 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, drowsiness or affect concentration in some people, especially during the first few days. Make sure you know how you react to STOCRIN before you drive a car or operate machinery. If you drink alcohol, dizziness or drowsiness may be worse.

Side 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 side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Frequently it is difficult to tell whether side effects are the result of taking STOCRIN, 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 STOCRIN.

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

In adults:

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

- skin rash or itchiness or increased sensitivity to sunlight
- dizziness, tiredness, or sleepiness
- nausea
- stomach pain
- headache

- inability to concentrate
- abnormal dreaming
- difficulty sleeping
- breast enlargement in men
- increased fat appearing in areas such as the back of the neck, breasts, stomach and/or back
- loss of body fat from areas such as face, arms and/or legs
- changes in your co-ordination or ability to balance
- flushing
- tremors
- ringing in the ears

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

Some of these side effects may be worse if you:

- drink alcohol
- take medicines for certain mental illnesses, including depression, schizophrenia, psychoses, anxiety
- take recreational drugs

In children 3 to 16 years old:

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

- skin rash or itchiness or increased sensitivity to sunlight
- dizziness
- headache
- fever
- nausea or vomiting
- stomach pain, diarrhoea
- cough
- aches or pains
- increased fat appearing in areas such as the back of the neck, breasts, stomach and/or back
- loss of body fat from areas such as face, arms and/or legs

These are the more common side effects of STOCRIN in children.

In adults and children

Tell your doctor immediately if you notice any of the following:

- severe dizziness, spinning sensation
- tingling or numbness of the hands or feet
- blurred vision
- mental changes, including seeing, feeling or hearing things that are not there (also called hallucinations)
- mood changes, including depression, suicidal thoughts or actually committing suicide, angry behaviour, strange thoughts, anxiousness, and catatonia (condition in which the patient is rendered motionless and speechless for a period). People who have or have had mental illnesses appear to be at greater risk of these effects.

Because some of these may be serious side effects, you may need urgent medical attention.

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 nettle rash
- fainting
- fast or irregular heart beat
- wheeziness due to tightness in the chest
- convulsions or fits
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and/or dark coloured urine

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

Other side 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 side effects. You may not experience any of them.

After using STOCRIN

Storage

Keep your tablets or solution in the original bottle, until it is time to take them.

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

Write the date on the bottle of solution when you opened it, and throw out any remaining solution after one month.

The solution contains a preservative which helps prevent germs growing in the solution for the first month after opening the bottle. After this time, there is a greater risk that the solution may become contaminated. A new bottle should be opened.

If your doctor tells you to stop taking STOCRIN, or the tablets or solution have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

STOCRIN is available in three strengths of tablets and one strength of solution:

- 50 mg tablet- yellow round tablet with "113" on one side & plain on the other
- 200 mg tablet- yellow round tablet with "223" on one side & plain on the other
- 600 mg - yellow capsule-shaped tablet with 225 debossed on one side & plain on the other.
- 30 mg/mL oral solution - clear to slightly yellow liquid.

Tablets

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 contains 30 tablets.

Liquid

A bottle of STOCRIN oral solution contains 180 mL

Ingredients

Active ingredient:

- STOCRIN 50 mg contains 50 mg efavirenz
- STOCRIN 200 mg contains 200 mg efavirenz
- STOCRIN 600 mg contains 600mg efavirenz
- STOCRIN 30 mg/mL contains 30 mg efavirenz per mL.

Inactive ingredients:

Tablets

- lactose monohydrate
- magnesium stearate
- croscarmellose sodium
- cellulose-microcrystalline
- sodium lauryl sulfate
- hypromellose
- hypromellose
- titanium dioxide
- macrogol 400
- iron oxide yellow CI 77492 (50 mg, 200 mg and 600 mg tablets only)
- carnauba wax

Liquid

- medium chain triglycerides
- benzoic acid
- strawberry/mint flavour

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

Supplier

STOCRIN is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited
A.B.N. 14 000 173 508
Level 1, Building A, 26 Talavera Road, Macquarie Park, NSW 2113

This leaflet was prepared in May 2017.

Australian Register Numbers:

Tablets

50 mg bottle - AUST R 125198 - not currently available in Australia

200 mg bottle - AUST 125199

600 mg bottle - AUST R 82789

Liquid

30 mg/mL oral solution - AUST R 82790

®Registered Trademark of Merck & Co. Inc.,

Copyright © 2014 Merck & Co., Inc

All rights reserved.

S-LRD-PPI-MK0831-MF-022017