

STOCRIN®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using STOCRIN?

STOCRIN contains the active ingredient Efavirenz. 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.

For more information, see Section [1. Why am I using STOCRIN?](#) in the full CMI.

2. What should I know before I use STOCRIN?

Do not use if you have ever had an allergic reaction to STOCRIN or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use STOCRIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with STOCRIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use STOCRIN?

Your doctor will tell you how many tablets you need to take each day.

- For adults and children weighing greater than or equal to 40 kg, the normal dose is 600 mg 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.

More instructions can be found in Section [4. How do I use STOCRIN?](#) in the full CMI.

5. What should I know while using STOCRIN?

Things you should do	<ul style="list-style-type: none">• Report any changes in your condition to your doctor immediately to ensure any infections which occur due to your low immunity are treated promptly.• Continue to use safe sexual practices.
Things you should not do	<ul style="list-style-type: none">• 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.
Driving or using machines	<ul style="list-style-type: none">• 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

	<p>know how you react to STOCRIN before you drive a car or operate machinery.</p>
<p>Looking after your medicine</p>	<p>Keep your tablets in the original bottle, until it is time to take them</p> <p>Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:</p> <ul style="list-style-type: none"> • in the bathroom or near a sink, or • in the car or on window sills.

For more information, see Section [5. What should I know while using STOCRIN?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, STOCRIN can cause side effects, some may be serious, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using STOCRIN.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

STOCRIN

Active ingredient: *Efavirenz*

Consumer Medicine Information (CMI)

This leaflet provides important information about using STOCRIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using STOCRIN.**

Where to find information in this leaflet:

- [1. Why am I using STOCRIN?](#)
- [2. What should I know before I use STOCRIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use STOCRIN?](#)
- [5. What should I know while using STOCRIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using STOCRIN?

STOCRIN contains the active ingredient Efavirenz.

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.

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).

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

2. What should I know before I use STOCRIN?

Warnings

Do not use 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.**

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

Check with your doctor if you:

- **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes**
- **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
- **you consume large amounts of alcohol or use recreational drugs**
- **you are pregnant or intend to become pregnant**
- **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.

- **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.

Pregnancy

Check with your doctor if 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.

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.

Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

Children

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.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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*.
- pimozide (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.

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

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, boceprevir, sofosbuvir/velpatasvir and sofosbuvir/velpatasvir/voxilaprevir 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect STOCRIN.

4. How do I use 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 greater than or equal to 40 kg, the normal dose is 600 mg 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.

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 STOCRIN

Swallow STOCRIN with a glass of water.

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 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 use STOCRIN

If you miss a dose, take it as soon as you remember, and then go back to taking your tablet 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 use too much STOCRIN

If you think that you have used too much STOCRIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using STOCRIN?

Things you should 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.

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 should 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.

Driving or using machines

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.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects in adults

Less serious side effects	What to do
<p>Tell your doctor if you notice any of the following and they worry you:</p> <ul style="list-style-type: none">● skin rash or itchiness or increased sensitivity to sunlight● dizziness, tiredness, or sleepiness● nausea● stomach pain● headache● inability to concentrate	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● 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

Common side effects in children 3 to 16 years old

Less serious side effects	What to do
<p>Tell your doctor if you notice any of the following and they worry you:</p> <ul style="list-style-type: none">• 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	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

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

Serious side effects in adults and children

Serious side effects	What to do
<p>Tell your doctor immediately if you notice any of the following:</p> <ul style="list-style-type: none">• 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	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
at greater risk of these effects.	

Some nervous system symptoms (e.g., confusion, slow thoughts and physical movement, and delusions [false beliefs] or hallucinations [seeing or hearing things that others do not see or hear]) may occur months to years after beginning STOCRIN therapy.

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

Other Serious Side effects

Other serious side effects	What to do
<ul style="list-style-type: none"> ● any severe skin reaction ● pinkish, itchy swellings on the skin, also called hives or nettlerash ● 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, 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Other serious side effects	What to do
itching, yellowing of the skin and eyes, and/or dark coloured urine	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What STOCRIN contains

Active ingredient (main ingredient)	efavirenz
Other ingredients (inactive ingredients)	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

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

Do not take this medicine if you are allergic to any of these ingredients.

What STOCRIN looks like

STOCRIN is available in three strengths of tablets:

50 mg tablet- yellow round tablet with "113" on one side & plain on the other (AUST R 125198*)

200 mg tablet- yellow round tablet with "223" on one side & plain on the other (AUST 125199)

300mg tablet - white capsule-shaped tablet with "224" in purple on both sides (AUST R 82787* & AUST R 82786*)

600 mg - yellow capsule-shaped tablet with "225" debossed on one side & plain on the other (AUST R 82789)

*These pack sizes not currently available in Australia

Who distributes STOCRIN

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road,

Macquarie Park, NSW 2113, Australia

This leaflet was prepared on 27 January 2023.

CCPPI-MK0831-MF-062022

RCN: 000024479-AU

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