

STOCRIN & PREGNANCY



What STOCRIN is used for

- STOCRIN is used to help treat HIV infection. It is used in combination with other appropriate medicines used to treat the HIV. Examples include PI's such as KALETRA. They also include (NRTIs) such as AZT or (3TC*).
- STOCRIN belongs to a group of medicines called NNTRI's. It works by interrupting the formation of new HIV particles in already infected cells.



Safety concerns with Stocrin

- ❑ Do not take STOCRIN if:
 - ❑ you have an allergy to STOCRIN
 - ❑ you are pregnant or are planning to become pregnant
 - ❑ you are breast feeding or plan to breast feed



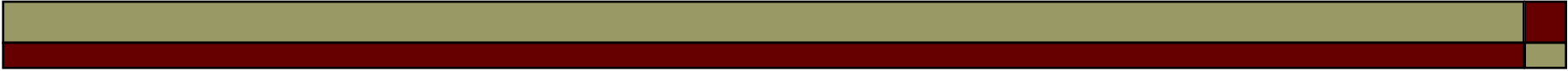
Before you start to take it

- Tell your doctor if:
- you have any allergies to any other medicines
- you have any medical conditions, especially the following:
 - liver disease, including chronic hepatitis B or C
 - If you are on any anti-cholesterol medication



Taking other medicines

- ❑ Some medicines should not be taken with STOCRIN as they may cause a life-threatening interaction. These include:
- ❑ Cimetidine(Hexamet) used to treat stomach ulcers
- ❑ cisapride (Prepulsid*), used to treat stomach reflux

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- triazolam (Halcion*), used to treat anxiety, depression or for sleeplessness
 - midazolam (Dormicum*), used as a sedative before surgical procedures
 - Ketoconazole(Ketazol) to treat fungal infections
 - Carbamazepine(Tegretol), used to treat psychiatric conditions



Adverse Effects

- skin rash
- nausea
- dizziness
- headache
- fatigue
- insomnia (sleeplessness)
- drowsiness
- abnormal dreaming (nightmares)



□ Tell your doctor immediately if you develop any of the following:

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

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



Pregnancy

- HIV infection reduces fertility & ill patients often have reduced libido. However, both libido & fertility improve with effective ARV therapy. Patients often initially decide not to have children, but change their minds as they get well on ARV's. Contraception & family planning are important components of care.



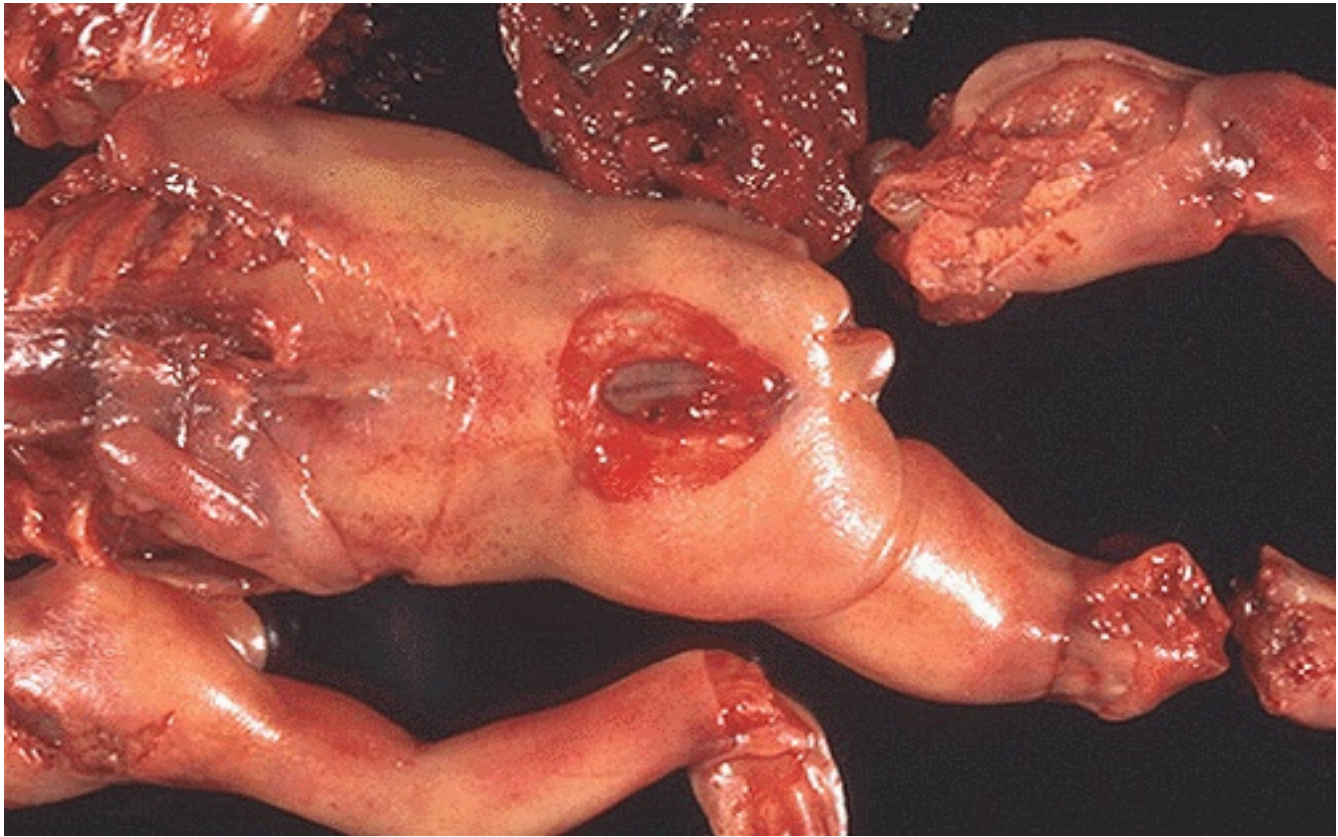
Cont...

- Efavirez (Stocrin) is teratogenic in primates. Two cases have recently been reported of neural tube defects after women conceived whilst taking stocrin. It is essential that adequate contraception be taken by women given stocrin. Termination of pregnancy should be offered if pregnancy occurs on stocrin. If the woman elects not to terminate then stocrin must be stopped and level 3 ultrasound done at around 18 weeks.

NTD

- ❑ You may ask, "What is a neural tube defect (NTD)?"
- ❑ NTDs are birth defects that occur when the neural tube does not form correctly.
- ❑ Neural tube defects usually occur during the first month of pregnancy, before many women know they are pregnant.







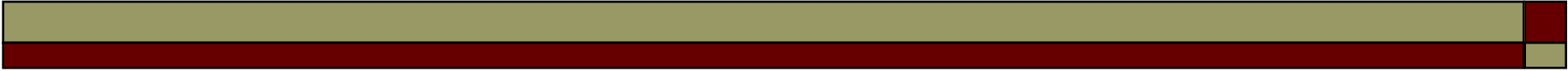
Contraception

- ❑ A pregnancy test is recommended before starting treatment with efavirenz.
- ❑ In addition, it is recommended that women with the potential to become pregnant use two methods of contraception. One method of contraception should be a reliable barrier contraceptive, such as condoms, and the other method should be an oral or other hormone contraceptive, such as birth control pills.
- ❑ Stocrin can reduce the efficacy of the oral contraceptive pills especially the lower doses pills.



Pregnancy continued

- During the first 14 weeks of pregnancy, the foetus is most vulnerable to any toxic effects of drugs.
- Efavirenz can be used during the first trimester of pregnancy only if the potential benefit justifies the potential risk to the foetus, such as in pregnant women lacking other therapeutic options.

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- ❑ According to the FDA, limited data are available regarding birth defects occurring after intrauterine exposure to stocrin.
 - ❑ A study showed that in pregnancy outcomes of 206 women exposed to stocrin (mostly in the first trimester), birth defects occurred in 5 (5.68%) of 188 live births with first-trimester exposure,
 - ❑ and in 0 of 13 live births with second- or third-trimester exposure.(Stocrin is occasional introduced in the third trimester if limited options)



AID FOR AIDS data analysis

Ever on stocrin	13,936		Women ever authorised on Stocrin
Ever on stocrin + ever pregnant+ current (overlap)	396		Currently registered, and previously simultaneously on Stocrin and pregnant.

Trimester1 only	68	17.2%	On Stocrin during the first trimester.
Trimester2 only	74	18.7%	On Stocrin during the second trimester.
Trimester3 only	45	11.4%	On Stocrin during the third trimester.
Trim1 + Trim2	209	52.8%	On Stocrin during the first and second trimester, although not necessarily only one and two, i.e. some go to third trimester (105).
Total	396	100.0%	Currently registered, and previously simultaneously on Stocrin and pregnant.