

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE for:

APPLICATION NUMBER: 020685/S005

TRADE NAME: Crixivan capsules

GENERIC NAME: Indinavir sulfate

SPONSOR: Merck Research Laboratories

APPROVAL DATE: 2/19/97

NDA 20-685/S-006

FEB 19 1997

Merck Research Laboratories
Attention: Larry Bell, M.D.
Director, Regulatory Affairs
P.O. Box 4, BLA-30A
West Point, PA 19486-0004

Dear Dr. Bell:

We acknowledge your supplemental new drug application dated December 13, 1996, that was received on December 17, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CRIXIVAN™ (indinavir sulfate) capsules.

The supplemental application provides a patient package insert (PPI) for CRIXIVAN™. We have completed the review of this supplemental application and we find it acceptable. Accordingly, the supplemental application is approved effective on the date of this letter.

Should you have any questions, please contact David Clinton Staten, Jr., Regulatory Health Manager, at (301) 827-2335.

Sincerely yours,



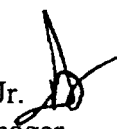
Donna J. Freeman, M.D.
Acting Director
Division of Anti-Viral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research



MEMORANDUM

DATE: February 7, 1997

NDA NUMBER: 20-685/S-005 ¹²

FROM: David Clinton Staten, Jr. 
Regulatory Health Manager

DATE OF SUBMISSION: December 13, 1996

APPLICANT NAME AND ADDRESS: Merck Research Laboratories

PRODUCT NAME: Trade Name: CRIXIVAN™
Generic: Indinavir Sulfate
Dosage Form: Caplets

MATERIALS REVIEWED:

1. Approved FPL
2. December 13, 1996 patient package insert (PPI)

A line-by-line review of this submission has been completed. The contents of the PPI is consistent with the October 22, 1996 draft and to the approved FPL. An Acknowledge and Retain letter will be sent to the sponsor.

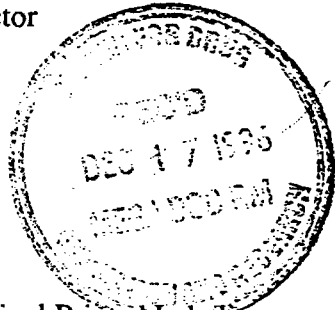
Larry P. Bell, M.D.
Director
Regulatory Affairs

Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point PA 19486
Fax 610 397 2516
Tel 610 397 2310
215 652 5000

December 13, 1996

These copies are OFFICIAL FDA Copies
not desk copies.

Donna Freeman, M.D. - Acting Director
Division of Antiviral Drug Products
HFD-530, CDER, FDA
9201 Corporate Boulevard
Rockville, Maryland 20850



S. Kucera
1/28/97

Dear Dr. Freeman:

Final Printed Labeling

NDA 20-685: CRIXIVAN™ (Indinavir Sulfate)

Please refer to the above mentioned approved new drug application. Please also refer to your letter of October 22, 1996 in which you state you have no additional comments regarding our proposed patient package insert (PPI) submitted June 5, 1996 and revised August 19, 1996 in response to comments from the Division of Antiviral Drug Products and Drug Marketing, Advertising and Communications.

Attached in response to your October 22, 1996 letter are the following:

- Printed patient package insert #9024501 (Issued September 1996) - 15 copies
- Clean running text - 1 copy
- Hard copy of WordPerfect version - 1 copy
- Computer disk containing circular in WordPerfect format - 1 copy

The patient package insert is new and the first used in production and will become effective on or about January 31, 1997 and will apply to all packages of CRIXIVAN™ distributed from the company's manufacturing facilities.

Questions concerning this matter should be directed to Larry P. Bell, M.D. (610/397-2310) or, in my absence Bonnie J. Goldmann, M.D. (610/397-2383).

Sincerely yours,

A handwritten signature in cursive script that reads 'Larry P. Bell'.

Larry P. Bell, M.D.
Director
Regulatory Affairs

Attachments
Q/YARB/SAR/CRIX/SS20685

Certified No. P 914 177 405

APPROVED

FEB 19 1997

2

9024501

CRIXIVAN® (indinavir sulfate) Capsules
Patient Information about
CRIXIVAN (KRIK-sib-van)
for HIV (Human Immunodeficiency Virus) Infection
Generic name: indinavir (in-DIH-nuh-veer) sulfate

Please read this information before you start taking CRIXIVAN. Also, read the leaflet each time you renew your prescription, just in case anything has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss CRIXIVAN when you start taking your medication and at regular checkups. You should remain under a doctor's care when using CRIXIVAN and should not change or stop treatment without first talking with your doctor.

What is CRIXIVAN?

CRIXIVAN is an oral capsule used for the treatment of adults with HIV (Human Immunodeficiency Virus) when therapy is warranted. HIV is the virus that causes AIDS (acquired immune deficiency syndrome). CRIXIVAN is a new type of HIV drug called a protease (PRO-tee-ase) inhibitor.

How does CRIXIVAN work?

CRIXIVAN is a protease inhibitor that fights HIV. It may help lower the amount of HIV in your body (called "viral load") and raise your CD4 (T) cell count.

CRIXIVAN may be prescribed alone. CRIXIVAN may also be prescribed with other anti-HIV drugs such as ZDV (also called AZT), 3TC, ddI, ddC, or d4T. CRIXIVAN works differently from these other anti-HIV drugs. Talk with your doctor to see if you should take CRIXIVAN alone or with other anti-HIV drugs.

CRIXIVAN has been studied in adults. It has not been studied in children and adolescents.

How should I take CRIXIVAN?

There are six important things you must do to help you benefit from CRIXIVAN:

1. **Take CRIXIVAN capsules every day as prescribed by your doctor. Continue taking CRIXIVAN unless your doctor tells you to stop. Take the exact amount of CRIXIVAN that your doctor tells you to take, right from the very start. To help make sure you will benefit from CRIXIVAN, you must not skip doses or take "drug holidays". If you don't take CRIXIVAN as prescribed, the activity of CRIXIVAN may be reduced (due to resistance).**

2. **Take CRIXIVAN capsules every 8 hours around the clock, every day.** It may be easier to remember to take CRIXIVAN if you take it at the same time every day. If you have questions about when to take CRIXIVAN, your doctor or health care provider can help you decide what schedule works for you.
3. **If you miss a dose by more than 2 hours, wait and then take the next dose at the regularly scheduled time.** However, if you miss a dose by less than 2 hours, take your missed dose immediately. Then take your next dose at the regularly scheduled time. Do not take more or less than your prescribed dose of CRIXIVAN at any one time.
4. **Take CRIXIVAN with water.** You can also take CRIXIVAN with other beverages such as skim milk, juice, coffee, or tea.
5. **Ideally, take each dose of CRIXIVAN without food but with water at least one hour before or two hours after a meal.** Or you can take CRIXIVAN with a light meal. Examples of light meals include:
 - dry toast with jelly, juice, and coffee (with skim milk and sugar if you want)
 - cornflakes with skim milk and sugar

Do not take CRIXIVAN at the same time as any meals that are high in calories, fat, and protein (for example — a bacon and egg breakfast). When taken at the same time as CRIXIVAN, these foods can interfere with CRIXIVAN being absorbed into your bloodstream and may lessen its effect.

6. **Drink at least six 8-ounce glasses of liquids (preferably water) throughout the day, every day. CRIXIVAN has caused kidney stones in some patients.** By having enough fluids in your body you may help reduce the chances of forming a kidney stone. Call your doctor or other health care provider if you develop kidney pains (middle to lower stomach or back pain) or blood in the urine.

Does CRIXIVAN cure HIV or AIDS?

CRIXIVAN is not a cure for HIV or AIDS. People taking CRIXIVAN may still develop infections or other conditions associated with HIV. Because of this, it is very important for you to remain under the care of a doctor.

It is not yet known whether taking CRIXIVAN will extend your life or reduce your chances of getting other illnesses associated with HIV. Information about how well the drug works is available from clinical studies up to 24 weeks.

Does CRIXIVAN reduce the risk of passing HIV to others?

CRIXIVAN has not been shown to reduce the risk of passing HIV to others through sexual contact or blood contamination.

Who should not take CRIXIVAN?

Do not take CRIXIVAN if you have had a serious allergic reaction to CRIXIVAN or any of its components.

What other medical problems or conditions should I discuss with my doctor?

Talk to your doctor if:

- You are pregnant or if you become pregnant while you are taking CRIXIVAN.
We do not yet know how CRIXIVAN affects pregnant women or their developing babies.
- You are breast-feeding. You should stop breast feeding if you are taking CRIXIVAN.

Also talk to your doctor about:

- Problems with your liver, especially if you have mild or moderate liver disease caused by cirrhosis.
- Problems with your kidneys.
- Any medicines you are taking or plan to take, including non-prescription medicines.

CRIXIVAN® (indinavir sulfate) Capsules

9024501

Can CRIXIVAN be taken with other medications?*

Drugs you should not take with CRIXIVAN:

SELDANE®
(terfenadine)
VERSED®
(midazolam)
PROPULSID®
(cisapride)

HISMANAL®
(astemizole)
HALCION®
(triazolam)

Taking CRIXIVAN with the above medications could result in serious or life-threatening problems (such as irregular heartbeat or excessive sleepiness).

In addition, you should not take CRIXIVAN with rifampin, known as RIFADIN®, RIFAMATE®, RIFATER®, or RIMACTANE®.

Drugs you can take with CRIXIVAN include:

RETROVIR®
(zidovudine, ZDV
also called AZT)

EPIVIR™
(lamivudine, 3TC)

ZERIT®
(stavudine, d4T)

isoniazid
(INH)

BACTRIM®/SEPTA®
(trimethoprim/sulfamethoxazole)

DIFLUCAN®
(fluconazole)

BIAXIN®
(clarithromycin)

ORTHO-NOVUM 1/35®
(oral contraceptive)

TAGAMET®
(cimetidine)

VIDEX® (didanosine, ddl) — If you take CRIXIVAN with VIDEX®, take them at least one hour apart.

MYCOBUTIN® (rifabutin) — If you take CRIXIVAN with MYCOBUTIN®, your doctor may adjust the dose of MYCOBUTIN.

CRIXIVAN® (indinavir sulfate) Capsules

9024501

NIZORAL® (ketoconazole) — If you take CRIXIVAN with NIZORAL®, your doctor may adjust the dose of CRIXIVAN.

Talk to your doctor about any medications you are taking.

What are the possible side effects of CRIXIVAN?

Like all prescription drugs, CRIXIVAN can cause side effects. The following is **not** a complete list of side effects reported with CRIXIVAN when taken either alone or with other anti-HIV drugs. Do not rely on this leaflet alone for information about side effects. Your doctor can discuss with you a more complete list of side effects.

Some patients treated with CRIXIVAN in clinical studies developed kidney stones; this occurred in about 4% of patients. Drinking at least 6 glasses of liquid each day may help reduce the chances of forming a kidney stone. Call your doctor or other health care provider if you develop kidney pains (middle to lower stomach or back pain) or blood in the urine.

Increases in bilirubin (one laboratory test of liver function) have been reported in approximately 10% of patients. Usually, this finding has not been associated with liver problems. However, on rare occasions, a person may develop yellowing of the skin and/or eyes.

In clinical studies, side effects occurring in 2% or more of patients included: abdominal pain, fatigue or weakness, flank pain, feeling unwell, nausea, diarrhea, vomiting, acid regurgitation, loss of appetite, dry mouth, back pain, headache, trouble sleeping, dizziness, taste changes, rash, upper respiratory infection, dry skin, and sore throat.

Other side effects occurring in 0.5%-2% of patients in clinical studies included: sleepiness, fever, indigestion, excessive gas, muscle pain, leg pain, anxiety, depression, decreased skin sensation, itching, and painful or difficult urination.

Side effects occurring rarely, in less than 0.5% of patients in clinical studies, and also considered serious included: gall bladder inflammation, liver cirrhosis, pneumonia, and swollen kidneys due to blocked urine flow.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

How should I store CRIXIVAN capsules?

- Keep CRIXIVAN capsules in the bottle they came in and at room temperature (59°-86°F).
- Keep CRIXIVAN capsules dry by leaving the small desiccant "pillow" in the bottle. Keep the bottle closed.

This medication was prescribed for your particular condition. Do not use it for any other condition or give it to anybody else. Keep CRIXIVAN and all medicines out of the reach of children. If you suspect that more than the prescribed dose of this medicine has been taken, contact your local poison control center or emergency room immediately.

This leaflet provides a summary of information about CRIXIVAN. If you have any questions or concerns about either CRIXIVAN or HIV, talk to your doctor.

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Issued September 1996

MERCK & CO., INC.
West Point, PA 19486, USA

CRIXIVAN® (indinavir sulfate) Capsules

9024501

Patient Information about CRIXIVAN (KRIK-sih-van)

for HIV (Human Immunodeficiency Virus) Infection

Generic name: indinavir (in-DIH-nuh-veer) sulfate

APPROVED

FEB 19 1997

Read this information before you start taking CRIXIVAN. Also, read the leaflet each time you renew your prescription, just in case something has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss CRIXIVAN when you start taking your medication and at regular checkups. You should remain under a doctor's care when using CRIXIVAN and should not change or stop your medication without first talking with your doctor.

What is CRIXIVAN?

CRIXIVAN is an oral capsule used for the treatment of adults with HIV (Human Immunodeficiency Virus) when therapy is indicated. HIV is the virus that causes AIDS (acquired immune deficiency syndrome). CRIXIVAN is a new type of HIV drug called a protease (PRO-tee-ase) inhibitor.

How does CRIXIVAN work?

CRIXIVAN is a protease inhibitor that fights HIV. It helps to lower the amount of HIV in your body (called "viral load") and raise your CD4 (T) cell count.

CRIXIVAN may be prescribed alone. CRIXIVAN may also be prescribed with other anti-HIV drugs such as ZDV (also called AZT), 3TC, ddI, ddC, or didanosine. CRIXIVAN works differently from these other anti-HIV drugs. Talk with your doctor to see if you should take CRIXIVAN alone or with other anti-HIV drugs.

CRIXIVAN has been studied in adults. It has not been studied in children and adolescents.

When should I take CRIXIVAN?

There are six important things you must do to get the most benefit from CRIXIVAN:

1. Take CRIXIVAN capsules every day as prescribed by your doctor. Continue taking CRIXIVAN unless your doctor tells you to stop. 2. Take the exact amount of CRIXIVAN that your doctor tells you to take, right from the very beginning. To help make sure you will benefit from CRIXIVAN, you must not skip doses or take "drug holidays". If you don't take CRIXIVAN as prescribed, the activity of CRIXIVAN may be reduced (due to resistance).

3. Take CRIXIVAN capsules every 8 hours around the clock, every day. It may be easier to remember to take CRIXIVAN if you take it at the same time every day. If you have questions about when to take CRIXIVAN, your doctor or health care provider can help you decide what schedule works for you.

4. Do not take less than your prescribed dose of CRIXIVAN at any one time.

4. Take CRIXIVAN with water. You can also take CRIXIVAN with other beverages such as skim milk, juice, coffee, or tea.
5. Ideally, take each dose of CRIXIVAN without food but with water at least one hour before or two hours after a meal. Or you can take CRIXIVAN with a light meal. Examples of light meals include:

dry toast with jelly, juice, and coffee (with skim milk and sugar if you want)
corn flakes with skim milk and sugar

Do not take CRIXIVAN at the same time as any meals that are high in calories, fat, and protein (for example — a bacon and egg breakfast). When taken at the same time as CRIXIVAN, these foods can interfere with CRIXIVAN being absorbed into your bloodstream and may lessen its effect.

6. Drink at least six 8-ounce glasses of liquids (preferably water) throughout the day, every day. CRIXIVAN has caused kidney stones in some patients. By having enough fluids in your body you may help reduce the chances of forming a kidney stone. Call your doctor or other health care provider if you develop kidney pains (middle to lower stomach or back pain) or blood in the urine.

Does CRIXIVAN cure HIV or AIDS?

CRIXIVAN is not a cure for HIV or AIDS. People taking CRIXIVAN may still develop infections or other conditions associated with HIV. Because of this, it is very important for you to remain under the care of a doctor.

It is not yet known whether taking CRIXIVAN will extend your life or reduce your chances of getting other illnesses associated with HIV. Information about how well the drug works is available from clinical studies up to 24 weeks.

Does CRIXIVAN reduce the risk of passing HIV to others?

CRIXIVAN has not been shown to reduce the risk of passing HIV to others through sexual contact or blood contamination.

Who should not take CRIXIVAN?

Do not take CRIXIVAN if you have had a serious allergic reaction to CRIXIVAN or any of its components.

What other medical problems or conditions should I discuss with my doctor?

Talk to your doctor if:

CRIXIVAN®
(INDINAVIR SULFATE) CAPSULES

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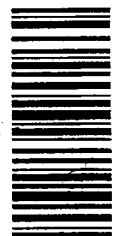


CRIXIVAN®
(INDINAVIR SULFATE) CAPSULES

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CRIXIVAN®



CRIXIVAN®
(INDINAVIR SULFATE) CAPSULES

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CRIXIVAN® (indinavir sulfate) Capsules

Patient Information about CRIXIVAN (KRIK-sih-van)

for HIV (Human Immunodeficiency Virus)
Generic name: indinavir (in-DIH-nuh-vee-ir)

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CRIXIVAN has been studied in adults. It has not been studied in children and adolescents.

How should I take CRIXIVAN?

There are six important things you must do to help you benefit from CRIXIVAN:

1. **Take CRIXIVAN capsules every day as prescribed by your doctor.** Continue taking CRIXIVAN unless your doctor tells you to stop. Take the exact amount of CRIXIVAN that your doctor tells you to take, right from the very start. To help make sure you will benefit from CRIXIVAN, you must not skip doses or take "drug holidays". If you don't take CRIXIVAN as prescribed, the activity of CRIXIVAN may be reduced (due to resistance).
2. **Take CRIXIVAN capsules every 8 hours around the clock, every day.** It may be easier to remember to take CRIXIVAN if you take it at the same time every day. If you have questions about when to take CRIXIVAN, your doctor or health care provider can help you decide what schedule works for you.

less than you any one time

4. **Take CRIXIVAN with milk, juice, or food but with or two hours before or after meals.** CRIXIVAN will be absorbed better with meals including dry toast, skim milk, or corn flakes.
5. **Ideally, take CRIXIVAN with or two hours before or after meals.** CRIXIVAN will be absorbed better with meals including dry toast, skim milk, or corn flakes.

Do not take CRIXIVAN with meals that are high in fat (for example, fried foods). When taken with these foods, CRIXIVAN will be absorbed into your body and its effect will be lessened.

6. **Drink at least 8 glasses of water every day.** CRIXIVAN may cause some side effects such as dizziness, headache, or pain in your body or joints. If you are taking other health care products, such as kidney pain medicine or blood thinners, talk to your doctor.

Does CRIXIVAN affect other conditions?

CRIXIVAN is not known to affect other conditions. However, if you have this condition, it is very important to be under the care of a doctor.

It is not yet known if CRIXIVAN will extend your life or if it will affect other illnesses. Clinical studies are ongoing to find out about how well CRIXIVAN works.

Does CRIXIVAN affect others?

CRIXIVAN has not been studied for the possibility of passing HIV to others or blood contamination.

Who should not take CRIXIVAN?

Do not take CRIXIVAN if you have an allergic reaction to any of the components.

What other medicines should I discuss with my doctor?

Talk to your doctor about all the medicines you are taking.

Please read this information before you start taking CRIXIVAN. Also, read the leaflet each time you renew your prescription, just in case anything has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss CRIXIVAN when you start taking your medication and at regular checkups. You should remain under a doctor's care when using CRIXIVAN and should not change or stop treatment without first talking with your doctor.

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less than your prescribed dose of CRIXIVAN at any one time.

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 - dry toast with jelly, juice, and coffee (with skim milk and sugar if you want)
 - corn flakes with skim milk and sugar

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What other medical problems or conditions should I discuss with my doctor?

Talk to your doctor if:

- You are pregnant or if you become pregnant while you are taking CRIXIVAN.
- We do not yet know how CRIXIVAN affects pregnant women or their developing babies.
- You are breast-feeding. You should stop breast-feeding if you are taking CRIXIVAN.

CRIXIVAN
(INDINAVIR SULFATE) C

90245



CRIXIVAN
(INDINAVIR SULFATE) C

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SULFATE) CAPSULES

CRIXIVAN



CRIXIVAN
(INDINAVIR SULFATE) C





9024501

CRIXIVAN® (indinavir sulfate) Capsules

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- Problems with your liver, especially if you have mild or moderate liver disease caused by cirrhosis.
- Problems with your kidneys.
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Can CRIXIVAN be taken with other medications?*

Drugs you should not take with CRIXIVAN:

SELDANE® (terfenadine)	HISMANAL® (astemizole)
VERSED® (midazolam)	HALCION® (triazolam)
PROPULSID® (cisapride)	

Taking CRIXIVAN with the above medications could result in serious or life-threatening problems (such as irregular heartbeat or excessive sleepiness).

In addition, you should not take CRIXIVAN with rifampin, known as RIFADIN®, RIFAMATE®, RIFATER®, or RIMACTANE®.

Drugs you can take with CRIXIVAN include:

RETROVIR® (zidovudine, ZDV also called AZT)	EPIVIR™ (lamivudine, 3TC)
ZERIT® (stavudine, d4T)	isoniazid (INH)
BACTRIM®/SEPTRA® (trimethoprim/ sulfamethoxazole)	DIFLUCAN® (fluconazole)
BIAXIN® (clarithromycin)	ORTHO-NOVUM 1/35® (oral contraceptive)
TAGAMET® (cimetidine)	

VIDEX® (didanosine, ddI) If you take CRIXIVAN

CRIXIVAN® (indinavir sulfate) Capsules

Some patients treated with CRIXIVAN in clinical studies developed kidney stones; this occurred in about 4% of patients. Drinking at least 6 glasses of liquid each day may help reduce the chances of forming a kidney stone. Call your doctor or other health care provider if you develop kidney pains (middle to lower stomach or back pain) or blood in the urine.

Increases in bilirubin (one laboratory test of liver function) have been reported in approximately 10% of patients. Usually, this finding has not been associated with liver problems. However, on rare occasions, a person may develop yellowing of the skin and/or eyes.

In clinical studies, side effects occurring in 2% or more of patients included: abdominal pain, fatigue or weakness, flank pain, feeling unwell, nausea, diarrhea, vomiting, acid regurgitation, loss of appetite, dry mouth, back pain, headache, trouble sleeping, dizziness, taste changes, rash, upper respiratory infection, dry skin, and sore throat.

Other side effects occurring in 0.5%-2% of patients in clinical studies included: sleepiness, fever, indigestion, excessive gas, muscle pain, leg pain, anxiety, depression, decreased skin sensation, itching, and painful or difficult urination.

Side effects occurring rarely, in less than 0.5% of patients in clinical studies, and also considered serious, included: gall bladder inflammation, liver cirrhosis, pneumonia, and swollen kidneys due to blocked urine flow.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

How should I store CRIXIVAN capsules?

- Keep CRIXIVAN capsules in the bottle they came in and at room temperature (59°-86°F).
- Keep CRIXIVAN capsules dry by leaving the small desiccant "pillow" in the bottle. Keep the bottle closed.

cirrhosis.

- Problems with your kidneys.
- Any medicines you are taking or plan to take, including non-prescription medicines.

Can CRIXIVAN be taken with other medications?*

Drugs you should not take with CRIXIVAN:

SELDANE® (terfenadine)	HISMANAL® (astemizole)
VERSED® (midazolam)	HALCION® (triazolam)
PROPULSID® (cisapride)	

Taking CRIXIVAN with the above medications could result in serious or life-threatening problems (such as irregular heartbeat or excessive sleepiness).

In addition, you should not take CRIXIVAN with rifampin, known as RIFADIN®, RIFAMATE®, RIFATER®, or RIMACTANE®.

Drugs you can take with CRIXIVAN include:

RETROVIR® (zidovudine, ZDV also called AZT)	EPIVIR™ (lamivudine, 3TC)
ZERIT® (stavudine, d4T)	isoniazid (INH)
BACTRIM®/SEPTA® (trimethoprim/ sulfamethoxazole)	DIFLUCAN® (fluconazole)
BIAXIN® (clarithromycin)	ORTHO-NOVUM 1/35® (oral contraceptive)
TAGAMET® (cimetidine)	

VIDEX® (didanosine, ddl) — If you take CRIXIVAN with VIDEX®, take them at least one hour apart.

MYCOBUTIN® (rifabutin) — If you take CRIXIVAN with MYCOBUTIN®, your doctor may adjust the dose of MYCOBUTIN.

NIZORAL® (ketoconazole) — If you take CRIXIVAN with NIZORAL®, your doctor may adjust the dose of CRIXIVAN.

Talk to your doctor about any medications you are taking.

What are the possible side effects of CRIXIVAN?

Like all prescription drugs, CRIXIVAN can cause side effects. The following is **not** a complete list of side effects reported with CRIXIVAN when taken either alone or with other anti-HIV drugs. Do not rely on this leaflet alone for information about side effects. Your doctor can discuss with you a more complete list of side effects.

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This medication was prescribed for your particular condition. Do not use it for any other condition or give it to anybody else. Keep CRIXIVAN and all medicines out of the reach of children. If you suspect that more than the prescribed dose of this medicine has been taken, contact your local poison control center or emergency room immediately.

This leaflet provides a summary of information about CRIXIVAN. If you have any questions or concerns about either CRIXIVAN or HIV, talk to your doctor.

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