APPLICATION NUMBER: 020685/S005

TRADE NAME: Crixivan capsules

GENERIC NAME: Indinavir sulfate

SPONSOR: Merck Research Laboratories

APPROVAL DATE: 2/19/97
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
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.
December 13, 1996

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

Dear Dr. Freeman:

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,

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

Attachments
Q/YARB/SAR/CRIX/SS20685

Certified No. P 914 177 405
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, ddl, 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.
Can CRIXIVAN be taken with other medications?*

Drugs you should not take with CRIXIVAN:

SELGANE®
(terfenadine)
VERSED®
(midazolam)
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)
ZERIT®
(stavudine, d4T)
BACTRIM®/SEPTRA®
(trimethoprim/sulfamethoxazole)
BIAXIN®
(clarithromycin)
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.

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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CRIXIVAN® (indinavir sulfate) Capsules

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

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 prescription, and at regular checkups. You should be under a doctor's care when using CRIXIVAN and should not change or stop treatment without first talking with your doctor.

Is CRIXIVAN?

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

Does CRIXIVAN work?

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

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

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

Should I take CRIXIVAN?

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

- 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 holidays. If you don't take CRIXIVAN as prescribed, the activity of CRIXIVAN may be used (due to resistance).
- 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 other health care provider can help you decide what schedule works for you.
- Less than your prescribed dose of CRIXIVAN at any one time.
- Take CRIXIVAN with water. You can also take CRIXIVAN with other beverages such as skim milk, juice, coffee, or tea.
- 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.

- 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:
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?
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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. Do not take CRIXIVAN with milk, juice, or food. Take CRIXIVAN with meals including dry toast, skim milk, or corn flakes.

4. Take CRIXIVAN with milk, juice, or food but with or two hours before or after meals including dry toast, skim milk, or corn flakes.

5. Take CRIXIVAN with milk, juice, or food but with or two hours before or after meals including dry toast, skim milk, or corn flakes.

6. Drink at least (preferably two) glasses of water while taking CRIXIVAN.

Does CRIXIVAN affect other medical conditions?
CRIXIVAN is not known to affect other medical conditions. It is not yet known whether CRIXIVAN can extend your life or improve other illnesses. Talk with your doctor about how well you feel and how well you are doing clinically.

Does CRIXIVAN affect other medicines?
CRIXIVAN has not been studied in patients taking CRIXIVAN in combination with other medicines. It is not known whether CRIXIVAN may affect other medicines or whether other medicines may affect CRIXIVAN.

Who should not take CRIXIVAN?
Do not take CRIXIVAN if you have a known allergic reaction to this, it is very important to discuss these medicines with your doctor first.

What other medicines should I discuss with my doctor?
Talk to your doctor about any other medicines you may be taking or considering taking. It is important to discuss these medicines with your doctor before you start taking CRIXIVAN.
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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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)
   - 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:

- 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.
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CHIXIVAN® (indinavir sulfate) capsules

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.

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, ddl).

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.
candida infection.  

- 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)  

VERSED® (midazolam)  

PROPSULSID® (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)  

BACTRIM®/SEPTRA® (trimethoprim/sulfamethoxazole)  

BIAxin® (clarithromycin)  

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.  

 Issued September 1996