

Seattle Urological Associates
Telephone 206.292.6488

CONSENT FOR BIOPSY OF PROSTATE

NOTE: Do not take aspirin or any aspirin containing compounds for at least 7 days before your biopsy.

I understand that I have been scheduled for a needle biopsy of the prostate. This is to be done with a small needle placed through the rectal wall into the suspicious areas of the prostate to see if cancer of the prostate exists. Most often the needle will be guided by an ultrasound probe, but on occasion, a finger guided biopsy will be done.

I have been informed that with the biopsy, possible risks and complications exist and may occur during or after the procedure. These include loss of blood, infection, burning with urination, urinary retention which might require catheterization. I understand that I may have blood in my ejaculate for some time and possibly lower my sperm counts. I acknowledge that no warranty or guarantee has been made to me as to the results of my procedure or cure of my condition. I understand that prostate cancer may exist and not be found on these biopsies. Additional biopsies may be indicated at a later date. Follow-up visits, along with repeat PSA testing, is mandatory.

I acknowledge that any tissues or parts removed surgically may be disposed of by the hospital or physician in accordance with accustomed practice.

I certify that my physician or physicians as listed above have informed me of the nature and character of the proposed procedure, of the anticipated results of the proposed procedure, of the possible alternative forms of treatment, and the recognized serious possible risks, complications and the anticipated benefits involved in the proposed procedure and the alternative forms of treatment, including non-treatment.

I understand that any aspect of this consent form that I do not understand can be explained to me in further detail by asking my physician(s) or their associates.

I certify that this form has been explained to me and that I have read it, or have had it read to me and that I understand its contents. You have both the right and obligation to make decisions concerning your health care. Your physician can provide you with the necessary information and advice, but as a member of the healthcare team, you must enter into the decision making process. This form has been designed to acknowledge your acceptance of treatment recommended by your physician.

Patient or Guardian Signature _____ Date _____

Name (print) _____ Witness _____

The biopsy procedure stated on this form, including the possible risks, complications, alternative treatments (including non- treatment) and anticipated results, was explained by me to the patient.

Physician's Signature _____ Date _____

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\YOU HAVE BEEN SCHEDULED FOR THE FOLLOWING.. PROSTATIC ULTRASOUND AND BIOPSY

TIME TO REPORT ...DAY _____ DATE _____ TIME _____ [am] [pm]

SCHEDULED AT... Seattle Urological Associates 1221 Madison Street Suite #1210
Valet parking is available at the front door. Self parking 1/2 block east under the Nordstrom Building. Another garage is located southeast 2 blocks at Broadway/Marion. Street parking can be found but may require a trip to feed the meter. Coming north on I-5 exit at Madison and head east (right) 6 blocks. Coming south exit I-5 at James and head east (left) 5 blocks to Boren. Turn left 5 blocks to Madison and then right 2 blocks to 1221 Madison. From I-90 follow signs to I-5 north Vancouver and exit at Madison. Head east (right) 6 blocks

DESCRIPTION OF PROSTATIC ULTRASOUND AND BIOPSY:

Ultrasound uses harmless sound waves to give us pictures of the prostate and allows us to accurately guide a biopsy needle to areas of concern. Indications for prostate biopsy include suspicion of cancer either by suspicious finger exam of the prostate or by elevation of a prostate cancer screening blood test (PSA). The procedure is done in the office without need of anesthesia. Initially, a complete finger exam is done. Next the ultrasound probe, finger-like in size and shape, is placed into the rectum. With slight movement of the probe, many different views are obtained. When areas of suspicion are seen, biopsies will be taken. A spring loaded fine needle is placed through the probe and pointed directly at the lesion. Anywhere from 6 to 20 biopsies may be taken. These biopsies are not usually painful. The entire exam takes 20-30 minutes. You may have some soreness around the rectum for up to one hour. You may also notice blood in the urine and stool for a few days, and in the semen for up to a month. We will not have the biopsy results for two to seven days -- so be patient.

POSSIBLE RISKS OF PROSTATIC ULTRASOUND AND BIOPSY:

Blood may be noted in the stool and urine for a few days or longer and in the semen for up to 2 or 3 months. Infection of the prostate or in the urine can occur even with antibiotic preparation. You should call if you develop fever, chills, severe pain or have continuous or significant bleeding. A full consent form will be provided. A full consent form is included in the packet.

PREPARATION FOR PROSTATIC ULTRASOUND AND BIOPSY:

*** No aspirin products for 7-10 days before the biopsy ***

1. No dietary restrictions on the day of the procedure.
2. A Fleets enema two hours before the visit. Buy at any drug store and follow the instructions on the package. This is also the optimal time to take the antibiotic on the day of your procedure.
3. We will supply you with either samples or a prescription for an antibiotic. The pills must be started BEFORE the biopsy. If you have been given 2 sample pills (Cipro 500 mgs), please take one pill the night before your procedure and one pill two (2) hours before the procedure

FOLLOW UP INSTRUCTIONS:

We will call you with biopsy results as soon as we receive them unless you have requested otherwise. If you have not heard from us in 5 working days, then call us to get a status report.

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POST TRANS RECTAL ULTRASOUND AND PROSTATE BIOPSY INSTRUCTIONS

Dear Patient:

Today you underwent a biopsy of your prostate under ultrasound guidance. To prevent complications from this procedure, please follow these instructions.

1. Increase your fluid intake for the next 1-2 days to decrease formation of blood clots in your urine. If your urine is completely clear for the first few urinations, you will probably not have to worry about this. Some spotting of the urine with blood may occur for the first week, even a month -- not to worry and it will go away.
2. You may experience discomfort in the rectum or base of your penis. This is normal and should be of no concern. In addition, you may have a small amount of blood in your stool when you have a bowel movement.
3. You may also notice blood or discoloration in your semen if you are sexually active. This is also normal and may last for a few weeks or even months until the blood is cleared out of your prostate. You do not need to call us with blood in your semen.
4. Limit your activity, particularly strenuous ones, for 24 hours. Staying off your feet until the next morning is probably a good idea.

However, IT IS IMPORTANT THAT YOU CONTACT US AS SOON AS POSSIBLE if any of the following symptoms occur:

Persistent burning or discomfort with urination
Chills or Fevers
Blood clots or excessive blood in the urine or stool making it difficult to urinate
Difficulty or inability to urinate

If problems do occur as listed above then during the week from 9:00 am to 5:00 pm, call our office at the number listed above and ask for your doctor. Explain the problem or symptoms to the nurse if your doctor is not available. If necessary, she will let you speak to another physician or will try to reach your doctor. If you call after hours or on weekends, you will be automatically connected to our answering service, who will put you in touch with the physician-on-call.

We plan to call you as soon as the results of the biopsy are available. Be patient, as the pathologist have to be certain about the interpretation of your biopsy. This may require additional opinions from other members of the Department of Pathology. We should have the results in two to five working days. If you have NOT heard from us by then, call us so that we may check on the progress of your biopsy.

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Biopsy -- What does it mean

Definitions

A "biopsy" is defined as 'the process of removing a sample of body tissue to examine it for the presence of disease'. There are many reasons for requiring a biopsy, but the most common is to help determine if cancer is present in the tissue being biopsied.

Biopsies can be done in a variety of ways. The most common types of biopsy are: excisional biopsy, incisional biopsy, needle biopsy, and aspiration biopsy.

Excisional biopsy means that all of the suspicious area in question is removed.

Incisional biopsy means that a part of the suspicious area in question is removed.

Needle biopsy means that a hollow needle is placed into the suspicious area and a core of tissue is removed.

Aspiration biopsy means that a very thin hollow needle is placed into the suspicious areas and, using suction, individual cells are drawn out.

What are the risks of a biopsy?

The risks vary depending on the technique and body part that is being biopsied. All biopsies have some common risks that are associated with almost any surgical procedure...bleeding, pain and infection. These risks should be understood by any patient undergoing a biopsy.

Another risk is that the biopsy results may be inconclusive or difficult to interpret. Additional biopsies or opinions may be required to help with this problem.

Who interprets the biopsy?

A biopsy is interpreted by a physician called a 'pathologist'. The tissues removed are prepared in many ways, often referred to as 'staining'. Preparation and staining and interpretation may require two days or more. The 'stained' tissue is placed between two small pieces of clear glass (which is called a 'slide') and then examined under a microscope.

The pathologist can look at the tissue presented and give an opinion as to whether it is normal or not. The pathologist may take into consideration the patient's medical condition and other laboratory tests and previous biopsy materials before giving an opinion or 'diagnosis'.

How long does it take to get the results of a biopsy?

The length of time for biopsy results varies from minutes to days. A technique called 'frozen section' can give results in a very short time, but it is a technique that has a higher likelihood of giving an incorrect or incomplete diagnosis. This technique is used almost exclusively in the operating room, where decisions have to be made immediately.

In most cases, biopsy results are obtained within two to three days. If the biopsy material is not clear cut, delays may occur. The pathologist may need to have other pathologists look at the biopsy, or additional and/or special preparations or staining may be needed. In some cases, the slides need to be sent away to a pathologist with special knowledge or expertise of a certain problem.

What can a biopsy tell?

Some of the more common interpretations of biopsies include:

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- #1. Normal tissue, no abnormalities
- #2. Not normal, but not cancerous or malignant (often some type of inflammation)
- #3. Not normal - difficult to interpret
- #4. Not normal - not cancerous but a pre-cancerous condition
- #5. Cancer

What are some of the concerns about biopsy results?

The biopsy shows no cancer (#s 1 and 2)

This finding is obviously the best for the patient, but the patient must realize that the biopsy was done because of some suspicion on the part of the physician that a disease such as cancer might exist.

A biopsy can reveal cancer, but a biopsy does not rule out the existence of cancer. If the specimen does not contain the cancer cells within it, cancer may exist somewhere else in the areas that were not biopsied.

To restate this important point, a patient could still have cancer even if the biopsies do not show it. That is why physicians will ask to follow up patients who had negative biopsies to see how they progress. If the patient's situation remains suspicious, additional biopsies of the area in question may need to be done.

The biopsy is difficult to interpret (#3)

Many reasons exist for a difficult interpretation. The biopsy material may have been damaged or distorted during the biopsy, transportation or preparation. Sometimes there is just not enough tissue presented to make an accurate diagnosis. Sometimes the tissue does not have the characteristics that allow the pathologist to make a certain diagnosis. Remember, a pathologist must interpret the biopsy and pathologists may disagree on the findings.

If the reasons for biopsy are still present, the physician will usually request that additional biopsies be performed.

The biopsy shows a 'pre-cancerous' condition (#4)

This finding is quite common in many parts of the body (prostate, bladder, breast, cervix, for example). This means that the tissue has some of the characteristics of a cancer or malignancy but not enough to state that cancer exists at that time. Sometimes these conditions are called 'carcinoma-in-situ' or 'intra-epithelial neoplasia'. These findings warrant close follow-up and, in many cases, require additional biopsies at a later time. In some areas of the body, the pre-cancerous situation is so strongly linked with the subsequent development of cancer that treatment is begun (such as the bladder).

The biopsy shows cancer (#5)

Most biopsies are done looking for cancers or malignancies. If the biopsy specimen contains almost all normal tissue but a small area of the specimen is interpreted to have cancer, the final diagnosis will still be cancer.

Even when a pathologist interprets tissue as showing cancer, one must realize that the biopsies are interpreted and there can be disagreement between pathologists on what is cancerous and what is not. Most pathologists will show the materials to other pathologists to confirm their

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findings (consultations), so that the final report is usually not the result of only one pathologist looking at the materials. If the reasons for biopsy were strong and cancer is found, it is unlikely that another pathologist is going to find that no cancer exists.

Second opinions on biopsy materials can be obtained without undergoing another biopsy. The second pathologist needs only to look at the first pathologist's slides to give an opinion.

Summary

A biopsy is a serious matter. As discussed above, many different situations can arise which may need discussion with your physician. Please ask if you have any questions.

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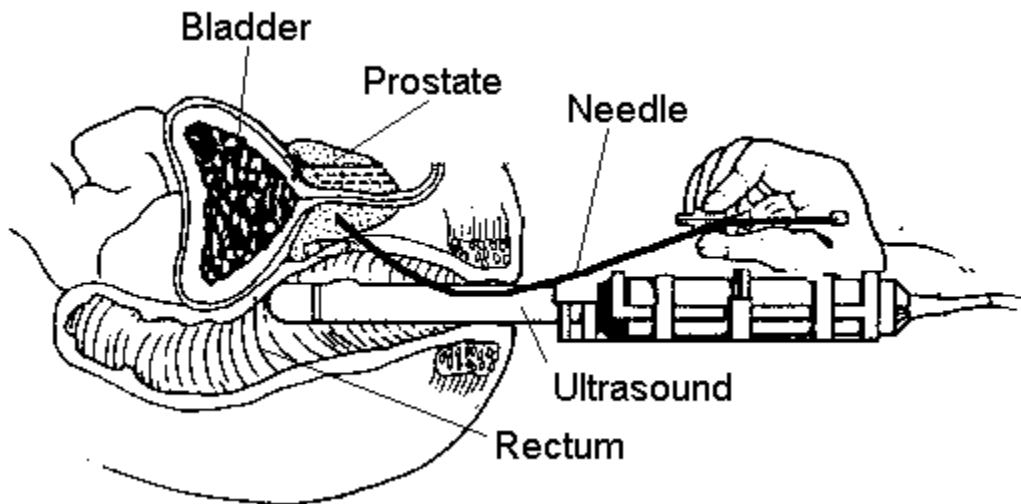
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FREQUENTLY ASKED QUESTIONS ABOUT ULTRASOUND GUIDED TRANSRECTAL NEEDLE BIOPSY OF PROSTATE

What are the indications for a transrectal ultrasound guided prostate needle biopsy (also referred to as a TRUS)

A transrectal ultrasound guided prostate needle biopsy is done to check the prostate gland for the presence of cancer.

This is generally indicated when ANY of the following occur:
suspicion is raised by an abnormal prostate specific antigen (PSA) blood test
suspicion is raised by a rising prostate specific antigen (PSA) blood test
by an abnormal digital (finger) examination of your prostate
by a prior biopsy that showed cells that were not normal (atypia or what is referred to by urologists as PIN or prostatic intraepithelial neoplasia)



What does a transrectal ultrasound guided prostate needle biopsy mean?

Transrectal means that the ultrasound and biopsy will be done through the rectal wall after the ultrasound device is placed through the anus into the rectum.

Ultrasound (or sonogram) are harmless sound waves used in a medical imaging device to give us pictures of certain body parts

Ultrasound Guided means that the biopsy will be guided to the area of concern by an ultrasound machine.

A biopsy is the medical term which describes the removal of a piece of tissue from the body for microscopic examination to check for the presence of disease.

A needle biopsy specifically refers to using a needle to obtain a small piece of tissue which can then be examined.

What is the preparation for the biopsy?

A prostate needle biopsy is a minor procedure which takes only 15-20 minutes to perform, and is generally done in our office. However, some preparation is needed to ensure that the biopsy will go smoothly and safely.

To ensure that bleeding risks are minimized no aspirin products can be used for 7 days before the biopsy. If you are taking any blood thinner, such as warfarin or Coumadin, we need to carefully

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plan a period of time off the drugs prior to the biopsy. Non-steroidal anti-inflammatory medication such as ibuprofen or naprosyn and Vitamin E should be stopped three days before the biopsy. Call us if you forget to stop your aspirin or blood thinners. We may want to re-schedule the biopsy.

A Fleets enema should be administered (by you) about two hours before the visit. Buy the enema at any drug store and follow the instructions on the package. This is done to cleanse the rectum of stool to allow us to get a clear view of the prostate with the ultrasound probe. As a reminder, you should also be taking your remaining antibiotic at about this time.

We will supply you with either samples or a prescription for an antibiotic. The pills must be started BEFORE the biopsy. Please read the instructions carefully. The antibiotics will start the day before the biopsy and another pill will be taken on the morning of the biopsy. The best antibiotic levels are obtained if the second pill is taken approximately 2 hours before the biopsy.

You must sign a consent form that declares that you understand the procedure and the risks involved. (if you forget your form at home, another will be provided)

Do not urinate completely within 15 minutes of your biopsy. It is okay to partially empty your bladder if you have a strong desire to urinate.

No dietary restrictions on the day of the procedure are needed.

What happens, step by step, during the biopsy procedure?

Arrival

After arriving at the office, we will ensure that you have complied with pre-biopsy instructions and have signed the consent form. If you have not taken the antibiotics or not stopped your aspirin, we will reschedule your biopsy.

Bathroom

You may want to make a quick stop in the restroom after your arrive to partially empty your bladder if it is full. Do not empty your bladder completely as a small amount of urine in the bladder helps distinguish the prostate from the inside of the bladder.

Changing room

You will be then escorted to a changing room and given a paper gown to wear. You will need to undress completely except for your socks and undershirt and put on the gown so that it opens in the rear. You will then come into the biopsy room.

Biopsy Room

To perform the biopsy, you will be asked to lie down on your side on the exam table. When the ultrasound begins we will have you bend both knees towards your chest and hold them there until the examination is completed.

Digital Rectal Examination

We will begin in most cases by performing a digital (finger) rectal exam of the prostate and to ensure that the rectum is not full of stool and to re-examine the prostate gland for nodules or irregularities.

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Ultrasound Probe

The ultrasound probe, which is somewhat wider than a finger, is lubricated and then gently inserted through the anus into your rectum until it rests just behind your prostate (a matter of 2-3 inches).

Using ultrasound waves, we will see the inside of your prostate on a television monitor. First, we will scan the entire prostate and take measurements of the prostate size as well as any suspicious areas. These measurements will take about 4-5 minutes. Once these measurements are completed we are ready to biopsy the prostate.

Biopsy of Prostate

The ultrasound is also essential in guiding the placement of the needle into the prostate to obtain accurate biopsy tissue samples. After aiming the ultrasound probe at a certain area of the prostate the biopsy needle will be inserted through the ultrasound probe and placed through the rectal wall to reach your prostate.

The needle is relatively thin and you may feel a pinch or some pressure as it is inserted into your prostate. We use an automated spring-loaded needle firing mechanism which, when triggered, very quickly and relatively painlessly removes a small prostate tissue sample inside the needle. Local anaesthesia (lidocaine (similar to but not Novocaine) may be used to reduce discomfort.

The automated spring mechanism makes a snapping or popping sound with each needle biopsy. We will warn you when the popping is to occur. The assistant will then take each specimen, label it and return the biopsy gun to the urologist to biopsy another area of the prostate.

Number of Biopsies?

We may take several biopsies from your prostate gland in this fashion, depending upon the situation. There is no minimum or maximum number of biopsies but the number of biopsies taken averages from eight to sixteen.

Using an automated biopsy needle with the guidance of ultrasound, six to twelve biopsies can easily be obtained in less than five minutes with only minimal discomfort to you. Again, generally, no anesthesia of any kind is required or needed.

In some circumstances we will also take biopsies using a finger guided method. The ultrasound probe is removed from the rectum and the urologist places a finger inside the rectum up to any suspicious area. Using the same biopsy gun and needle, additional biopsies will be taken.

Procedure completed

After the biopsies are completed you will turn onto your back and rest for a moment or two. Then you will be helped off the table and escorted back to the changing room. You can clean up and if needed you may want to empty your bladder before leaving. Note: You may see some blood in the urine, even a small clot. This is not unexpected.

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After the biopsy where should I go?

You should head home immediately from the biopsy procedure. We suggest that you curtail your activity until the next day. If you see blood in the urine or stool, you must get off your feet and drink plenty of fluids. You may shower or bathe whenever you wish. You may resume regular activity the following day. If you see blood, however, you must again curtail activity until the day after the bleeding stops.

What are the complications of prostate biopsy?

The complication rate after this form of biopsy is in the region of 2-4% (2 to four men out of 100).

Complications include bleeding, infection and inability to urinate.

Bleeding

Occasionally after a prostate biopsy some bleeding may occur in the urine, stool or semen

Urine:

You are likely to see some blood in the urine for the first few days. This bleeding might be noted at the beginning or end of urination or throughout the entire stream. Rarely, bleeding may persist for one to two weeks on and off. Exercise or sex may precipitate bleeding. If so, restrict these activities for a week. Call us if you are unable to urinate at any time - bleeding or not.

Semen:

If you are sexually active, there is likely to be blood mixed with the sperm at the time of ejaculation. This is referred to as hematospermia or hemospermia by physicians. Hematospermia is not surprising as the prostate's main function is to produce semen, the fluid that is ejaculated with sexual intercourse. Traces of blood may persist for weeks (rarely, even months). Blood in the semen may be red or brown or a rusty color. Hematospermia is almost never serious and does NOT represent a threat to you or your partner. You do not need to restrict sexual activity if the only bleeding you see occurs with ejaculation.

Stool:

The biopsy is done through the rectal wall. Therefore seeing blood in the stool is not surprising either. Rectal bleeding is actually rare other than some mild spotting for the first few days. Any significant bleeding that is noted after a week should be brought to our attention.

Infection:

With any internal procedure, such as a biopsy, a small chance of infection exists. If infection is to occur it will be in the prostate or urinary tract. The use of antibiotics pre-biopsy reduces but does not eliminate this possibility.

A urinary tract infection can occur anytime within the first week or two after the biopsy but usually happens within two to three days. Symptoms that might be noted are from the lower urinary tract (bladder and prostate). Urinary frequency, burning with urination, sense of incomplete emptying of the bladder are the most common symptoms.

If the infection is severe it may reach the blood stream. Fevers, chills, shaking, sweating and lack of energy may be noted. A blood stream infection is very serious and even life threatening.

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If symptoms of a blood infection are seen you must contact us immediately. If you cannot reach us then you must contact your regular doctor or go to the emergency room.

For any infection we will start you on antibiotics. If we are not sure whether you have an infection, we often start antibiotics until the urine tests (and sometimes, blood tests) are completed. The most important test is called a urine culture and it determines whether an infection really exists in the urinary tract. Urine cultures take at least 48 to 72 hours to complete.

Urinary tract obstruction

Occasionally there can be some swelling of the prostate gland after the biopsy, leading to difficulty in urination. If that happens, and you are unable to pass urine at all then you should telephone us for further advice. If you cannot reach us then you will need to come to the emergency room. It may be necessary to insert a small tube called a catheter through the penis and into the bladder to drain the urine out. How long the catheter remains in the bladder depends on a number of factors including how much urine was in the bladder at the time of catheterization and whether the patient has had any trouble passing urine prior to the biopsies being taken. If we did not place the catheter ourselves, you must call us the next day to discuss plans to have the catheter removed.

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LEVOFLOXACIN OR LEVAQUIN OR CIPROFLOXACIN OR CIPRO XR

Levaquin (levofloxacin) and Cipro (ciprofloxacin) are broad spectrum antibiotics commonly used to treat urinary tract infections and used as preventative medications for prostate biopsies.

Dosing instructions

You will be given two pills of either Levaquin 500 mg or Cipro 500mgs. Please take the first pill the night prior to the biopsy, preferably at bedtime. Please take the second pill in the morning of the biopsy at least two hours before the biopsy. You should use the Fleets enema to cleanse the rectum about the same time.

SPECIAL INSTRUCTIONS

If you are using other prescribed medications you should inform your physician. Mineral supplements, vitamins with iron or minerals, calcium-aluminum or magnesium-based antacids, or sucralfate should not be taken within two hours before or after taking Levaquin. Take all the medicine prescribed even after you begin to feel better. If you have had no signs of improvement within three days, or still have signs of infection when the medication is completed, give us a call.

Rarely, Levaquin or Cipro causes dizziness or lightheadedness. Do not drive a car or operate machinery until you know how Levaquin will affect you.

What special dietary instructions should I follow while using Levaquin or Cipro XR ?
Drink at least eight glasses of water a day (other liquids are OK, water is best.) Do not take antacids such as Tums or Roloids or Maalox within two hours of Levaquin. Caffeinated beverages are OK to drink.

What side effects can Levaquin or Cipro XR cause? What can I do about them?
Nausea and diarrhea can occur. If so, take Levaquin with a light snack or a meal.
Headache or restlessness. Contact us if these effects are severe or persist.
Skin rash. Stop taking Levaquin immediately and contact us or your regular doctor.
Other side effects rarely occur with Levaquin. If anything unusual is happening or persisting, please let us know.

What other precautions should I follow while taking Levaquin or Cipro XR ?
Do not allow children to take this drug. Some patients can be sensitive to the sun and sunburn while taking this medication. Use a hat and sunscreen until this medication is completed.

What if I forget to take the drug?

Call us to see if the procedure needs to be rescheduled