

NIMEGEN CAPSULES

Each soft capsule contains : ISOTRETINOIN 10MG

Information for the patient (male and female)

NIMEGEN is a medicine used to treat certain types of severe acne, difficult to treat by other methods. It is **IMPORTANT** that you read the following information.

NIMEGEN CAN CAUSE DEFORMED BABIES IF IT IS TAKEN BY A FEMALE WHEN SHE IS PREGNANT.

**Important information for female patients**

- ◆ DO NOT TAKE NIMEGEN IF YOU ARE OR MAY BECOME PREGNANT DURING YOUR TREATMENT.
- ◆ YOU MUST AVOID BECOMING PREGNANT WHILE YOU ARE TAKING NIMEGEN AND FOR AT LEAST ONE MONTH AFTER YOU STOP TAKING NIMEGEN.
- ◆ YOU MUST DISCUSS EFFECTIVE BIRTH CONTROL WITH YOUR DOCTOR BEFORE BEGINNING NIMEGEN TREATMENT, AND YOU MUST USE EFFECTIVE BIRTH CONTROL :
  - œ FOR AT LEAST ONE MONTH BEFORE YOU START NIMEGEN ;
  - œ WHILE YOU ARE TAKING NIMEGEN; AND
  - œ FOR AT LEAST ONE MONTH AFTER YOU STOP TAKING NIMEGEN.BEARING IN MIND THAT ANY METHOD OF BIRTH CONTROL CAN FAIL,
  - œ IT IS RECOMMENDED THAT YOU EITHER ABSTAIN FROM SEXUAL INTERCOURSE OR USE TWO RELIABLE METHODS OF BIRTH CONTROL AT THE SAME TIME.
- ◆ DO NOT TAKE NIMEGEN UNTIL YOU ARE SURE THAT YOU ARE NOT PREGNANT.
  - œ YOU MUST HAVE A SERUM OR URINE PREGNANCY TEST WITHIN THE TWO WEEKS BEFORE YOU START NIMEGEN.
  - œ YOU MUST WAIT UNTIL THE SECOND OR THIRD DAY OF YOUR NEXT NORMAL MENSTRUAL PERIOD BEFORE YOU START NIMEGEN.
- ◆ CONTACT YOUR DOCTOR IMMEDIATELY IF YOU DO BECOME PREGNANT WHILE TAKING NIMEGEN OR DURING THE FIRST MONTH AFTER THE TREATMENT HAS STOPPED.
  - œ YOU SHOULD DISCUSS WITH YOUR DOCTOR THE SERIOUS RISK OF YOUR BABY HAVING SEVERE BIRTH DEFORMITIES BECUASE YOU ARE TAKING OR HAVE TAKEN NIMEGEN, YOU SHOULD ALSO DISCUSS THE DESIRABILITY OF CONTINUING WITH YOUR PREGNANCY.
- ◆ DO NOT BREAST FEED WHILE TAKING NIMEGEN.

Important information for all patients (male and female)

PREGNANCY MUST BE AVOIDED BY ANY FEMALE TAKING NIMEGEN AS NIMEGEN CAN CAUSE DEFORMED BABIES. (See Important Information For Female Patients).

Be sure to return to your doctor as scheduled.

It is important for your doctor to see you regularly, preferably every month, when you are taking NIMEGEN. Blood tests and other tests allow your doctor to check your response to NIMEGEN. Discuss your progress and any concerns with your doctor.

Do not give NIMEGEN to any one else who have similar symptoms.

NIMEGEN has been prescribed for each person by their own doctor because of possible side effects (see below).

• **IMPORTANT : NIMEGEN can cause deformed babies if taken by a female when she is pregnant.**

Do not donate blood, while you are taking NIMEGEN or for at least one month after you stop taking NIMEGEN. This is because your blood should not be given to a pregnant female.

Other information for all patients (male and female)

Things you should tell your doctor before starting NIMEGEN :

1. Tell your doctor if you have ever had any unusual or allergic reaction to isotretinoin, etretinate, tretinoin or Vitamin A preparations. Also tell your doctor if you are allergic to any other substances such as foods, preservatives or dyes.
2. Tell your doctor if you or any members of your family have diabetes because NIMEGEN may affect blood sugar levels. Your doctor may decide that blood sugar testing is important in your case.
3. Tell your doctor if you or any member of your family have liver disease, heart disease or depression.
4. Tell your doctor if you are sensitive to parabens. They are used in the NIMEGEN gelatin capsule.
5. Talk to your doctor before taking NIMEGEN :
  - If you have ever had any kind of mental health problems. This includes depression, aggressive tendencies or mood changes. It also includes thoughts about hurting yourself or ending your life. This is because your mood may be affected while taking NIMEGEN.

Mental health problems

You may not notice some changes in your mood and behavior and so it is very important that you tell your friends and family that you are taking this medicine. They may notice these changes and help you quickly identify any problems that you need to talk to your doctor about.

CONTACT YOUR DOCTOR STRAIGHT AWAY IF YOU GET SIGNS OF ANY OF THESE MENTAL PROBLEMS. YOUR DOCTOR MAY TELL YOU TO STOP TAKING NIMEGEN. THAT MAY NOT BE ENOUGH TO STOP THE EFFECTS: YOU MAY NEED MORE HELP, AND YOUR DOCTOR CAN ARRANGE THIS.

Treatment progress:

During the first few weeks of treatment, your acne may seem to get worse. Redness and itching of the affected skin are common initial effects. These should disappear as you continue to take NIMEGEN. Most often, the first signs of healing occur after two to three weeks of treatment. It may take one to two months before beneficial effects are seen. Most patients with severe acne notice a marked improvement after one or two courses of treatment with NIMEGEN.

Side effects:

Tell your doctor if any of your side effects do not clear up in a few weeks after taking NIMEGEN

As with other medications, unwanted effects may occur with NIMEGEN.

Some of the most common side effects are :

- v Dryness of the skin, lips, mouth, and lining of the nose. Some other reactions that may occur include: facial or body rash, flaking of the skin, itching, peeling of the palms and soles, increased sensitivity to the sun (see below), inflammation of the lips, mild nose bleed, bleeding and inflammation of the gums, aches and pains in joints (see below), easily injured skin and increased fatigue. You may experience some redness, dryness (see below), irritation of the eyes or decreased night vision (see below). These side effects are generally temporary and disappear when NIMEGEN treatment is stopped.
- v Check with your doctor to see if any change in your medication is needed, especially if these effects become bothersome.
- v If you wear contact lenses, you may find them uncomfortable during treatment because NIMEGEN may cause dry eyes. This may continue after treatment has stopped.
- v In some patients thinning of hair has occurred. In rare cases this hair loss persisted after treatment was completed.
  - Rare effects (may affect up to 1 in every 1000 people)
    - Depression or related disorders. Signs of this include sad or altered mood, anxiety, feelings of emotional discomfort
    - Existing depression getting worse
    - Becoming violent or aggressive
  - Very rare effects (may affect up to 1 in every 10,000 people)
    - Some people have had thoughts or feelings about hurting themselves or ending their own lives (suicidal thoughts), have had tried to end their own lives (attempted suicide), or have ended their lives (suicide). These people may not appear to be depressed.
    - Unusual behavior.
    - Signs of psychosis: a loss of contact with reality, such as hearing voices or seeing things that are not there.

Special precautions you should take:

- q Do not use vitamin preparations or health food supplements that contain Vitamin A as NIMEGEN is related to Vitamin A. The Vitamin A in these products may add to the unwanted effects of NIMEGEN. Check with your doctor or pharmacist if you are unsure about the Vitamin A content of any product you are taking.
  - q Do not use NIMEGEN with any of the following:
    - Etretinate
    - Tretinoin (eg. Retin A)
    - Tetracyclines (medicine for infections)
- It is important to inform your doctor before using any of the above medications.
- q Protect yourself from excessive exposure to the sun. NIMEGEN may increase the sensitivity of your skin to the sun.
  - q A number of patients on NIMEGEN have experienced decreased night vision. Onset can be sudden. Be careful when driving or operating any vehicle at night.

Special symptoms you should tell your doctor about:

- Tell your doctor if you have aches or pains in bones or joints or difficulty in moving. Bone changes have been detected by x-ray examination in patients taking NIMEGEN. The extent of any harm from these changes is not presently known.
- Tell your doctor immediately if you experience any of the following symptoms because these side effects may possibly result in permanent effects. These symptoms may be early signs of rare but more serious side effects which your doctor may want to check as soon as possible,
  - œ HEADACHES, NAUSEA, VOMITING, BLURRED VISION, OTHER VISUAL PROBLEMS, CHANGE IN MOOD, MENTAL DEPRESSION;
  - œ SEVERE STOMACH PAIN, DIARRHEA, RECTAL BLEEDING;
  - œ PERSISTENT FEELING OF DRY EYES, DECREASE IN NIGHT VISION;
  - œ YELLOWING OF THE SKIN OR EYES AND/OR DARK URINE.

Tell your doctor about any unusual or severe symptoms that appear during treatment.

GENERAL GUIDELINES WHEN TAKING YOUR MEDICATIONS:

- Call your doctor if you have any questions or have severe or troubling symptoms;
- Keep NIMEGEN out of reach of the children;
- Read your prescription label carefully and be sure to take the exact amount of medicine prescribed by your doctor. Your doctor may change your prescribed dose from time to time. Therefore, it is important that you check the label each time it is given to you. If you have any questions, call your doctor.
- Take NIMEGEN with food or just after a meal. If you forget to take a dose of NIMEGEN, it can be taken later on the same day. But do not take more NIMEGEN in one day than what your doctor has prescribed. If it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.
- Protect NIMEGEN capsules from light and heat.
- Store at 15–30°C

THIS SUMMARY DOES NOT CONTAIN ALL KNOWN INFORMATION ABOUT NIMEGEN. TALK TO YOUR DOCTOR IF YOU HAVE ANY QUESTIONS.