

[text printed on 'prescription pak' blister cards]

**ALL PATIENTS:**

**It is important for your health that you read all the information you received with this prescription and from your prescriber**

This package provides **reminders** of important safety facts about Accutane, but it does **not** contain all the information you need to know. It is important for you to know how to take Accutane correctly and what side effects to watch for.

Read all the information you get about Accutane from your prescriber and pharmacist, including the **Medication Guide** provided with this package.

The prescription you got at your prescriber's office should have had a special yellow self-adhesive sticker on it. The sticker is **YELLOW**. If your prescriptions for Accutane do not have this yellow self-adhesive sticker, call your prescriber. The pharmacy should not fill prescriptions for Accutane unless they have the yellow self-adhesive sticker.

You should read, understand and sign an **Informed Consent/Patient Agreement** before you take Accutane. Contact your prescriber if you have not signed this form (male patients must sign one form and female patients must sign two forms).

**Never share Accutane** because it can cause serious side effects including **severe birth defects**.

**Special Warning for Female Patients**

**CAUSES BIRTH DEFECTS**



**DO NOT GET PREGNANT**

**Accutane causes serious birth defects. Do NOT take Accutane if you are pregnant.**

**It is very important for you to read and understand the information about preventing pregnancy on the back of this package, in the Medication Guide, and in the materials given to you by your prescriber. If you do not have the Medication Guide, and a video and the *Be Smart, Be Safe, Be Sure* booklet about pregnancy prevention, don't start taking Accutane. Call your prescriber.**

Most people have further questions after reading so much important information about pregnancy prevention and birth defects. If there is anything you are not sure about, do **not** take Accutane until your questions have been answered by your prescriber.

### ***Important Information for All Patients***

#### ***Mental problems and suicide***

Some patients have become depressed or developed other serious mental problems while they were taking Accutane or shortly after stopping Accutane. Some patients taking Accutane have had thoughts of ending their own lives (suicidal thoughts). Some people have tried to end their own lives (attempted suicide) and some people have ended their own lives (committed suicide). No one knows if Accutane caused these problems or behaviors or if they would have happened even if the person did not take Accutane.

#### **Stop taking Accutane and call your prescriber right away if you:**

- Start to feel sad or have crying spells.
- Lose interest in activities you once enjoyed.
- Sleep too much or have trouble sleeping.
- Become more irritable than usual.
- Have a change in your appetite or body weight.
- Have trouble concentrating.
- Withdraw from your friends or family.
- Feel like you have no energy.
- Have feelings of worthlessness or inappropriate guilt.

- Start having thoughts about hurting yourself or taking your own life (suicidal thoughts).

Tell your prescriber if you or someone in your family has ever had a mental illness or if you take any medicines for a mental illness (for example, depression).

***Other serious side effects to watch for***

**Stop taking Accutane and call your prescriber if you develop any of the problems on this list or any other unusual or severe problems.** If not treated, they could lead to serious health problems. Serious permanent problems do not happen often.

- Headaches, nausea, vomiting, blurred vision (increased brain pressure).
- Severe stomach pain, diarrhea, rectal bleeding, or trouble swallowing.
- Yellowing of your skin or eyes and/or dark urine.
- Changes in hearing.
- Allergic reactions (if you know you are sensitive to “parabens”, tell your prescriber because it is a preservative in the gelatin capsule of Accutane).
- Bone or muscle pain.
- Vision changes, including trouble seeing at night (this can start suddenly, so be very careful when driving or operating any vehicle at night).
- Persistent fever, chills, or sore throat.

**Other Important Information is found in the **Medication Guide** and in the booklet from your prescriber:**

- Common side effects that are not serious but that you should tell your prescriber about.
- How to take Accutane.
- Things to avoid during Accutane treatment.
- Ways to get more information if you need it.

## Accutane Causes Serious Birth Defects

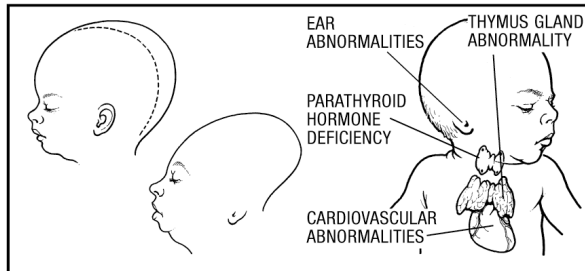
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**Highlights of Warning to Female Patients. (It is important to watch the video and read all information in the *Be Smart, Be Safe, Be Sure* booklet given to you by your prescriber.)**

- You MUST NOT take Accutane if you are pregnant because any amount can cause severe birth defects, even for short periods during pregnancy.
- You MUST NOT become pregnant while taking Accutane, or for 1 month after you stop taking Accutane.
- You will not get your first prescription for Accutane until there is proof you have had 2 negative pregnancy tests as instructed by your prescriber (a negative test means that it does not show pregnancy).
- You cannot get monthly refills for Accutane unless there is proof that you have had a negative pregnancy test every month during Accutane treatment.
- Even the best methods of birth control can fail. Therefore, 2 separate, effective forms of contraception must be used at the same time for at least 1 month before beginning therapy, during therapy, and for 1 month after Accutane therapy has stopped.
- Stop taking Accutane right away and call your prescriber immediately if you have sex without birth control, miss your period or become pregnant while you are taking Accutane. If you get pregnant in the month after you have stopped Accutane treatment, call your prescriber immediately.

### **Very severe birth defects have occurred with Accutane use including:**

- **Severe Internal Defects:** defects that you cannot see—involving the brain (including lower IQ scores), heart, glands and nervous system.
- **Severe External Defects:** defects that you can see—such as low-set, deformed or absent ears, wide-set eyes, depressed bridge of nose, enlarged head and small chin.



[illustration of how to remove capsules]

Figure A

Store at controlled room temperature (59° to 86°F, 15° to 30°C). Protect from light.

**FEMALE PATIENTS:  
DO NOT GET PREGNANT** **xx MG**

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Jonathan Wilkin  
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