

# iMedix: Your Personal Health Advisor.

## Isotretinoin Capsule

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### Description

**Side Effects** Dry lips and mouth, minor swelling of the eyelids or lips, crusty skin, nosebleeds, upset stomach, or thinning of hair may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. To relieve dry mouth, suck on (sugarless) hard candy or ice chips, chew (sugarless) gum, drink water, or use a saliva substitute. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: mental/mood changes (such as depression, anxiety, thoughts of suicide), tingling feeling in the skin, back/joint/muscle pain, signs of infection (such as sore throat that doesn't go away, fever), painful swallowing, peeling skin on palms/soles. Isotretinoin may rarely cause disease of the pancreas (pancreatitis) that may rarely be fatal. Stop taking this medication and tell your doctor right away if you develop: severe stomach pain, nausea/vomiting that is severe or doesn't stop. Stop taking this medication and tell your doctor right away if you have any very serious side effects, including: severe headache, vision changes, ringing in the ears, hearing loss, chest pain, yellowing eyes/skin, dark urine, severe diarrhea, rectal bleeding. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

**Uses** This medication is used to treat severe cystic acne (also known as nodular acne) that has not responded to other treatment (such as benzoyl peroxide or clindamycin applied to the skin or tetracycline or minocycline taken by mouth). It belongs to a class of drugs known as retinoids. It works by decreasing facial oil (sebum) production. High amounts of sebum can lead to severe acne. If left untreated, severe acne may cause permanent scarring.

**How to use Isotretinoin Capsule** Read the Medication Guide provided by your pharmacist before you start using isotretinoin and each time you get a refill. Read and sign a Patient Information/Informed Consent form before you start taking this medication. If you have any questions about isotretinoin, consult your doctor or pharmacist before taking the medication. Take this medication by mouth as directed by your doctor, usually twice daily for 15 to 20 weeks. Swallow the capsules whole. Do not crush or chew them. Some brands of this drug say to take this

medication with meals while other brands say that it may be taken with or without food. Food helps increase absorption of this drug into your bloodstream. Ask your doctor or pharmacist for more information. Take this medication with a full glass of water (8 ounces/240 milliliters) unless your doctor directs you otherwise. Do not lie down for at least 10 minutes after taking this medication. The dosage is based on your medical condition, weight, and response to treatment. Your acne may worsen during the first few days of taking this drug, and it may take up to 1-2 months before you notice the full benefit of this medication. If severe acne returns, a second course of treatment may be started after you have stopped taking the drug for 2 months. The manufacturer does not recommend long-term use of isotretinoin. Do not take more than the recommended dose. Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not handle this medication or breathe the dust from the capsules. **Warnings** Women who are pregnant must not use isotretinoin. Women must avoid becoming pregnant while taking this medication. Serious (sometimes fatal) birth defects, miscarriages, and premature births have occurred when this drug has been used during pregnancy. For female patients, two effective forms of birth control (or complete avoidance of sexual intercourse) must be used for 1 month before starting isotretinoin, during use, and for 1 month after stopping this drug. You must also have monthly pregnancy-avoidance counseling from your doctor. Do not use “minipills” for birth control (non-estrogen-containing pills) since they may not work as well with isotretinoin. If you are late in having your period, or if you have sexual intercourse at any time without using two effective forms of birth control, stop taking this medication and contact your doctor right away. To receive this medication in the United States, you must understand, agree to, and carefully follow the requirements of the iPLEDGE REMS Program. If you live in Canada or any other country, consult your doctor and pharmacist for your country’s regulations. Talk with your doctor about the risks and benefits of using this medication. **Precautions** Before taking isotretinoin, tell your doctor or pharmacist if you are allergic to it; or to vitamin A-related drugs (other retinoids such as tretinoin); or if you have any other allergies. This product may contain inactive ingredients (such as soybean, parabens), which can cause allergic reactions or other problems. Some people who are allergic to peanuts may also be allergic to soy. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: diabetes, family or personal history of high blood fats (triglycerides), mental/mood problems (such as depression), liver disease, obesity, eating disorders (such as anorexia nervosa), alcohol abuse, pancreatitis, bone loss conditions (such as osteoporosis/osteomalacia, decreased bone density). Do not donate blood while you are taking isotretinoin and for at least 1 month after you stop taking it. This medication may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors. Tell your doctor right away if you get sunburned or have skin blisters/redness. Isotretinoin can affect your night vision. Do not drive, use machinery, or do any activity that requires clear vision after dark until you are sure you can perform such activities safely. If you wear contact lenses, you may not tolerate them as well as usual while using this medication. Contact your doctor for more information. Do not have cosmetic procedures to smooth your skin (such as waxing, laser, dermabrasion) during and for 6 months after isotretinoin therapy. Skin scarring may occur. Avoid the use of alcohol while taking this medication because it may increase the risk of certain side effects (such as pancreatitis). Limited information suggests isotretinoin may cause some bone loss effects. Playing contact or repetitive impact sports (such as football, basketball, soccer, tennis) may result in bone problems, including an increased risk of broken bones. Limited information also suggests isotretinoin may stop normal growth in some children (epiphyseal plate closure). Consult your doctor for more details. Older adults may be more sensitive to the side effects of this drug, especially the effects on bones. Children may be more sensitive to the side effects of this drug, especially back/joint/muscle pain. This drug must not be used during pregnancy or by those who may become pregnant during treatment. If you become pregnant or think you may be pregnant, inform your doctor right away. Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not handle this medication or breathe the dust from the capsules. You must have two negative pregnancy tests before starting this medication. You must have a monthly pregnancy test during treatment with isotretinoin. If the test is positive, you must stop taking this medication and consult your doctor right away. It is unknown if this medication passes into breast milk. However, similar drugs pass into breast milk. Breast-feeding while using this drug is not recommended. Ask your doctor when you can breast-feed after stopping treatment. Consult your doctor before breast-feeding. **Overdose** If someone has overdosed

and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: vomiting, stomach pain, facial flushing, headache, loss of balance. Do not allow anyone else to take this medication. It can cause birth defects and other serious health problems. Lab and/or medical tests (such as pregnancy test, blood cholesterol/triglyceride levels, liver function, white blood count, eye exams) should be done while you are taking this medication. Keep all medical and lab appointments. Consult your doctor for more details. If you miss a dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications out of reach of children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company. Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug are: tetracyclines (such as minocycline, tetracycline), vitamin A-type drugs (such as acitretin, bexarotene), vitamin A, drugs that cause bone loss (for example, anti-seizure drugs such as phenytoin, corticosteroids such as prednisone). Tell your doctor when you start any new drug, and discuss if you should use additional reliable birth control. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well. (

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**Side Effects**

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**Uses**

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**Interactions**

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**Other Details**

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