Alitretinoin (Systemic)

Brand Names: Canada
Toctino

Warning

- Do not take if you are pregnant or if you may get pregnant. The risk of very bad and sometimes deadly birth defects is very high if you take this drug at any time while you are pregnant. Any unborn baby can be harmed. There is no good way to tell if an unborn baby has been harmed. The risk of losing an unborn baby is also raised, and premature births have happened. Your doctor will talk about the bad effects before starting you on this drug. If you get pregnant while taking this drug or within 1 month after you stop taking it, call your doctor right away. If you know all the facts and can follow how to take this drug you must sign a patient fact/consent form. Do not sign the form and do not take this drug if you do not know everything on the form.

- Use 2 kinds of birth control that you can trust 1 month before care begins, during care, and for at least 1 month after care ends.

- Raised pressure in the brain has happened with this drug. This can cause long lasting loss of eyesight and sometimes death. Call your doctor right away if you have a bad headache, dizziness, upset stomach or throwing up, or seizures. Call your doctor right away if you have weakness on 1 side of the body, trouble speaking or thinking, change in balance, or change in eyesight.

What is this drug used for?

- It is used to treat hand eczema.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to alitretinoin, vitamin A, or any other part of this drug.
• If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.

• If you are allergic to soya lecithin or alike food products such as soybeans or peanuts, talk with the doctor.

• If you have any of these health problems: High cholesterol, high triglycerides, kidney disease, liver disease, or thyroid disease.

• If you have too much vitamin A in the blood.

• If you are not able to break down fructose.

• If you are able to get pregnant and are not using 2 kinds of birth control.

• If you are planning to get pregnant within 1 month before care, during care, or within 1 month after care has ended.

• If you are breast-feeding. Do not breast-feed while you take this drug.

• If you are taking any of these drugs: Demeclocycline, doxycycline, minocycline, tetracycline, a product that has vitamin A in it, a product that is like vitamin A, or St. John’s wort.

• If you are taking any of these drugs: Amiodarone, isotretinoin, or tazarotene.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

**What are some things I need to know or do while I take this drug?**

• Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.

• Avoid driving and doing other tasks or actions that call for you to be alert or have clear eyesight until you see how this drug affects you.
Lowered night eyesight may happen. This may be sudden. This may clear up after you stop the drug but sometimes it may not go away.

Use care when driving at night or doing other tasks in lowered lighting.

If you have high blood sugar (diabetes), this drug may sometimes raise blood sugar. Talk with your doctor about how to keep your blood sugar under control.

Do not donate blood while using this drug and for 1 month after stopping.

This drug may cause high cholesterol and triglyceride levels. Talk with the doctor.

Have blood work checked as you have been told by the doctor. Talk with the doctor.

Skin may look worse before it looks better.

You may get sunburned more easily. Avoid sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that protects you from the sun.

This drug may cause weak bones and tendon problems in some people. The chance of bone problems like broken bones may be raised in people who play certain sports. Talk with the doctor.

Do not give to a child younger than 18 years of age.

This drug may affect being able to father a child. Talk with the doctor.

You must have 2 pregnancy tests that show you are not pregnant before starting this drug. You will need a pregnancy test every month in order to get more drugs. Talk with your doctor.

Do not use progestin-only birth control pills (minipills). They may not work well. Talk with your doctor.

If you have sex without using 2 kinds of birth control that you can trust, if you think you may be pregnant, or if you miss your period, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very
bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.

- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.

- Muscle pain or weakness.

- Very bad bone or joint pain.

- Change in eyesight, eye pain, or very bad eye irritation.

- Dry eyes.

- Change in how contact lenses feel in the eyes.

- Any unexplained bruising or bleeding.

- Very bad and sometimes deadly pancreas problems (pancreatitis) have happened with this drug. Call your doctor right away if you have very bad stomach pain, very bad back pain, or very upset stomach or throwing up.

- Very bad bowel problems may happen with this drug (inflammatory bowel disease). Tell your doctor right away if you have signs like very bad loose stools (diarrhea), belly pain, bleeding from the rectum, or rectal pain. This may clear up after you stop the drug but sometimes it may not go away.

- This drug may raise the chance of low mood (depression). The risk may be greater in people who have had low mood or thoughts or actions of suicide in the past. Watch people who take this drug closely. Call the doctor right away if signs like low mood, nervousness, restlessness, grouchiness, panic attacks, or changes in mood or actions are new or worse. Call the doctor right away if any thoughts or actions of suicide occur.
What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Flushing.
- Redness.
- Dry lips.
- Dry mouth.
- Nose or throat irritation.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with a meal.
- Swallow whole. Do not chew, break, or crush.
- Take this drug at the same time of day.
- Use as you have been told, even if your signs get better.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- Do not take 2 doses on the same day.
How do I store and/or throw out this drug?

- Store in the original container at room temperature.
- Protect from light.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else’s drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief
summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.

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If you have any questions or concerns, talk with a member of your healthcare team. You can reach them Monday through Friday from 9:00 AM to 5:00 PM at ___________________________. After 5:00 PM, during the weekend, and on holidays, please call_____________________. If there’s no number listed, or you’re not sure, call 212-639-2000.

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