

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr **CLARUS**[®]

Isotretinoin Capsules, USP

Read this carefully before you start taking **CLARUS**[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CLARUS**[®].

Serious Warnings and Precautions

All patients must sign the informed consent form prior to starting therapy.

All Females:

Birth defects

- Isotretinoin can cause birth defects (deformed babies). It can also cause miscarriage, premature birth, or death of the baby. Adequate birth control measures are required when taking CLARUS[®] (see “*Important warnings for females taking CLARUS[®]*”)

All Patients:

Mental health problems and suicide

- Some patients, while taking isotretinoin or soon after stopping isotretinoin, have become depressed or developed other serious mental health problems. Signs of these problems include feelings of sadness, irritability, unusual tiredness, trouble concentrating, and loss of appetite. Some patients taking isotretinoin have had thoughts about ending their own lives (suicidal thoughts), tried to end their own lives, and some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on isotretinoin becoming aggressive or violent.

Neurologic (brain) problems

- Some patients have experienced benign intracranial hypertension while taking isotretinoin. This can happen if you take CLARUS[®] with certain antibiotics (tetracyclines). If you experience headaches, nausea, vomiting and visual disturbances talk to your doctor immediately.

For other possible serious side effects of CLARUS[®], see the “*Serious Side Effects and What to do About Them*” table.

What is CLARUS[®] used for?

CLARUS[®] is used to treat severe acne (nodular and or inflammatory acne). It is used when the acne cannot be cleared up by other treatments, including antibiotics.

CLARUS[®] can cause serious side effects. Before starting CLARUS[®], discuss with your doctor how bad your acne is, the possible benefits of CLARUS[®], and its possible side effects, to decide

if CLARUS[®] is right for you. Your doctor will ask you to read and sign a form indicating you understand some of the serious risks of CLARUS[®].

How does CLARUS[®] work?

- The way CLARUS[®] works is not known. It is thought to reduce sebum, an oily substance that is produced by small glands in the skin, called sebaceous glands. This may reduce bacteria and improve the acne.
- CLARUS[®] contains the active ingredient isotretinoin. This is a vitamin A derivative, belonging to the retinoid class of medicines. Retinoids are normally used to treat skin problems.
- 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 CLARUS[®]. 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 see a noticeable improvement after one or two courses of treatment with CLARUS[®].

What are the ingredients in CLARUS[®]?

Medicinal ingredients: isotretinoin

Non-medicinal ingredients: CLARUS[®] 10 mg capsules:
Ammonium hydroxide, beeswax yellow, gelatin, glycerin, hydrogenated vegetable oil, isopropyl alcohol, lecithin, medium chain triglyceride, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, red iron oxide, SDA 35A alcohol, soybean oil and synthetic black iron oxide.

CLARUS[®] 40 mg capsules:
Ammonium hydroxide, beeswax yellow, gelatin, glycerin, hydrogenated vegetable oil, isopropyl alcohol, lecithin, medium chain triglyceride, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, red iron oxide, SDA 35A alcohol, soybean oil, synthetic black iron oxide, titanium dioxide and yellow iron oxide.

CLARUS[®] comes in the following dosage forms:

CLARUS[®] capsules 10 mg and 40 mg are available in blister packages of 30 capsules.

Do not use CLARUS[®] under these conditions:

- Do not use CLARUS[®] if pregnant
- Do not get pregnant while taking CLARUS[®] and stop taking immediately if you do get pregnant (see *Serious Warnings and Precautions Box*).
- Do not breastfeed while taking CLARUS[®] and for 1 month after stopping CLARUS[®]. CLARUS[®] may pass through your milk and harm the baby.
- Do not take Vitamin A supplements. Vitamin A in high doses has many of the same side effects as CLARUS[®]. Taking both together may increase your chance of getting side effects.
- Do not take CLARUS[®] if you have liver or kidney disease.
- Do not take CLARUS[®] if you have high blood fat (lipid) levels.

- Do not take CLARUS® if you are sensitive to retinoids, soybean oil, or any other non-medicinal ingredient listed under: “*What are the ingredients in CLARUS®?*”

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CLARUS®. Talk about any health conditions or problems you may have, including if:

- you or someone in your family has ever had any mental illness, including depression, suicidal behaviour, or psychosis. Psychosis means a loss of contact with reality, such as hearing voices or seeing things that are not there. Also, you should tell your doctor if you are taking medicines for any of these problems.
- you or someone in your family have liver disease, kidney disease, heart disease or high cholesterol or, diabetes or asthma.
- you have had any bone disorders or anorexia (an eating disorder that causes abnormally low body weight).
- you or someone in your family have a history of alcoholism.
- you plan vigorous physical activity during treatment with CLARUS®.
- you have any food or drug allergies.

Other warnings you should know about:

Important warnings for females taking CLARUS®

- Do not take CLARUS® if you are pregnant.
- If you become pregnant, stop taking CLARUS® and contact your doctor immediately.
- Isotretinoin can cause deformed babies. There is an extremely high risk that your baby will be deformed if you are pregnant while taking isotretinoin. This risk exists even if CLARUS® is taken for a short time. If you are a female of childbearing potential, your physician should have discussed this risk with you, and explained how to avoid becoming pregnant while taking CLARUS®.
- You must avoid becoming pregnant while you are taking CLARUS® and for at least one month after you stop taking CLARUS®.
- You must discuss effective birth control with your doctor before beginning CLARUS® treatment, and you must use effective birth control:
 - For at least one month before you start CLARUS®;
 - While you are taking CLARUS®; and
 - For at least one month after you stop taking CLARUS®;
 Keep in mind that any method of birth control can fail.
- It is recommended that you either abstain from sexual intercourse or use two reliable methods of birth control at the same time, even if you have a history of infertility or are not sexually active.
- Do not take CLARUS® until you are sure that you are not pregnant.
- You must have two negative pregnancy tests, one of them must be done in a lab, before you start CLARUS®. You will need to take a test every month while on the drug and one month after you stop taking CLARUS®. If your menstrual period is abnormal in length and intensity, first contact your doctor (see the CLARUS® CLEAR™ program).
- You must wait until the second or third day of your next normal menstrual period before you start CLARUS®.
- Stop taking CLARUS® and contact your doctor immediately if you do become pregnant while taking CLARUS® or during the first month after treatment has stopped, if you miss your period, or if you have sexual intercourse without using effective birth control. You should

discuss with your doctor the serious risk of your baby having severe birth deformities because you are taking or have taken CLARUS®. You should also discuss the desirability of continuing with your pregnancy.

- Do not breast feed while taking CLARUS®.

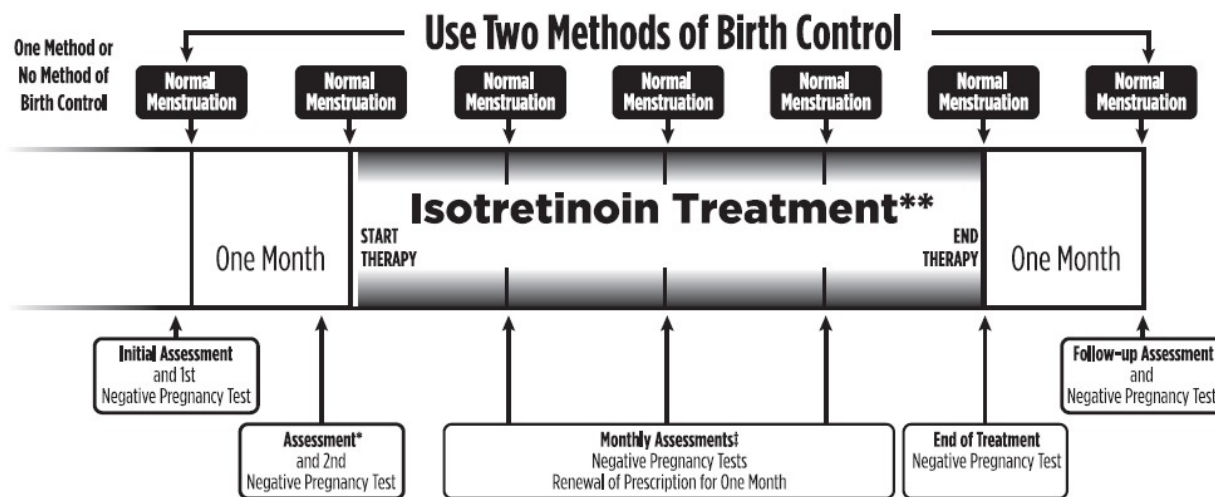
You should have been counselled using the manufacturer’s CLEAR™ program which includes:

- Comprehensive information about the risks of this drug
- A line drawing of a deformed baby
- A checklist of criteria you had to meet before receiving this drug
- Detailed information on birth control options
- A chart: “CLARUS® CLEAR™ program”
- An informed consent for you to review and sign. A copy of this form should be given to you by your doctor.

Please note that the manufacturer of CLARUS® provides confidential contraception counselling (from a healthcare professional). For more information, please contact Mylan Pharmaceuticals ULC.

If you were not counselled using the CLEAR™ Program, please contact your doctor for more information.

ISOTRETINOIN CLEAR™ PLAN



* To ensure that you are using two reliable methods of birth control at the same time.

** Duration of therapy is typically 3-4 months.

‡ To ensure that you are using two reliable methods of birth control at the same time and to detect any side effects that you may have from treatment.

All patients should read the rest of this Patient Medication Information.

Do not take CLARUS® unless you completely understand its possible risks and are willing to follow all of the instructions in this Patient Medication Information.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CLARUS®:

- Low-dose contraceptives (birth control pills). Low dose birth control pills may not work while you are taking CLARUS®.
- Antibiotics (such as tetracyclines),
- Corticosteroids,
- Phenytoin
- Vitamin Supplements including Vitamin A
- St. John's Wort.

What you should avoid while taking CLARUS®:

- Do not give blood while you take CLARUS® and for 1 month after stopping CLARUS®. If someone who is pregnant gets your donated blood, the baby may be exposed to CLARUS® and may be born with birth defects.
- Do not have cosmetic procedures to smooth your skin, such as waxing, dermabrasion, or laser procedures, while you are using CLARUS® and for at least 6 months after you stop. CLARUS® can increase your chance of scarring or inflammation of the skin from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.
- Avoid the use of artificial ultraviolet lights such as the ones used in tanning machines and protect yourself from excessive sunlight. CLARUS® may make your skin more sensitive to ultraviolet (UV) light. When necessary, sunscreen with a high protection factor of at least SPF 15 should be used
- Avoid the use of exfoliative anti-acne agents.

How to take CLARUS®:

If you are of childbearing age, your doctor will limit your CLARUS® prescription to 30 days, so that continued treatment will require a new prescription. Be sure to have your new prescription filled at your pharmacy within 7 days after seeing your doctor.

Do not share CLARUS® with other people. It can cause serious health problems. Take CLARUS® with food or just after a meal.

Usual dose:

- 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 you fill your CLARUS® prescription. If you have any questions, call your doctor.
- Be sure to return to your doctor as scheduled. It is important for your doctor to see you regularly, every month, when you are taking CLARUS®. Blood tests and other tests allow your doctor to check your response to CLARUS®. Discuss your progress and any concerns with your doctor.

Overdose:

If you think you have taken too much CLARUS[®], contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose of CLARUS[®] it may be taken later the same day, but, do not take more CLARUS[®] in one day than your doctor has prescribed. Do not double dose.

What are possible side effects from using CLARUS[®]?

These are not all the possible side effects you may feel when taking CLARUS[®]. If you experience any side effects not listed here, contact your healthcare professional.

Some of the most common side effects are:

- dryness of the skin, lips, mouth, and lining of the nose. It is recommended that you use a skin-moisturizing ointment or cream and a lip balm from the start of treatment of CLARUS[®].
- facial or body rash, flaking of the skin, itching, peeling of the palms and soles,
- increased sensitivity to the sun, sunburn,
- inflammation of the lips,
- mild nose bleed,
- bleeding and inflammation of the gums,
- easily injured skin and increased fatigue,
- redness, dryness, or irritation of the eyes.

If you wear contact lenses, you may find them uncomfortable during treatment because CLARUS[®] may cause dry eyes. This may continue after treatment has stopped. Dry eyes can be helped by applying a lubricating eye ointment or tear replacement therapy.

In some patients variable amounts of hair loss have occurred. In rare cases, this hair loss persisted after treatment was completed.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Mental health problems such as depression or psychosis (a severe mental disturbance) <ul style="list-style-type: none">• changes in your mood such as becoming depressed, feeling sad, or having crying spells• losing interest in your usual activities• changes in your normal sleep patterns• becoming more irritable or aggressive than usual (for example, temper outbursts, thoughts of violence)• losing your appetite, becoming unusually tired			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<ul style="list-style-type: none"> • having trouble concentrating • withdrawing from family and friends • having thoughts about taking your own life (suicidal thoughts) <p>Your doctor may recommend a consultation with a specialist if you become depressed or experience these changes in mood.</p>			
<p>Inflammation of the liver, pancreas or intestine (bowel)</p> <ul style="list-style-type: none"> • severe stomach pain, diarrhea, rectal bleeding; yellowing of the skin or eyes and/or dark urine. 			✓
<p>Bone and Muscle Changes</p> <ul style="list-style-type: none"> • aches or pains in bones or joints, back pain, or difficulty in moving, muscle pain, especially after vigorous exercise • muscle weakness with or without pain can be a sign of serious muscle damage <p>Tell a healthcare provider you are taking CLARUS® if you break a bone.</p>			✓
<p>Hyper-sensitivity (allergic) reactions</p> <ul style="list-style-type: none"> • hives, swollen face or mouth, trouble breathing, fever, rash, red patches, bruises 			✓
<p>Increased pressure in the brain</p> <ul style="list-style-type: none"> • bad headaches, blurred vision, dizziness, nausea, vomiting, seizures (convulsions) and stroke. 			✓
<p>Hearing and vision differences</p> <ul style="list-style-type: none"> • changes in your hearing or ringing in your ears • changes in your vision especially at night, decreased night vision may occur suddenly in some patients (take caution when driving at night), persistent feelings of dry eyes 			✓
<p>Heart problems</p> <ul style="list-style-type: none"> • chest pain, palpitations, vascular thrombotic disease, stroke, leg swelling, seizures (convulsions), slurred speech, problems moving or any other serious unusual problems. 			✓
<p>Pregnancy issues during or after treatment</p> <ul style="list-style-type: none"> • Birth defects, miscarriage, premature birth or death of baby. <p>Do not take CLARUS® if you are pregnant.</p>			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Problems with blood sugar levels <ul style="list-style-type: none"> fainting, become very thirsty, urinating a lot, feeling weak. 			✓
Serious Skin Reactions such as erythema multiforme (EM), Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) <ul style="list-style-type: none"> blisters, peeling skin, severe red/purple rash, fever, conjunctivitis (red or inflamed eyes) multiple lesions and sores, particularly in your mouth, nose, eyes and genitals 			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Keep out of reach and sight of children.**
- CLARUS® should be stored at controlled room temperature (15°C to 30°C). Store in the original package. Protect from exposure to heat and light.
- CLARUS® does not need to be refrigerated.

It is recommended that CLARUS® not be disposed of in household waste or waste water. Please return any unused CLARUS® to the pharmacist or use an established "collection system" if available in your location.

If you want more information about CLARUS®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (www.mylan.ca); or by calling 1-844-596-9526.

This leaflet was prepared by Mylan Pharmaceuticals ULC
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For more information about birth control or for confidential counselling call the toll-free number at 1-855-500-9991 or visit the CLARUS® website at www.claruscLEARprogram.ca.