

Clarus[®]

Isotretinoin Capsules, USP

CLEAR[™]

Program

A Guide for Patients

CLEAR[™] (Clinical Education and Awareness Resource)
Updated: November 27, 2019



A Guide for Patients

Important information about this guide

Your doctor has talked to you about taking Clarus[®] (Isotretinoin Capsules USP) to help get rid of your acne. Before your next appointment with your doctor:

- ✓ Read the Patient Medication Information that comes with your prescription for Clarus
- ✓ Read this guide book
 - You will learn how to take Clarus, its common side effects and important safety information about Clarus
- ✓ If you're female, carefully read through the Pregnancy Prevention section of this guide
 - You must talk to your doctor about using birth control while taking Clarus
 - Choose two effective forms of birth control that you will use together
- ✓ Write down your questions
 - If you have any questions about taking Clarus, be sure to discuss them with your doctor at your next appointment
- ✓ Read and sign the Informed Consent Form included in the CLEAR[™] Plan Package
 - If you are a female, you must read and sign Part I and Part II of the form
 - If you are male, you must read and sign Part I of the form
 - If you are under the age of 18 (subject to provincial legislation), one of your parents or your guardian must read and sign the document(s) for you

- ✓ Give one copy of your signed Informed Consent Form to your doctor
 - Your doctor must keep a signed copy of the Informed Consent Form in your medical file
 - You should keep the other copy of your signed Informed Consent Form

For more information

For more information about birth control or for confidential counselling call the toll-free number at 1-877-776-7711 or visit the Clarus website at www.clarusclearprogram.ca.

Common Questions About Acne

What causes acne?

Your skin has thousands of oil glands that produce sebum to moisturize your skin and help it act as a protective barrier. Sebum within each oil gland is carried to the skin's surface through pores. The highest density of oil glands is found on your face, especially at the nose, forehead and mid-cheek areas. The largest oil glands are found on the back and mid-chest. This explains, in part, why acne appears mostly on the face, chest and back.

But what actually causes acne is still unknown. Hormones may play a role in pore blockage and increased oil production. Unfortunately, you may inherit acne-prone skin – particularly the type susceptible to the more severe, scarring forms of the condition.

Who gets acne?

More than 85% of teenagers get acne, but anyone can get acne, including adults.¹

Where can acne appear?

You can have acne on any part of your skin where sebaceous glands are found. These are the glands that produce oil/wax for the skin. Acne can appear on the face, chest and back, and even on the arms and thighs.

What is severe acne?

Severe acne is when many red, swollen, tender lumps form in the skin. These can be the size of pencil erasers or larger.

What is persistent acne?

Persistent acne, also known as recalcitrant acne, is acne that is resistant to oral antibiotics or topical antibiotic lotions, creams or gels.

What can make acne worse?

The most common things that can aggravate your acne are: cleansing your skin too much, and squeezing, picking, or popping zits. Excessive cleansing, particularly with overzealous use of abrasive facial scrubs, can irritate your skin and worsen inflammation.

How is acne treated?

Acne treatment ranges from cleansers, topical gels and creams for mild acne, to antibiotic or hormonal pills for moderate cases of acne.

Clarus is a medicine used to treat severe acne (nodular and/or inflammatory acne) and acne that cannot be cleared up by other treatments, including antibiotics. The mechanism of action of Clarus is not known. It is believed to act on the sebaceous glands (sweat-producing glands) to reduce sebum excretion. This may indirectly reduce bacterial activity associated with acne and improve the condition. The first signs of healing most often occur after two to three weeks of treatment. It may take one to two months before beneficial effects are seen. Please work closely with your doctor and take your Clarus as prescribed.

Where can I get more information about acne?

You can find out more about acne on the following websites:

- www.clarusclearprogram.ca
- <https://www.canada.ca/en/health-canada/services/drugs-medical-devices/acne-treatments.html>

About Clarus[®]

Clarus is a medicine taken by mouth to treat the most severe form of acne (nodular and/or inflammatory acne) that cannot be cleared up by any other acne treatments, including antibiotics.

Clarus belongs to a class of drugs called retinoids. Clarus is the name brand version of isotretinoin, an ingredient related to Vitamin A.

Please be aware of significant warnings for people taking Clarus, such as the high potential of birth defects and other health problems. Read this booklet carefully, as well as the ‘Patient Medication Information’ that comes with your prescription for Clarus, especially “[Important warnings for females taking CLARUS](#)” and “What are possible side effects from using CLARUS?”.

About Clarus side effects

Clarus can cause serious side effects.

Before starting Clarus, talk to your doctor about how bad your acne is, the possible benefits of Clarus, and possible side effects. Your doctor will ask you to read and sign an Informed Consent Form. By signing the Informed Consent Form, you are showing that you understand some of the serious risks of Clarus.

For more information about side effects, please read the Patient Medication Information document that is given to you with your Clarus prescription.

Note: You should read the Patient Medication Information every time you get a prescription or a refill for Clarus because there may be new information.

How to take Clarus

Depending on your dosage of Clarus, you’ll probably take it for at least 12 to 16 weeks. This is called a course of therapy. If you require a second course of therapy, it will start eight or more weeks after your first course is done.

Read your prescription label carefully and take the exact amount of medicine prescribed by your doctor. The amount of Clarus you should take has been chosen just for you. Your dose of Clarus is based on your body weight, and your doctor may change your prescribed dose from time to time, so it’s important to check the label every time you fill your prescription. If you have any questions, call your doctor.

Clarus comes in the form of a soft gelatine capsule. Do not chew or suck on the capsule. Swallow your Clarus capsule whole with a full glass of liquid. It should be taken with food or just after a meal. If you forget to take your dose at mealtimes, you can take it with a later meal that day, but don’t take more Clarus in one day than your doctor has prescribed. Do not double dose.

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.

How to store Clarus

You don’t need to refrigerate Clarus, but it should be kept in its original package at a temperature of 15-30°C, protected from sunlight and heat.

Be sure to keep Clarus out of the reach and sight of children.

Special Handling Instructions for Clarus

Do not put Clarus capsules down the drain, flush them down the toilet or put them in the garbage. Please return any unused Clarus capsules to your pharmacist or use the collection system for medicines if one is available in your area.

Talk To Your Doctor

Before you take Clarus, tell your doctor:

- If you are pregnant or planning to get pregnant, or if you are breast feeding
- 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)
- If you are taking medicines for any mental illness, including depression, suicidal behaviour, or psychosis
- If you or any member of your family has liver disease, kidney disease, heart disease, high cholesterol, diabetes or asthma
- If you or someone in your family have a history of alcoholism
- If you plan vigorous physical activity during treatment with Clarus
- If you have had any bone disorders
- If you have had anorexia (an eating disorder that causes abnormally low body weight)
- If you are sensitive to retinoids, soybean oil, or retinoids, soybean oil, or any other non-medicinal ingredient in Clarus (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 capsules are made with Kosher-certified gelatin. They do not contain parabens, or canthaxanthin (which can contain peanut oil)
- If you have any food or drug allergies

- About all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines
- If you 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.
- If you are taking low-dose contraceptives (birth control pills). Low dose birth control pills may not work while you are taking Clarus. Ask your doctor or pharmacist if you are not sure what type you are using
- If you are taking St. John's Wort, which might make birth control pills work less effectively
- If you are taking antibiotics (such as tetracyclines), corticosteroids or phenytoin.

Before you start taking Clarus, you should have a blood test to check your complete blood count, blood triglyceride and cholesterol levels, blood glucose levels and how your liver is functioning.

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.

What You Need To Know

Know the facts

The following pages discuss some of the important things you need to know before you start taking Clarus. If you have any questions, please talk to your doctor. If you are a woman taking Clarus, please pay special attention to the Pregnancy Prevention section of this guide.

Facts for everyone taking Clarus	
Do not use Clarus if you are pregnant.	Clarus can cause birth defects (deformed babies). It can also cause miscarriage, premature birth, or death of the baby.
Do not get pregnant while taking Clarus and for one month after treatment. (Isotretinoin can cause serious birth defects.)	<ul style="list-style-type: none">• Start to use two methods of effective birth control together for at least one month before, during, and for one month after Clarus therapy, or don't have sex during this time.• Have two negative pregnancy tests performed in a licensed laboratory.<ul style="list-style-type: none">- The first pregnancy test should be done once you and your doctor have decided to use Clarus.- The second pregnancy test should be done within 11 days before starting Clarus.• Wait until the second or third day of your next normal period before starting Clarus.• Have a pregnancy test performed in an approved laboratory every month you take Clarus and one month after treatment stops.• If your period is abnormal in length or intensity, contact your doctor.• If you become pregnant, stop taking Clarus and contact your doctor immediately.
Do not breast feed while taking Clarus and for one month after treatment.	Clarus may pass through your milk and harm the baby.
If you become depressed or have any serious mental problems tell your doctor immediately. It may be necessary to stop Clarus treatment.	Signs of mental health problems include: <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 that you once enjoyed• Changes in your normal sleep patterns• Becoming more irritable or aggressive than usual (for example, temper outbursts, thoughts of violence)

If you become depressed or have any serious mental problems tell your doctor immediately. It may be necessary to stop Clarus treatment.

(Continued)

- Losing your appetite or a change in your body weight
- Becoming unusually tired
- Feeling like you have no energy
- Having trouble concentrating
- Having feelings of worthlessness or guilt
- Withdrawing from family and friends
- Having thoughts about hurting yourself or taking your own life (suicidal thoughts)
- Starting to act on dangerous impulses
- Starting to see or hear things that are not real

Some patients taking isotretinoin have had thoughts about putting an end to 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.

Stop using Clarus and call your doctor immediately if you develop a serious skin reaction.

- Symptoms of a skin reaction include blisters, peeling skin, severe red/purple rash, multiple lesions and sores, particularly in your mouth, nose, eyes and genitals, as well as facial and tongue swelling.
- Some patients taking Clarus have had serious skin reactions, such as erythema multiforme (EM), Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) which can result in hospitalization, disability and/or death.

Do not take tetracyclines with Clarus.

For some antibiotics, you may have to stop taking Clarus until the antibiotic treatment is finished. Use of tetracyclines with Clarus together can increase the chances of getting increased pressure in the brain. Certain antibiotics interfere with the effectiveness of birth control pills.

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 or if you have high blood fat (lipid) levels.

Tell your doctor if you have any of these health problems.

Do not take Clarus if you are sensitive to any of its ingredients, including retinoids, soybean oil, or any other non-medicinal ingredients listed.

- If you have an allergic reaction while taking Clarus, stop taking Clarus and contact your doctor immediately.

Do not take Clarus if you are sensitive to any of its ingredients, including retinoids, soybean oil, or any other non-medicinal ingredients listed

(Continued)

- 10 mg capsules contain 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.
- 40 mg capsules contain 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.

Do not give blood while taking Clarus and for one month after treatment.

If someone who is pregnant gets your donated blood, her baby may be exposed to Clarus and may be born with birth defects.

Do not take low-dose contraceptives, antibiotics, corticosteroids, phenytoin, and natural health products such as herbs (i.e., St. John's Wort) with Clarus unless you talk to your doctor.

These medications may interact with Clarus or Clarus may interfere with the actions of these medications.

Do not use abrasive cleansers or exfoliative anti-acne agents on your skin while taking Clarus.

Some skin products, like exfoliants, may be irritating to your skin while you are taking Clarus.

Do not have cosmetic procedures to smooth your skin such as waxing, dermabrasion, or laser procedures while taking 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 light. When necessary, sunscreen with a high protection factor of at least SPF 30 should be used.

Do not share Clarus with anyone.

Clarus is a prescription product that can cause serious side effects. A doctor must prescribe it.

Avoid drinking alcohol while on Clarus.

You are at a greater risk of liver damage with the combination of isotretinoin and alcohol.

See your doctor regularly.

Isotretinoin may affect blood fat, cholesterol, or sugar levels so it's important to see your doctor regularly.

Tell all healthcare practitioners (i.e. your family doctor, dentist, cosmetic surgeon) that you are taking Clarus.

Isotretinoin can interfere with other prescriptions and treatments.

When To See Your Doctor

You should visit your doctor monthly to check how you are doing on this medication. If you get any of the following symptoms while you are taking Clarus, you must tell your doctor immediately because it may be necessary to stop Clarus:

- You get pregnant, or get pregnant within one month after stopping Clarus,
- Changes in your mood such as becoming depressed, feeling sad, or having crying spells, and/or other signs of mental health problems such as:
 - 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
 - Having trouble concentrating
 - Withdrawing from family and friends
 - Having thoughts about taking your own life (suicidal thoughts)
- Bad headaches, blurred vision, dizziness, nausea, vomiting, seizures (convulsions) and stroke
- Severe stomach pain, diarrhea, rectal bleeding
- Yellowing of the skin or eyes and/or dark urine
- Changes in your hearing or ringing in your ears
- Changes in your vision, especially at night; decreased night vision may occur and be sudden in some patients; take caution when driving at night
- Persistent feelings of dry eyes
- 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. Tell a healthcare provider you are taking Clarus if you break a bone.
- Hives, swollen face or mouth, trouble breathing, fever, rash, red patches, bruises
- Fainting, becoming very thirsty, urinating a lot, feeling weak
- Chest pain, palpitations, vascular thrombotic disease, stroke, leg swelling, seizures (convulsions), slurred speech, problems moving or any other serious unusual problems
- 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
- Your acne becomes worse

Protect yourself from the sun

Clarus may increase your sensitivity to the sun. Avoid long periods in the sun. When you are in the sun, use a broad-spectrum sunscreen with an SPF of 30 or higher to help protect your skin. When choosing a sunscreen to use on your face, back and chest, choose one that's oil-free, won't cause blackheads (non-comedogenic), and won't cause acne (non-acnegenic).

What You Can Expect

How you'll feel

As with any acne medication, you'll probably have some side effects during your treatment. Please refer to the Patient Medication Information document for more information. Most side effects usually decrease over time.

Talk to your doctor if you have any concerns about your medication or how it affects you. The more your doctor knows about how you're responding to Clarus, the easier it is for him/her to determine if you are on the appropriate dose of medication.

The first couple of weeks

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.

If you develop a serious skin reaction with symptoms such as blisters, peeling skin, severe red/purple rash, multiple lesions and sores, particularly in your mouth, nose, eyes and genitals, as well as facial and tongue swelling, stop using Clarus and call your doctor immediately.

How to deal with potential side effects

The following table shows common side effects and offers some general advice. If you have any of these reactions, let your doctor know about it at your next visit, or even sooner if the side effects becomes too uncomfortable.

What you can expect	What you can do
Chapped lips	Apply a specially-formulated lip ointment to moisten and soften your lips.
Dry nose	Apply a nasal lubricant to avoid nosebleeds. Use a humidifier in your bedroom.
Peeling of the palms and soles	See your doctor. He/she may need to adjust your Clarus dosage.
Itchy skin, dry skin	Apply a non-irritating, water-based moisturizer that won't clog your pores. To help reduce further drying, wash your face with a non-irritating, water-based cleanser.
Dry mouth	See your doctor. He/she may need to adjust your Clarus dosage.
Redness of the face	Apply a non-irritating water-based moisturizer that won't clog your pores. To help reduce further drying, wash your face with a non-irritating, water-based cleanser.
Hair thinning	In most cases, hair thinning is temporary, but tell your doctor because he/she may need to change your dosage. In a very small number of cases, hair thinning might be permanent.
Increased sensitivity to the sun	See your doctor. He/she may need to adjust your Clarus dosage.
Sunburn	See your doctor. He/she may need to adjust your Clarus dosage.
Inflammation of the lips	See your doctor. He/she may need to adjust your Clarus dosage.

What you can expect	What you can do
Facial or body rash	See your doctor. He/she may need to adjust your Clarus dosage.
Mild nose bleed	See your doctor. He/she may need to adjust your Clarus dosage.
Bleeding/inflammation of gums	See your doctor. He/she may need to adjust your Clarus dosage.
Easily injured skin	See your doctor. He/she may need to adjust your Clarus dosage.
Increased fatigue	See your doctor. He/she may need to adjust your Clarus dosage.
Redness, dryness or irritation of the eyes	See your doctor. He/she may need to adjust your Clarus dosage.
Dry eyes	Use an artificial tears product. If you wear contact lenses, choose a product that's compatible with your contacts.

Pregnancy Prevention

Before you take Clarus

Before you decide to take Clarus you must have discussed the consequences of becoming pregnant during Clarus therapy with your doctor, and clearly understood them.

Clarus can cause birth defects (deformed babies). It can also cause miscarriage, premature birth, or death of the baby. There is an extremely high risk that your baby will be deformed if you are pregnant while taking Clarus or up to one month after treatment has stopped. This risk exists even if Clarus is taken for a short time. Therefore, adequate birth control measures are essential when taking Clarus.

Contraception: Effective contraception must be used for at least one month before starting Clarus treatment, during treatment and for at least one month following the the discontinuation of Clarus treatment.

It is recommended that two reliable forms (**Primary and Barrier forms**) of contraception be used simultaneously. At least one of these forms of contraception must be a primary form (i.e. oral contraceptive, contraceptive patch, vaginal ring, intra-uterine device), unless the patient has undergone a hysterectomy.

Remember, any birth control method can fail.

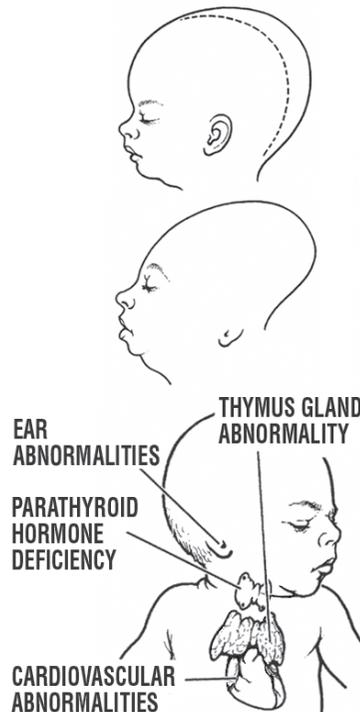
If you are a female of childbearing age, your physician should have discussed the risk with you, and explained how to avoid becoming pregnant while taking Clarus.

Some birth defects commonly associated with taking isotretinoin during pregnancy are:

- Low-set, deformed or absent ears
- Wide-set eyes
- Depressed bridge of nose
- Enlarged head
- Small chin

More severe birth defects are:

- Mental retardation
- Internal defects affecting the brain, heart, lymph glands, and nervous system



Do's and don'ts of taking Clarus

Do	Don't
Do discuss effective methods of birth control with your doctor before beginning Clarus therapy.	Do not become pregnant for one month before, during, or for one month after taking Clarus.
Do have two blood or urine pregnancy tests in a licensed laboratory before starting Clarus therapy. The first pregnancy test should be done once you and your doctor have decided to use Clarus. The second pregnancy test should be done within 11 days before starting Clarus. Wait until the second or third day of your next normal period before starting Clarus.	Do not take Clarus if you are pregnant.
Do use two reliable methods of birth control at the same time 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, even if you have a history of infertility or are not sexually active.	Do not take Clarus until you and your doctor are sure you are not pregnant.
Do wait until the second or third day of your next normal menstrual period before you start Clarus.	Do not take Clarus if you have not had two negative pregnancy tests before starting Clarus.
Do have a monthly pregnancy test while taking Clarus and one month after stopping Clarus.	Do not take Clarus if you cannot avoid pregnancy.
Use two reliable methods of birth control together, even if you have a history of infertility or are not sexually active (unless you have had a hysterectomy).	Do not have sex if you are not using two reliable methods of birth control at the same time for at least one month before you start Clarus, while you are taking Clarus, and for one month after you stop taking Clarus.
Do remember that any method of birth control can fail.	Do not take Clarus if you are breastfeeding.
Do let your doctor or pharmacist know what brand of birth control you are taking.	Do not take low-dose, progestogen birth control pills (also known as 'mini-pills'). Progestogen-only birth control pills may not work while you are taking Clarus.

Pregnancy Prevention

Stop taking Clarus and contact your doctor immediately if:

- You become pregnant while taking Clarus or during the first month after treatment has stopped
- You miss your period

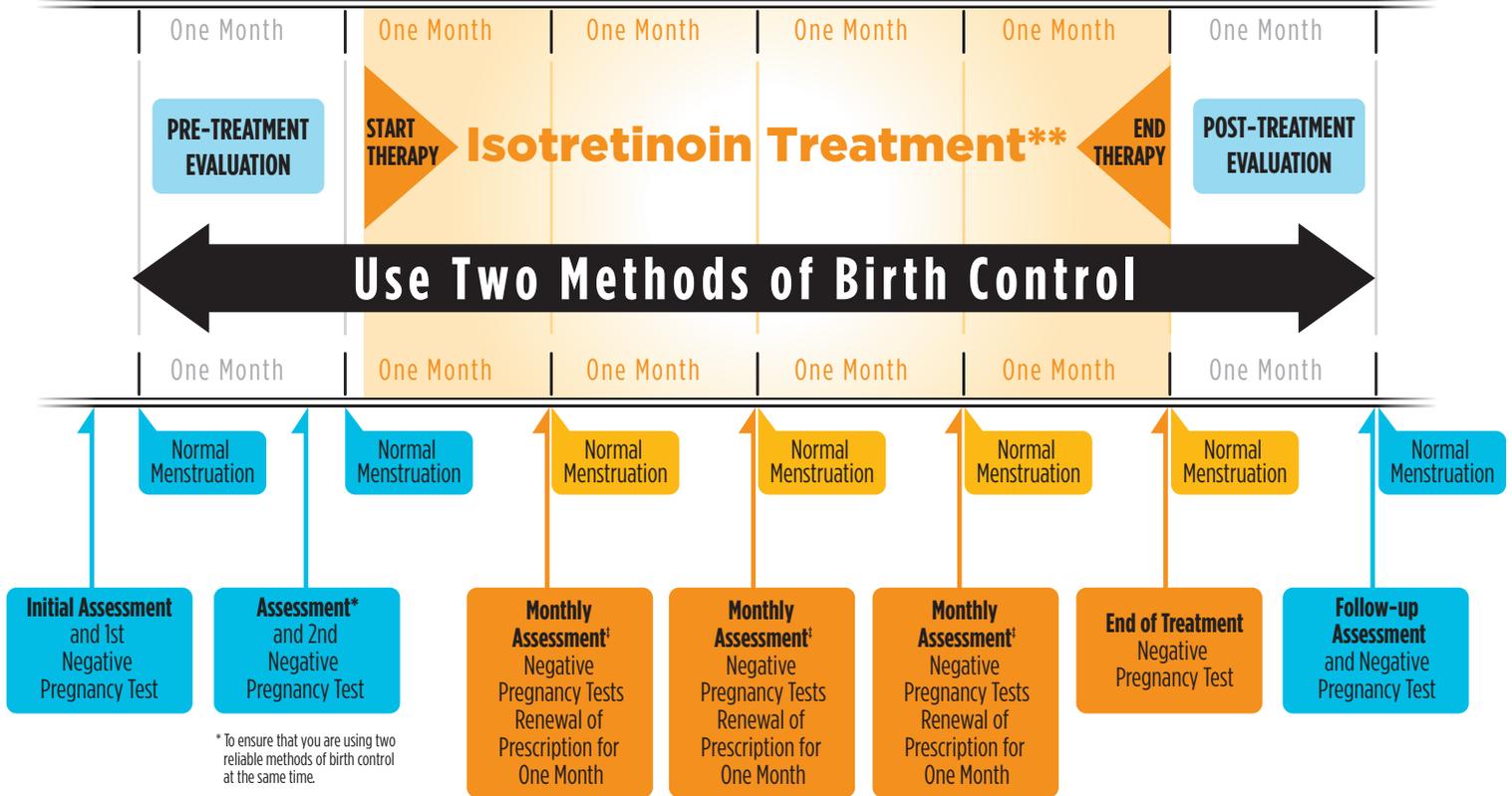
- If your period is abnormal in length (shorter or longer than usual) and intensity
- You have sex without using effective birth control.

Safety information about Clarus and pregnancy

Important information about Clarus and pregnancy, and confidential counselling is available:

Toll-free phone number: 1-877-776-7711

Clarus® CLEAR™ Program



* 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.

Frequently Asked Questions About Birth Control

What is effective birth control?

Remember any birth control method can fail. Effective birth control means using a reliable combination of at least two birth control methods at the same time to prevent pregnancy.

Are there any birth control methods I should avoid?

Yes. If you are serious about avoiding pregnancy, you should not use the rhythm method (also known as fertility awareness) or the withdrawal method — they are risky and unreliable.

Don't use the rhythm method/fertility awareness

Fertility awareness is not a very effective form of contraception. In this method, a woman keeps track of her monthly menstrual cycle by taking her temperature, checking the thickness of mucous in her vagina, and by tracking her periods on a calendar.

Teens in particular shouldn't rely on this method, because their cycles are still unpredictable. Some women may be tempted to have sex during their fertile periods, and it won't work if their partners aren't willing to cooperate.

Don't use the withdrawal method

In this method, a man withdraws his penis from a woman's vagina before ejaculation. Withdrawal requires a lot of self-control and practice, and it can be difficult to get the timing right.

When should I start/stop using birth control?

To prevent pregnancy during Clarus therapy, 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.

What is considered unprotected sex?

In the case of Clarus, unprotected sex means not using **two forms of effective birth control every time you have sex** while taking Clarus and for one month after you stop taking Clarus.

Regardless of how it happens, unprotected sex opens the door to the possibility of an unwanted pregnancy. Unprotected sex also happens if you find yourself in one of these situations:

- You had an accident, such as a broken or slipped condom or slipped diaphragm
- You forgot to take your birth-control pills for two or more days before having sex
- You had intercourse unexpectedly without using two methods of birth control
- You were forced to have sex or awoke to realize you were having sex
- You have vomiting or diarrhea within a few hours of taking your birth control pill

What should I do if I have unprotected sex while taking Clarus®?

Remember that you should never have unprotected sex while taking Clarus therapy and for one month after you stop the medication.

If you do have unprotected sex while taking Clarus, you can use emergency contraception such as Plan B or Contingency ONE. Plan B and Contingency ONE can be effective in preventing pregnancy if taken within 72 hours of unprotected sex or contraceptive failure. The earlier you use Plan B or Contingency ONE after unprotected sex, the greater the chance that it will work. If you are already pregnant, Plan B and Contingency ONE will have no effect on the pregnancy. Tell the pharmacist dispensing Plan B or Contingency ONE that you are on Clarus.

When mistakes happen, emergency contraception is your last chance to take control of your reproductive destiny, so make sure you know how to get it, just in case. You can get Plan B and Contingency ONE directly from your pharmacist or get a prescription for it from your doctor. If more than 72 hours have passed you should discuss other forms of emergency contraception with your doctor or pharmacist. Call your doctor, or the Action Canada for Sexual Health & Rights bilingual hotline, 1-888-642-2725, for information about getting emergency contraception in your area, or call the toll-free birth control counselling hotline at 1-877-776-7711.

Stop taking Clarus and contact your doctor immediately if you become pregnant while taking Clarus or during the first month after treatment has stopped.

Frequently Asked Questions

Can I get pregnant if I do it just once?

Yes. A woman who is ovulating can get pregnant on her very first time having sex, regardless of her age or her sexual history.

Will I get pregnant if I douche after sex?

Douching does very little to prevent conception. After sexual intercourse, the sperm enter the cervix where they are out of reach of any douching solution.

Can I get pregnant if I use birth control?

Yes you can. No matter what form of birth control you use, there is always the possibility it may fail, especially if used incorrectly. Always use two reliable forms of birth control together. The kind of birth control is also important. Progestogen-only birth control pills (mini-pills) may not work while you are taking Clarus. Ask your doctor or pharmacist if you are not sure what type you are using.

Are there certain times of the month when I can have unprotected sex?

No. Since each woman's menstrual cycle is different, it's almost impossible to predict which days are "safe". Sperm can survive for several days in a woman's body, so a couple could have sex well before the woman ovulates and still run the risk of pregnancy.

Can I get pregnant if I don't have an orgasm?

Yes. Pregnancy occurs when a man's sperm fertilizes a woman's egg. This can happen whether or not she has an orgasm.

Can I get pregnant if I have sex standing up or if on top during sex?

Yes. Positions make very little difference when it comes to getting pregnant. When a man deposits sperm into a woman's vagina, natural processes guide the sperm toward the woman's cervix and uterus. Whether she's on top, lying down or standing on her head really won't make much difference.

What should I do if my partner doesn't want me to use birth control?

If you and/or your partner are not committed to using two methods of effective birth control, do not take Clarus.

What you should know about emergency contraception

If you have sex without using effective birth control while still taking Clarus, stop taking Clarus immediately and call your doctor. Also call your doctor if you have sex without using birth control during the month after you stopped taking Clarus. Emergency contraception (EC) can be effective in preventing pregnancy if taken within 72 hours of unprotected sex or contraceptive failure.

When mistakes happen, emergency contraception is your last chance to take control of your reproductive destiny, so make sure you know how to get it, just in case. You can get Plan B and Contingency ONE directly from your pharmacist or get a prescription for it from your doctor. Call your doctor, or the Action Canada for Sexual Health & Rights bilingual hotline, 1-888-642-2725, for information about getting emergency contraception in your area, or call the toll-free birth control counselling hotline at 1-877-776-7711.

Using Birth Control

The following table outlines different methods of birth control. Read this carefully and you'll learn what they are, how they work and how effective they can be when used correctly.

Not being involved in any type of sexual behaviour is the only method of birth control that is 100% effective. Even if you use one of the recommended methods properly, there is still a risk of getting pregnant.

It is recommended that two reliable forms (**Primary and Barrier forms**) of contraception be used simultaneously. At least one of these forms of contraception must be a primary form (i.e. oral contraceptive, contraceptive patch, vaginal ring, intra-uterine device), unless the patient has undergone a hysterectomy. Remember, any birth control method can fail.

Methods	Type of birth control	What is It?	How it works	Effectiveness	Consider this
Primary	Oral Contraceptives (The Pill)	Birth control pills taken daily.	Uses female hormones to prevent pregnancy.	>99% effective	Side effects may include irregular bleeding, breast tenderness, nausea, weight gain and mood changes. There are rare but serious health risks for women 35 years+ who smoke. The progestogen-only mini-pills are not a suitable method of contraception during Clarus therapy.
Primary	Contraceptive Patch	A small, square beige patch that sticks to a woman's skin.	Uses female hormones to prevent pregnancy (similar to The Pill).	>99% effective	Side effects may include breast tenderness, headache, irregular bleeding and spotting, and skin reactions where the patch is applied. May be less effective for women with a body mass greater than 190 lbs (90 kg).

Methods	Type of birth control	What is it?	How it works	Effectiveness	Consider this
Primary	Vaginal Ring	A soft, flexible, clear plastic ring inserted into the vagina.	Uses female hormones to prevent pregnancy (similar to The Pill).	>98% effective	Side effects may include irregular bleeding, headaches, vaginal irritation, discomfort or discharge, nausea, and breast tenderness. Breakthrough bleeding (bleeding between periods) occurs in about 5% of women. Women who cannot take the birth control pill for medical reasons cannot use the ring either.
Primary	Intra-Uterine Device (IUD)	A small, T-shaped device with a copper wire inserted into the uterus.	The copper wire changes the chemistry in the uterus and destroys sperm.	98-99% effective Provides up to 5 years of contraception	Side effects may include increased cramps, spotting, depression, acne, headache, breast tenderness.
Barrier	Diaphragm	A saucer-shaped disk with a flexible spring rim that covers the cervix.	Prevents sperm from entering the uterus.	80-94% effective with spermicide. Must be kept in place for six hours after intercourse. It is reusable for several years with proper maintenance and storage.	Must be fitted by a doctor or a healthcare professional since they come in different sizes. Diaphragms should not be left in longer than 24 hours after insertion.
Barrier	Cervical Cap	A deep latex cap that fits inside the vagina against the cervix.	Prevents sperm from entering the uterus.	80-91% effective with spermicide	Must be used with spermicide, and must be kept in place for six hours after sexual intercourse.
Barrier	Contraceptive Sponge	A soft, round piece of foam, with low concentrations of spermicide.	Prevents sperm from entering the uterus. Spermicides kills sperm.	The Today sponge has a perfect use failure rate of 9-20% and a typical failure rate of 12-24%. One sponge can be used for up to 12 hours of sexual intercourse. Most effective when used with a condom.	Don't use if allergic to spermicide. Must be kept for at least six hours after intercourse.

Methods	Type of birth control	What is It?	How it works	Effectiveness	Consider this
Barrier	Condoms	Male condom – thin sheath that rolls down over the penis. Female condom – thin sheath inserted into the vagina.	Prevents sperm from entering the vagina.	The estimated probability of failure with perfect use of male condoms is 2%, whereas typical-use failure rates are approximately 18%. The 12 month pregnancy rate for perfect (correct and consistent) use of the female condom is 5%, while the typical-use failure rate is 21%.	Can break or slip off. Male condom is recommended to be used with other contraceptives.
Barrier	Spermicide	A cream (only for use with diaphragms), gel, foam, film or suppository, inserted into the vagina and used in combination with other methods of birth control.	Applied to the vagina to kill sperm.	Effective only when used in combination with a condom, cervical cap, or diaphragm. Vaginal spermicides are among the least effective of all modern family planning methods. Failure rate in the first year of use is 18% with perfect use and 28% with typical use.	Do not use spermicides alone.

Adapted from the Society of Obstetricians and Gynaecologists of Canada, Clinical Practice Guidelines: Canadian Contraception Consensus, 2015.

Questions and Answers

Is acne contagious?

No, acne is not contagious. See the section of this booklet called 'About Acne' for more information about the causes of acne.

Will I get acne if I eat junk food?

There are many myths about what causes acne. Chocolate and greasy foods are often blamed, but foods seem to have little effect on the development and course of acne in most people.

Do you get acne because you don't keep your face clean?

If you have acne, it does not mean that your skin is dirty. Cleansing and scrubbing your skin excessively will not help your acne. In fact, it may make it worse. Remember that the causes of acne affect oil glands, which are well below the surface of the skin. It is recommended to wash your face with a gentle oil-free cleanser. Ask your doctor for the best types of cleansers to use on your skin.

The sun seems to help my acne. Is this really true?

While it is true that sun exposure may dry out existing acne, it won't prevent new acne from forming. For some people, the sun can make their acne worse, and some acne medications, can make your skin sensitive to the sun, leading to serious sunburns. When you're in the sun, use a broad-spectrum sunscreen with an SPF of 30 or higher to protect your skin.

Will squeezing or picking my acne make it better or worse?

Squeezing or picking can damage the cells under your skin and cause the pimple to become inflamed or leave a permanent scar. As tempting as it is, you will be better off in the long run to leave pimples alone and let them heal on their own.

Can make-up camouflage my acne?

Camouflage make-up can be used to cover acne lesions. The best types of cosmetics to use for acne-prone skin are oil-free, non-acnegenic (may not cause acne) and non-comedogenic (may not cause blackheads or whiteheads).

Will Clarus make me feel depressed?

Major depression is a rare problem with children, but common among teens. In fact, up to one in every four people has suffered from depression by the end of adolescence.² Unfortunately, studies have shown that teens with acne have an even greater likelihood of being depressed.³

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. If you become depressed during or after isotretinoin therapy, it's important to tell your doctor immediately.

Consent Forms :

Why do I have to sign a consent form before taking Clarus?

The consent form is a policy requirement for taking Clarus. Signing the consent form, or having your parent or guardian sign it on your behalf, tells your doctor that you understand all the information you have received from your doctor about Clarus.

If you are male, you must read and sign Part I of the form. If you are female, you must read and sign Part I and Part II of the form.

Your doctor should explain all the information in the consent form to you, and you should also read it over carefully before you sign it. If there is anything you don't understand in the consent form, ask your doctor about it **before** you sign the form.

What should I do with my signed consent form?

Give one copy to your doctor to keep in your medical file and keep one copy for yourself.

Clarus[®]

Isotretinoin Capsules, USP

Bibliography and References

Accutane[™] Roche[®] Acne, Accutane[™] and You (Revision: 2016)

1. James WD. Clinical Practice: Acne. *N. Engl J Med.* 2005 Apr 7;352(14):1463-1472.
2. Kessler RC, Avenevoli S, Ries Merikangas K. Mood disorders in children and adolescents: an epidemiologic perspective. *Biol Psychiatry.* 2001 Jun 15;49(12):1002-14.
3. Gupta MA, Gupta AK. Depression and suicidal ideation in dermatology patients with acne, alopecia areata, atopic dermatitis and psoriasis. *Br J Dermatol.* 1998 Nov;139(5):846-50.

This patient information booklet does not contain all information about Clarus[®].
Talk to your doctor if you have questions.



**This patient information booklet does not contain all information about Clarus[®]. Talk to your doctor if you have questions.
CLARUS[®] and CLEAR[™] are registered trademarks of Mylan Pharmaceuticals ULC, a Viatriis company.
VIATRIS and VIATRIS & Design are trademarks of Mylan Inc., used under permission by Mylan Pharmaceuticals ULC, a Viatriis company.
©2022 Viatriis Inc. All rights reserved.**