

Clarus®

Isotretinoin Capsules

CLEAR™
Program

A Guide for Patients

CLEAR™ (Clinical Education and Awareness Resource)
Updated: January 31, 2017

 **Mylan**

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 Information for Consumer 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.

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 associated with 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 does acne develop?

You can have acne on any part of your skin where sebaceous glands are found. These are the glands that produce oil 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 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 acne) that cannot be cleared up by any other acne treatments, including antibiotics.

The active ingredient in Clarus is called isotretinoin, which is related to vitamin A. It belongs to a class of drugs called retinoids.

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 'Information for the Consumer' that comes with your prescription for Clarus, especially "What are the important warnings for females taking Clarus?" and "What special symptoms you must immediately tell your doctor about — Signs of mental health problems".

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 signing that you understand some of the serious risks of Clarus.

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

Note: You should read the Information for the Consumer 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.

The soft gelatin Clarus capsule is easy to swallow. 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 mealtime, you can take it with a later meal that day, but don't take more Clarus in one day than your doctor has prescribed. The reddish brown capsule is the 10 mg size and the orange brown capsule is the 40 mg size.

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 of children.

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 plan vigorous physical activity during treatment with Clarus,
- If you or a family member has bone loss (osteoporosis) or weak bones,
- If you have an eating problem called anorexia nervosa (where people eat too little),
- If you are sensitive to any of the other non-medicinal ingredients 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,
- If you are taking any vitamin preparations or health food supplements that contain Vitamin A,
- The brand of contraceptives you are taking. 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,
- If you are taking any medication, or herbal supplements like St. John's Wort, which might make birth control pills work less effectively,
- If you are taking an antibiotic (particularly tetracyclines), corticosteroids, phenytoin and products such as herbs.

Before you start taking Clarus, you should have a blood test to check your complete blood count, blood triglyceride and cholesterol 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 get pregnant while taking Clarus and for one month after treatment. (Isotretinoin can cause serious birth defects.)	<ul style="list-style-type: none">• 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 period before starting Clarus• 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 a pregnancy test performed in an approved laboratory every month you take Clarus and one month after treatment stops.
Do not breast feed while taking Clarus and for one month after treatment.	Isotretinoin 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.	<p>Signs of mental health problems include:</p> <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)

<p>If you become depressed or have any serious mental problems tell your doctor immediately. It may be necessary to stop Clarus treatment. <i>(Continued)</i></p>	<ul style="list-style-type: none"> • 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) • Acting on dangerous impulses • Seeing or hearing things that are not real <p>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.</p> <p>No one knows if isotretinoin caused these behaviours or if they would have happened even if the person did not take isotretinoin.</p>
<p>Do not give blood while taking Clarus and for one month after treatment.</p>	<p>If someone who is pregnant gets your donated blood, her baby may be exposed to Clarus and may be born with birth defects.</p>
<p>Do not take Vitamin A supplements.</p>	<p>Vitamin A in high doses has many of the same side effects as isotretinoin. Taking both together may increase your chance of getting side effects.</p>
<p>Do not take low-dose contraceptives, antibiotics, corticosteroids, phenytoin, or natural health products with Clarus unless you talk to your doctor.</p>	<p>If some other medicines are taken at the same time as Clarus, they can interact with each other or can cause negative effects in your body. Herbal supplements should be avoided while you are taking Clarus.</p>
<p>Do not use abrasive cleansers on your skin while taking Clarus.</p>	<p>Some skin products, like exfoliants, may be irritating to your skin while you are taking Clarus.</p>
<p>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.</p>	<p>Isotretinoin can increase the chance of scarring or skin inflammation from these procedures.</p> <p>Check with your doctor for advice about when you can have cosmetic procedures.</p>
<p>Avoid the use of artificial ultraviolet lights (such as the ones used in tanning machines) and protect yourself from excessive sunlight.</p>	<p>Isotretinoin may make your skin more sensitive to the ultraviolet light.</p>
<p>Do not share Clarus with anyone.</p>	<p>Clarus is a prescription product that can cause serious side effects. A doctor must prescribe it.</p>

Do not take antibiotics (especially tetracycline) with Clarus unless you talk to your doctor.	For some antibiotics, you may have to stop taking Clarus until your antibiotic treatment is finished. Using both drugs together can increase the chances of increased pressure in the brain. Some antibiotics interfere with the effectiveness of birth control pills.
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.
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 problems.
Do not take Clarus if you are sensitive to retinoids or any of the nonmedicinal ingredients in Clarus.	If you have an allergic reaction while taking Clarus, stop taking Clarus and contact your doctor.

When To See Your Doctor

You should visit your doctor monthly to check how you are doing. 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,
 - Experiencing changes in your regular 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,
- 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 – if a bone breaks, tell your doctor,
- Hives, swollen face or mouth, trouble breathing, fever, rash red patches, bruises
- Fainting, become very thirsty, urinating a lot, feeling weak,
- Leg swelling, seizures (convulsions), slurred speech, problems moving or any other serious unusual problems,
- Your acne becomes worse.

Protect yourself from the sun

Clarus may increase your sensitivity to the sun. Avoid long periods in the sun and any increase in your exposure time must be gradual to determine how much you can tolerate. 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. Don't be discouraged or stop taking Clarus without talking to your doctor first. Most side effects usually decrease over time. In fact, if you have dry skin, it means that your medication is doing what it's meant to do — reducing oil production.

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 taking the right amount of medication.

The first couple of weeks

During the first few weeks of treatment, your acne may seem to get worse before it gets better. This is only temporary. Redness and itching of the affected skin are common initial effects. Stay with your treatment because these effects should disappear as you continue to take Clarus. In fact, 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. Most patients with severe acne notice a marked improvement after one or two courses of treatment with Clarus.

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 (occurs in 96% of patients)	Apply a specially-formulated lip ointment to moisten and soften your lips.
Redness of the face (occurs in 55 % of patients)	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 nose (occurs in 51 % of patients)	Apply a nasal lubricant to avoid nosebleeds. Use a humidifier in your bedroom.
Dry, itchy skin (occurs in 30% of patients)	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.
Inflammation of eyelids (occurs in 19% of patients)	See your doctor. He/she may need to adjust your Clarus dosage.
Joint pain (occurs in 13% of patients)	Joint pain is usually related to exercise. Over-the-counter pain relief may help. Otherwise, see your doctor if the pain becomes troublesome.
Hair thinning (occurs in 13% of patients)	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 may be permanent.
Dry eyes (occurs in 11% of patients)	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

Warning — 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.

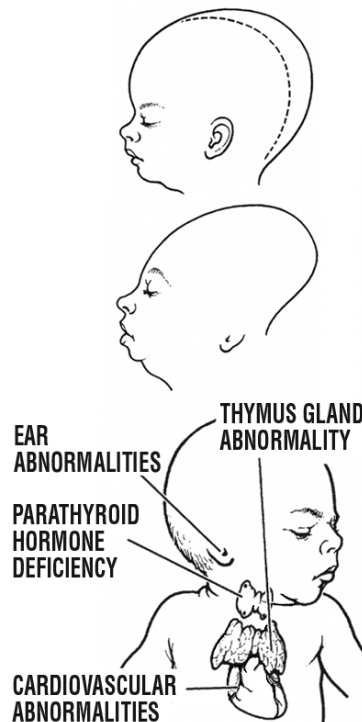
Clarus can cause deformed babies, loss of a baby before birth (miscarriage), death of the baby, and early (premature) births. There is an extremely high risk that your baby will be deformed if you are pregnant while taking Clarus. This risk exists even if Clarus is taken for a short time during pregnancy or if you become pregnant within one month after stopping Clarus. If you are a female of childbearing age, your physician should have discussed this 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 after 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 period before starting Clarus.	Do not take Clarus if you are, or may become pregnant during your Clarus treatment.
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.	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.
Do abstain from sexual intercourse or use two reliable methods of birth control together, even if you think you can't get pregnant (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 check the brand of birth control pills that you are taking or ask your doctor or pharmacist if you are not sure what type you are using.	Do not take low-dose, progestogen-only 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:

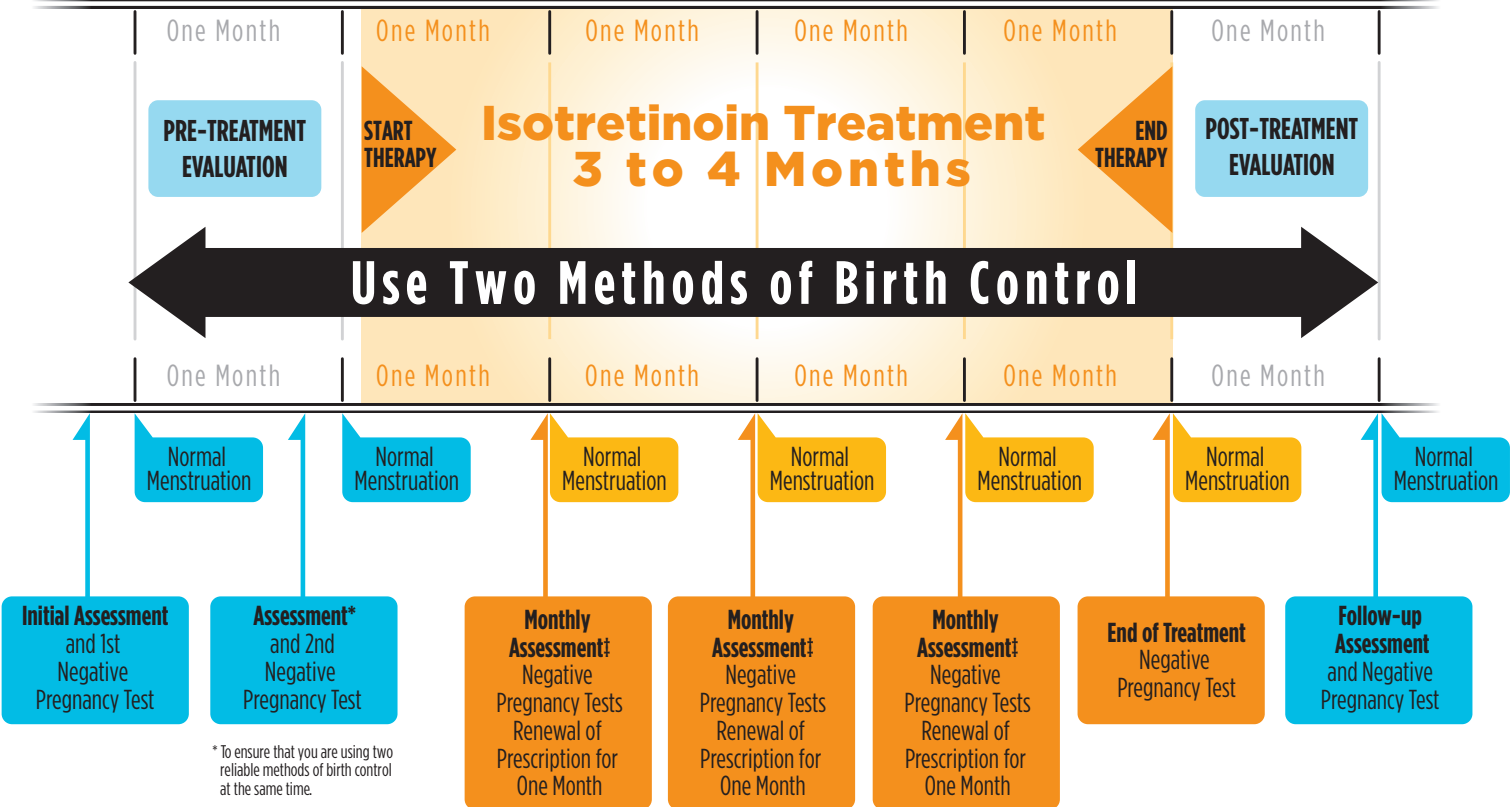
- You become pregnant while taking Clarus or during the first month after treatment has stopped,
- You missed your period,
- If your period is abnormal in length (shorter or longer than usual) and intensity,
- You have sex without using effective birth control.

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

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† 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?

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 mucus 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. Sometimes a woman may be tempted to have sex during her fertile period, and this method won't work if her partner isn'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 starting Clarus, all during Clarus therapy, and for one month after completing Clarus therapy.

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.

But if you do, 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.

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 Canadian Federation for Sexual Health 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, you can get pregnant if you use it 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 the woman is on top during sex?

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, such as Plan B or Contingency ONE, 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 Canadian Federation for Sexual Health 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.

Type of birth control	What is It?	How it works	Effectiveness	Consider this
Oral Contraceptives (The Pill)	Birth control pills taken daily.	Uses female hormones to prevent pregnancy.	>99% effective	<ul style="list-style-type: none"> Side effects may include irregular bleeding, headaches, vaginal irritation, discomfort or discharge, nausea, and breast tenderness Rare but serious health risks for women 35+ who smoke The progestogen-only mini-pill is not a suitable method of contraception during Clarus treatment
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	<ul style="list-style-type: none"> Side effects may include breast tenderness, headache, irregular bleeding and spotting, and skin reactions where the patch is applied
Vaginal Ring	A soft, flexible, clear plastic ring inserted into the vagina.	Uses female hormones to prevent pregnancy (similar to The Pill).	>98% effective	<ul style="list-style-type: none"> 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

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	<ul style="list-style-type: none"> Side effects may include increased cramps, spotting, depression, acne, headache, breast tenderness
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 Lasts for several years	<ul style="list-style-type: none"> Must be fitted by a doctor or a health worker since they come in different sizes
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	<ul style="list-style-type: none"> Must be used with spermicide, and must be kept in place for six hours after sexual intercourse
Contraceptive Sponge	A soft, round piece of foam, with low concentrations of spermicide.	Prevents sperm from entering the uterus. Spermicides kills sperm.	75-90% effective One sponge can be used for up to 12 hours of sexual intercourse Most effective when used with a condom	<ul style="list-style-type: none"> Don't use if allergic to spermicide
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.	Male condom is 86-97% effective Female condom is 79-85% effective Male condom is most effective when used with another contraceptive Both help prevent sexually transmitted diseases	<ul style="list-style-type: none"> Can break or slip off Male condom is recommended to be used with other contraceptives
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	<ul style="list-style-type: none"> Do not use spermicides alone

Adapted from the Society of Obstetricians and Gynaecologist of Canada, Clinical Practice Guidelines: Canadian Contraception Consensus, 2004.

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. The best thing to do is to gently wash your face twice a day with a mild soap and then pat dry. 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, like Clarus, can make your skin sensitive to the sun, leading to serious sunburns. When you're in the sun, it is always wise to use a sunscreen with an SPF of 15 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).

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 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. No one knows if isotretinoin caused these behaviours or if they would have happened even if the person did not take isotretinoin. 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.

Bibliography and References

Accutane[™] Roche[®] Acne, Accutane and You (Revision: 2006)

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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.

Notes



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