

# ABSORICA LD<sup>®</sup> (isotretinoin)

## ABSORICA LD Clinical Awareness Resource and Education C-A-R-E<sup>™</sup> Program

### An Educational Guide for Patients

**DISCLAIMER:** This material was developed by Sun Pharmaceutical, as part of the risk minimization plan for ABSORICA LD. This material is not intended for promotional use.



Pr **Absorica LD<sup>®</sup>**

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Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**

# Important Information About This Guide



Your doctor has talked to you about taking ABSORICA LD® (isotretinoin) capsules to help treat your acne. **Before your next appointment with your doctor:**

- Read the Patient Medication Information that comes with your prescription for ABSORICA LD.

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## Read this guidebook.

- You will learn how to take ABSORICA LD, its common side effects, and important safety information about ABSORICA LD.

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## 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 ABSORICA LD.
- Choose 2 effective forms of birth control that you will use.

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## Write down your questions.

- If you have any questions about taking ABSORICA LD, be sure to discuss them with your doctor at your next appointment.

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## Read and sign the Informed Consent Form included in the ABSORICA LD Clinical Awareness Resource and Education C-A-R-E™ Program Package.

- If you are 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** and **Part III** 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.

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## A copy of the signed Informed Consent Form is provided to both you and 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.

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# Common Questions About Acne

## What causes acne?

Your skin has thousands of oil glands that produce a substance called sebum, which helps moisturize your skin and acts as a protective barrier. Your pores carry the sebum within each oil gland to the skin's surface. The highest density of oil glands is found on your face—especially your nose, forehead, and mid-cheek areas. The largest oil glands are found on your back and the middle of your chest. This explains in part why acne appears mostly on the face, chest, and back.

The cause of acne is still unknown. Hormones play a role in blocked pores and increased oil production. Unfortunately, you may inherit acne-prone skin, particularly the type associated with the more severe, scarring forms of the condition.



## Who gets acne?

More than 85% of teenagers get acne, though anyone can get it—even adults.<sup>1</sup>

## Where does acne develop?

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

## What is severe acne?

Severe acne happens when many red, swollen, tender lumps form under the skin.

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# Common Questions About Acne (*continued*)

## 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 acne are cleansing your skin too much and squeezing, picking, or popping pimples. Excessive cleansing—particularly the overzealous use of abrasive facial scrubs—can irritate your skin and worsen inflammation.

## How is acne treated?

ABSORICA LD® (isotretinoin) is a medicine used to treat severe acne (severe nodular and/or inflammatory acne, acne conglobata, and recalcitrant acne) that cannot be cleared up by other treatments.



## Where can I get more information about acne?

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

 <https://www.acneaction.ca/>

 [www.ABSORICALD.ca](http://www.ABSORICALD.ca)

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# About ABSORICA LD<sup>®</sup> (isotretinoin)

ABSORICA LD is a medicine taken by mouth to treat the most severe forms of acne (called severe nodular and/or inflammatory acne, acne conglobata, and recalcitrant acne) that cannot be cleared up by other acne treatments.

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

Please be aware of significant warnings for people taking ABSORICA LD, such as the **high potential for birth defects and other health problems**. Read this booklet carefully, as well as the “Patient Medication Information” leaflet that comes with your ABSORICA LD prescription—particularly, “Serious Warnings and Precautions,” “Important Warnings for Females Taking ABSORICA LD,” and “What Are Possible Side Effects From Using ABSORICA LD?”

## About ABSORICA LD side effects

**ABSORICA LD can cause serious side effects.** Before starting ABSORICA LD, talk to your doctor about how severe your acne is, the possible benefits of ABSORICA LD, and its possible side effects to help you and your doctor decide if ABSORICA LD is right for you. Your doctor will ask you to read and sign a document called an Informed Consent Form. By signing the Informed Consent Form, you are showing that you understand the serious risks of ABSORICA LD.

For more information about side effects, please read the “Patient Medication Information” leaflet given to you with your ABSORICA LD prescription.

**ABSORICA LD and other isotretinoin-containing products are NOT substitutable.** ABSORICA LD and other isotretinoin-containing products can have similar strengths; however, these strengths have different bioavailability, and recommended dosages, and are not substitutable.

**Note:** You should read the “Patient Medication Information” leaflet every time you get a prescription or refill for ABSORICA LD because there may be new information.

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# About ABSORICA LD<sup>®</sup> (isotretinoin) *(continued)*

## How to take ABSORICA LD

You will probably take ABSORICA LD for at least 15 to 20 weeks. This is called a course of therapy. If you require a second course of therapy, it will start 2 months or more after you complete your first course of therapy.

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

ABSORICA LD is a hard gelatin capsule. Take the prescribed daily dose of ABSORICA LD as a single dose or in 2 divided doses during the day, with or without food. Take your ABSORICA LD capsules whole with a full glass of liquid. Do not chew or suck on the capsule. ABSORICA LD can hurt the tube that connects your mouth to your stomach (esophagus) if not swallowed whole.

## ABSORICA LD is available in the following strengths:



- |                                |                                |
|--------------------------------|--------------------------------|
| <input type="checkbox"/> 8 mg  | <input type="checkbox"/> 24 mg |
| <input type="checkbox"/> 16 mg | <input type="checkbox"/> 32 mg |

## How to store ABSORICA LD

Store ABSORICA LD at room temperature (15°C to 25°C) in the original package. Protect it from exposure to light.

Keep in a safe place out of the reach and sight of children.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# Talk to Your Doctor

## Before you take ABSORICA LD® (isotretinoin), tell your doctor if:

- You are pregnant, breastfeeding, or plan to become pregnant
- You or a family member has ever had any mental illness, including depression, mood disturbances, loss of contact with reality or aggression
- You or a family member has diabetes
- You are obese
- You regularly drink alcohol
- You have dry eyes
- You have any bone problems, including conditions called osteoporosis or osteomalacia
- You are taking medicines called corticosteroids used to treat various conditions
- You are taking anti-epileptic medicines used to treat seizures
- You have an eating disorder called anorexia that causes low body weight
- You play or plan to play high-impact sports or engage in vigorous exercise
- You plan to donate blood. You should not donate blood while you are taking ABSORICA LD and for 1 month after you stop taking it.
- You are taking supplements that contain vitamin A. You should not take these while you are taking ABSORICA LD.
- You are sensitive to retinoids or other ingredients in ABSORICA LD or the capsules:
  - Butylated hydroxyanisole, polysorbate-80, and soybean oil
  - Gelatin capsules contain titanium dioxide and the following dyes:
    - 8 mg—D&C Yellow #10, FD&C Blue #1, and FD&C Red #40;
    - 16 mg—FD&C Blue #1 and FD&C Red #40;
    - 24 mg—D&C Yellow #10 and FD&C Yellow #6;
    - 32 mg—black, red, and yellow iron oxide
  - The imprinting ink contains ammonia, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, shellac, and titanium dioxide

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# Talk to Your Doctor *(continued)*

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

## The following may interact with ABSORICA LD® (isotretinoin):

- Low-dose birth control pills. Low-dose birth control pills that contain progesterone only (mini pills) may not work while you are taking ABSORICA LD.
- Antibiotics (such as tetracyclines; e.g., minocycline, tetracycline) used to treat infections
- Corticosteroids (such as hydrocortisone, prednisone, etc.) used to treat inflammatory conditions.
- Phenytoin, used to treat seizures
- Vitamin supplements that contain vitamin A
- St. John's Wort, used to treat depression



## Tests and check-ups:

Stay under your doctor's care while you are taking ABSORICA LD. You must see your doctor regularly. For most patients this means seeing your doctor every month. For female patients, a pregnancy test is needed every month and at 1 month after stopping treatment.

Your doctor will perform the following tests before you start taking ABSORICA LD, after 1 month, and then as decided by your doctor:

- Check of blood fat levels, including triglyceride levels
- Check of liver function
- Check of kidney function
- Check of sugar levels in your blood

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# 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 ABSORICA LD® (isotretinoin). If you have any questions, please talk to your doctor. If you are a woman taking ABSORICA LD, please pay special attention to the **Pregnancy Prevention** section of this guide.

Facts for everyone taking ABSORICA LD	
Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects)	Have 2 negative pregnancy tests performed in a licensed laboratory. <ul style="list-style-type: none"><li>• The first pregnancy test should be done once you and your doctor have decided to use ABSORICA LD.</li><li>• The second pregnancy test should be done within 11 days before you start taking ABSORICA LD.</li></ul> Wait until the second or third day of your next period before starting ABSORICA LD. Start to use 2 methods of effective birth control together for at least 1 month before, during, and for 1 month after you stop taking ABSORICA LD, or don't have sex during this time. Have a pregnancy test performed in a licensed laboratory <b>every month</b> you take ABSORICA LD and <b>1 month after you stop treatment</b> .
Do not breast-feed while taking ABSORICA LD and for 1 month after treatment.	ABSORICA LD may pass through your milk and harm your baby.
If you become depressed or have any serious mental health problems, tell your doctor immediately. It may be necessary to stop taking ABSORICA LD.	Some patients treated with isotretinoin have become depressed. Some have attempted suicide or have committed suicide. Before you take ABSORICA LD, your doctor will assess you for mental health problems including depression. Tell your doctor if you are depressed, have ever been depressed, or if a family member is depressed. Stop taking ABSORICA LD and get immediate medical help if you have symptoms of depression. Signs of mental health problems include: <ul style="list-style-type: none"><li>• Changes in your mood, such as becoming depressed, feeling sad, or having crying spells</li><li>• Losing interest in your usual activities</li><li>• Changes in your normal sleep patterns</li><li>• Becoming more irritable or aggressive than usual (for example, temper outbursts, thoughts of violence)</li><li>• Losing your appetite, becoming unusually tired</li><li>• Having trouble concentrating</li><li>• Withdrawing from family and friends</li><li>• Having thoughts about taking your own life (suicidal thoughts)</li></ul>
Do not give blood or blood products while taking ABSORICA LD and for 1 month after treatment.	If someone who is pregnant gets your donated blood or blood product, her baby may be exposed to ABSORICA LD and may be born with birth defects.
Do not take vitamin A supplements.	Vitamin A in high doses has many of the same side effects as ABSORICA LD. Taking both together may increase your chance of having side effects.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# What You Need to Know *(continued)*

## Facts for everyone taking ABSORICA LD (isotretinoin) *(continued)*

Do not take low-dose contraceptives, antibiotics, corticosteroids, phenytoin, vitamin supplements including vitamin A, or St John's wort while taking ABSORICA LD unless you talk to your doctor.	If some other medicines are taken at the same time as ABSORICA LD, they can interact with each other or can cause negative effects in your body.
Do not use products for acne that exfoliate your skin while taking ABSORICA LD.	Some skin products, like exfoliates, may be irritating to your skin while you are taking ABSORICA LD.
Do not have cosmetic procedures to smooth your skin, such as waxing, dermabrasion, or laser procedures, while taking ABSORICA LD and for a period of 5 to 6 months after you stop.	ABSORICA LD 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 (UV) lights such as the ones used in tanning machines and protect yourself from excessive sunlight.	ABSORICA LD may make your skin more sensitive to UV light or sunlight. When necessary, use sunscreen with a high protection factor of at least SPF 15. Avoid long periods in the sun, and any increase in your exposure 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 and won't cause blackheads (non-comedogenic) or acne (non-acnegenic).
Do not share ABSORICA LD with anyone.	ABSORICA LD is a prescription product that can cause serious side effects. A doctor must prescribe it.
Do not take antibiotics (especially tetracyclines) with ABSORICA LD unless you talk to your doctor.	For some antibiotics, you may have to stop taking ABSORICA LD until the antibiotic treatment is finished. Use of both drugs together can increase the chances of increased pressure in the brain. Certain antibiotics can interact with ABSORICA LD.
See your doctor regularly.	ABSORICA LD may affect blood fat, cholesterol, sugar levels, liver function, or kidney function, which are monitored as a part of routine testing, so it's important to see your doctor regularly.
Tell all healthcare professionals (for example, your family doctor, dentist, cosmetic surgeon) that you are taking ABSORICA LD.	Isotretinoin can interfere with other prescriptions and treatments.
Do not take ABSORICA LD if you have liver or kidney disease, if you have hypervitaminosis A, or if you have high blood fat (lipid) levels.	Tell your doctor if you have any of these health problems.
Do not take ABSORICA LD if you are sensitive to retinoids, soybean oil, or any other non-medicinal ingredients in ABSORICA LD.	If you have an allergic reaction while taking ABSORICA LD, stop taking the drug and contact your doctor.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# When to See Your Doctor

You must stay under your doctor's care while you are taking ABSORICA LD® (isotretinoin). You should visit your doctor monthly to check how you are doing and for blood monitoring. ABSORICA LD may affect blood fat, cholesterol, sugar levels, liver function, or kidney function, which are monitored as a part of routine testing. Therefore, it is important to see your doctor at your regularly scheduled appointments.

Contact your doctor immediately if you get pregnant during treatment or within 1 month after stopping treatment with ABSORICA LD, if you develop any of the following symptoms or serious side effects while taking ABSORICA LD, or if your acne becomes worse.

Effect	Signs and symptoms	Stop taking the drug and tell your doctor immediately
<b>Mental health problems</b> such as depression or psychosis (a severe mental disturbance)	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; having trouble concentrating; withdrawing from family and friends; having thoughts about taking your own life (suicidal thoughts)	✓
<b>Liver problems</b>	Nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light-coloured bowel motions, dark-coloured urine	✓
<b>Pancreatitis</b> (Inflammation of the pancreas)	Severe upper stomach pain, often with nausea and vomiting	✓
<b>Intestine (bowel) problems</b>	Fever, abdominal pain, diarrhea often with blood and mucus, weight loss, or rectal bleeding	✓
<b>Bone and muscle problems</b>	Aches or pains in bones or joints, back pain, or difficulty in moving, muscle pain, especially after vigorous exercise; dark-coloured urine that is brown, red, or tea-coloured; muscle weakness with or without pain can be a sign of serious muscle damage; breaking of a bone	✓
<b>Allergic reactions</b>	Hives, swollen face or mouth, trouble breathing, fever, rash, red patches, bruises. In some patients, rashes can be serious. These include conjunctivitis (red or inflamed eyes, like "pink eye"); a rash with fever; blisters on legs, arms, or face; and/or sores in your mouth, throat, nose, or eyes; or if your skin begins to peel	✓
<b>Benign intracranial hypertension</b> (increased pressure in the brain)	Headaches, blurred vision, dizziness, nausea, vomiting, seizures (convulsions), and stroke. Symptoms of stroke include sudden numbness or weakness of your arm, leg, or face; and trouble walking, or loss of balance.	✓

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# When to See Your Doctor *(continued)*

Effect	Signs and symptoms	Stop taking the drug and tell your doctor immediately
<b>Hearing and vision problems</b>	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 feeling of dry eyes. In addition, some loss may occur in the sharpness of your vision (acuity).	✓
<b>Heart problems</b>	Chest pain, palpitations, stroke, leg swelling, seizures (convulsions), slurred speech, problems moving, or any other serious unusual problems; vascular thrombotic disease (formation of a blood clot within the blood vessels that can occur both within the arteries and veins): pain in one leg (usually the calf or inner thigh), swelling in the leg or arm, chest pain, numbness or weakness on one side of the body, sudden change in your mental state	✓
<b>Pregnancy issues during or after treatment</b>	Birth defects, miscarriage, premature birth, or death of baby	✓
<b>Problems with blood sugar levels</b>	Fainting, becoming very thirsty, urinating a lot, feeling weak	✓
<b>Serious skin reactions such as erythema multiforme (EM), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN)</b>	Severe red/purple rash; fever or not feeling well; red or inflamed eyes; facial and tongue swelling; blisters; peeling skin; multiple lesions and sores, especially in your mouth, nose, eyes, and genitals	✓

## Protect yourself from the sun

ABSORICA LD<sup>®</sup> may increase how sensitive your skin is to sun exposure. Avoid exposure to intense sunlight or to UV rays. When necessary, a sun-protection product with a high protection factor of a least SPF 15 should be used.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# What You Can Expect

## How you'll feel

You will likely have some side effects during your treatment with ABSORICA LD® (isotretinoin). Don't be discouraged or stop taking ABSORICA LD without talking to your doctor first.

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 ABSORICA LD, the easier it is to determine whether you are taking the right amount of medication.

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## The first couple of weeks

During the first few weeks of treatment, your acne may get worse. Redness and itching are common initial side effects. It may take 1 to 2 months before you see improvement.

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## 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 sooner if the side effect becomes too uncomfortable.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# What You Can Expect (*continued*)

What you can expect	What you can do
Chapped lips	Apply a lip ointment to moisten and soften your lips.
Facial rash	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	Apply a nasal lubricant to avoid nosebleeds. Use a humidifier in your bedroom.
Dry, itchy 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.
Joint pain	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	Tell your doctor if you experience hair thinning as he or she may need to change your dosage. In a very small number of cases, hair thinning may be permanent.
Dry eyes	Use an artificial tears product. If you wear contact lenses, choose a product that is compatible with your contacts.

Please note that this is not a complete list of possible side effects from treatment with ABSORICA LD<sup>®</sup> (isotretinoin). Talk to your doctor or pharmacist for additional information on possible side effects from ABSORICA LD.

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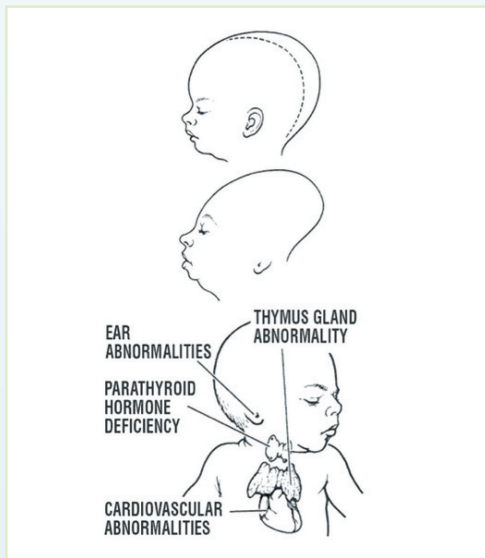
# Before You Take ABSORICA LD<sup>®</sup> (isotretinoin)

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

ABSORICA LD 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 ABSORICA LD.** This risk exists even if ABSORICA LD is taken for a short time, or you become pregnant within 1 month after stopping ABSORICA LD. If you are a female of childbearing age, your doctor should have discussed this risk with you and explained how to avoid becoming pregnant while taking ABSORICA LD.

ABSORICA LD may be released into semen. Male patients should use a condom or avoid sex to prevent passing ABSORICA LD to a female partner.

**Some birth defects commonly associated with taking ABSORICA LD during pregnancy are<sup>2</sup>:**



- 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 not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# Dos and Don'ts of Taking ABSORICA LD<sup>®</sup> (isotretinoin)

DO	DON'T
Do discuss effective methods of birth control with your doctor before beginning ABSORICA LD therapy.	Do not become pregnant for 1 month before, during, or for 1 month after you stop taking ABSORICA LD.
Do have 2 blood or urine pregnancy tests in a licensed laboratory before starting ABSORICA LD therapy. The first pregnancy test should be done after you and your doctor have decided to use ABSORICA LD. The second pregnancy test should be done within 11 days before starting ABSORICA LD. Wait until the second or third day of your next period before starting ABSORICA LD.	Do not take ABSORICA LD if you are pregnant or may become pregnant during ABSORICA LD treatment.
Do use 2 reliable methods of birth control at the same time for at least 1 month before you start ABSORICA LD, while you are taking ABSORICA LD, and for at least 1 month after you stop taking ABSORICA LD. At least 1 must be a primary method of birth control.	Do not take ABSORICA LD 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 ABSORICA LD following a negative pregnancy test.	Do not start taking ABSORICA LD if you have not had 2 negative pregnancy tests.
Do have a monthly pregnancy test while taking ABSORICA LD and 1 month after stopping ABSORICA LD.	Do not take ABSORICA LD if you cannot avoid pregnancy.
Do abstain from sexual intercourse or use 2 reliable methods of birth control together, even if you think you can't get pregnant or are not sexually active (unless you have had a hysterectomy).	Do not have sex if you are not using 2 reliable methods of birth control at the same time for at least 1 month before you start ABSORICA LD, while you are taking ABSORICA LD, and for 1 month after you stop taking ABSORICA LD.
Do remember that any method of birth control can fail.	Do not take ABSORICA LD if you are breastfeeding.
Do check the brand of birth control pills you are taking or ask your doctor or pharmacist, if you are not sure what type you are taking.	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 ABSORICA LD.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# Pregnancy Prevention

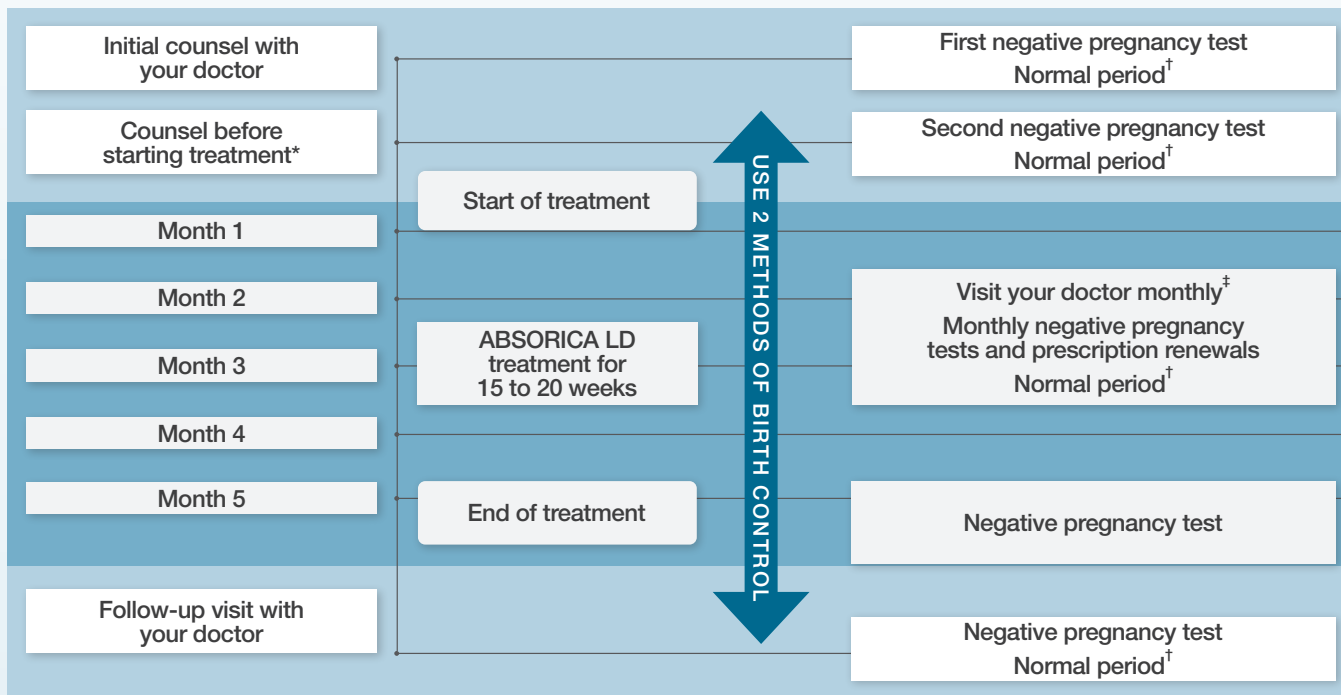
## Stop taking ABSORICA LD® (isotretinoin) and contact your doctor immediately if:

- You become pregnant while taking ABSORICA LD or during the first month after you've stopped your treatment with ABSORICA LD
- You missed your period
- You have sex without using effective birth control

## Safety information about ABSORICA LD and pregnancy

Important information about ABSORICA LD and pregnancy, and confidential counselling is available: **1-833-388-0532**.

### ABSORICA LD C-A-R-E™ Program Flowchart



\*To ensure that you are using 2 reliable methods of birth control at the same time.

<sup>†</sup>If you miss your period, call your doctor immediately.

<sup>‡</sup>To ensure that you are using 2 reliable methods of birth control at the same time and to detect any side effects that you may have from treatment.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

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# Frequently Asked Questions About Birth Control

## What is effective birth control?

Effective birth control means using a reliable combination of at least 2 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 birth control (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 tracking her periods on a calendar. You should not rely on this method because teens' cycles are still unpredictable.

Also 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 ABSORICA LD® (isotretinoin).

## When should I start/stop using birth control?

To prevent pregnancy during your treatment with ABSORICA LD, you must use effective birth control for at least 1 month before starting ABSORICA LD, throughout your treatment with ABSORICA LD, and for 1 month after you stop taking ABSORICA LD.

## What is considered unprotected sex?

In the case of ABSORICA LD, unprotected sex means not using 2 forms of effective birth control every time you have sex, beginning 1 month before starting ABSORICA LD, while taking ABSORICA LD, and for 1 month after stopping ABSORICA LD.

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 2 days or more before having sex.
- You had intercourse unexpectedly without using 2 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.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**

# Frequently Asked Questions About Birth Control *(continued)*

## **Can I get pregnant if I just do it once?**

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

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## **Will I get pregnant if I douche after sex?**

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

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## **Can I get pregnant if I use birth control?**

Yes. No matter what form of birth control you use, you can get pregnant if you use it incorrectly. Always use 2 reliable forms of birth control together while you are taking ABSORICA LD® (isotretinoin) and for 1 month after you stop taking ABSORICA LD. The kind of birth control is also important. Low-dose birth control may not work while you are taking ABSORICA LD. Ask your doctor or pharmacist if you are not sure what type of birth control you are using.

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

No. Each woman's menstrual cycle is different, so 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.

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## **Can I get pregnant if I have sex standing up or if the woman is 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 regardless of the position.

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## **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 2 methods of effective birth control, do not take ABSORICA LD.

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Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**

# What You Should Know About Emergency Contraception

If you have sex without using effective birth control while still taking ABSORICA LD® (isotretinoin), stop taking ABSORICA LD immediately and call your doctor. Also call your doctor if you have sex without using birth control during the month after you stop taking ABSORICA LD. Emergency contraception, such as Plan B® (levonorgestrel) or Contingency ONE (levonorgestrel), 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 or Contingency ONE directly from your pharmacist or get a prescription from your doctor.

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**For information about getting emergency contraception in your area, call your doctor or pharmacist or the toll-free birth control counselling hotline at 1-833-388-0532.**

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**

# Using Birth Control<sup>3</sup>

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 pill taken daily	Uses female hormones to prevent pregnancy.	Typical use: 91% effective	May increase the risk of blood clots, particularly in those who have certain blood disorders or a family history of blood clots; may cause breast tenderness, nausea, or headaches; may cause irregular bleeding or spotting.  The progestogen-only mini-pill or low-dose birth control is not a suitable method of contraception during treatment with ABSORICA LD® (isotretinoin).
Contraceptive patch	A 4 by 4 cm adhesive patch that sticks to a woman's skin, replaced weekly	Uses female hormones to prevent pregnancy (similar to the pill).	Typical use: 91% effective	May cause breast tenderness, nausea, or headaches; may cause irregular bleeding or spotting; may cause skin irritation.
Vaginal ring	A soft, flexible, plastic ring inserted into the vagina, replaced monthly	Uses female hormones to prevent pregnancy by stopping ovaries from releasing an egg (similar to the pill).	Typical use: 91% effective	May cause breast tenderness, nausea, or headaches; may cause irregular bleeding or spotting; may cause vaginal irritation, discomfort, or discharge.
Birth-control shot	An injection given in the upper arm or buttocks every 3 months. Contains only one hormone (progesterin)	The hormone stops ovaries from releasing an egg and thickens cervical mucus so sperm cannot pass through it.	Typical use: 94% effective  Perfect use: 99.8% effective	May cause temporary decrease in bone mineral density, increased bleeding during periods, or spotting between periods. May cause acne, headaches, breast sensitivity, or mood issues.

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**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**

# Using Birth Control<sup>3</sup> (continued)

Type of birth control	What is it?	How it works	Effectiveness	Consider this
Non-hormonal intrauterine contraceptive (Cu-IUC)	A small, copper-containing T-shaped device inserted into the uterus	The Cu-IUC acts as a foreign body, creating a hostile environment that prevents pregnancy.	99.2% effective. Provides 3 to 10 years of contraception.	May cause bleeding or spotting initially. There may be pain or discomfort during insertion. Insertion could result in infection or perforation of the uterus.
Hormonal intrauterine contraceptive (LNG-IUC)	A small, progestin-containing T-shaped device inserted into the uterus	The hormone thins the lining of the uterus and thickens the mucus on the cervix, making it harder for the sperm to reach an egg.	99.8% effective. Provides 3 to 10 years of contraception.	May cause bleeding or spotting initially. There may be pain or discomfort during insertion. Insertion could result in infection or perforation of the uterus.
Contraceptive implant	Below-skin implant placed in the upper arm	Releases progestin into the bloodstream to prevent ovaries from releasing an egg and thickens cervical mucus, making it harder for the sperm to reach an egg.	99.95% effective. Provides up to 3 years of protection.	Possible initial irregular bleeding. Side effects may include acne, headaches, breast sensitivity, mood issues.
Diaphragm	A cap made from latex or silicone and nylon that covers the cervix	Prevents sperm from entering the uterus. Should always be used with a spermicidal gel to immobilize or kill sperm.	Data lacking on the gel currently available. Previous studies show a higher failure rate than other contraception types.	Increased risk of urinary tract infections and toxic shock syndrome; users may have difficulty with correct insertion of the device. Should be used with spermicide.
Cervical cap	A deep silicone cap that fits inside the vagina against the cervix	Prevents sperm from entering the uterus. Should always be used with gel to immobilize or kill sperm.	No current data on the cap and gel available in Canada. Preliminary studies show a higher failure rate than other contraception types.	Must be kept in place for 6 hours after sexual intercourse but no longer than 48 hours; increased risk of urinary tract infections and toxic shock syndrome.

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**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**

# Using Birth Control<sup>3</sup> (continued)

Type of birth control	What is it?	How it works	Effectiveness	Consider this
Contraceptive sponge	A soft, round piece of foam that fits over the cervix and contains spermicide.	Prevents sperm from getting into the cervix. Spermicides kill sperm.	76% to 88% effective. Most effective when used with a condom.	Some users may have difficulty using it correctly.
Male condom	Latex, polyurethane, or polyisoprene sheath that rolls down over the penis.	A barrier contraception method, trapping sperm to keep it from fertilizing an egg.	82% effective with typical use; 98% when used perfectly. Male condom is most effective when used with another contraceptive. May help prevent sexually transmitted diseases.	Can break or slip off during intercourse. Must be stored and handled properly. Latex condoms not usable by those with latex allergies or sensitivity.
Female condom	Nitrile polymer sheath with a flexible ring at each end, inserted into the vagina.	A barrier contraception method, preventing contact between sperm and the vagina.	79% effective in typical use; 95% if used perfectly	Potential slippage or breakage issues. Rings may cause discomfort during sex.
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.	Inserted in the vagina to kill sperm.	72 to 82% effective	Must be used with a primary method of contraception; cannot be used alone.
Sterilization	Surgical procedures to prevent sperm from joining with egg. Called tubal ligation or salpingectomy in women and vasectomy in men.	In tubal ligation or salpingectomy, the egg cannot get to the uterus to be fertilized by the sperm. In vasectomy, the tubes that carry sperm are blocked, preventing egg fertilization.	Tubal ligation or salpingectomy: Highly effective; failure rates vary by type. Vasectomy: 98% effective	Permanent and irreversible. Possible short-term complications include pain, bleeding, infection at incision site.

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**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**



# Questions and Answers

## **Is acne contagious?**

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

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## **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.

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## **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. Cleaning 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 mild soap and then pat dry. Ask your doctor for the best type of cleansers to use on your skin.

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## **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 additional outbreaks of acne. For some people, the sun can make their acne worse and some acne medications, like ABSORICA LD® (isotretinoin), 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.

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# Questions and Answers *(continued)*

## **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 be inflamed or leave a permanent scar. As tempting as it is, you will be better off in the long run to leave it alone and let your skin heal on its own.

## **Can makeup camouflage my acne?**

Camouflage makeup 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 ABSORICA LD® (isotretinoin) make me feel depressed?**

Major depression is a rare problem in children but common among teens. In fact, up to 25% of teens have suffered from depression by the end of adolescence.<sup>4</sup> Unfortunately, studies have shown that teens with acne have an even greater likelihood of being depressed.<sup>5</sup>

Some patients treated with isotretinoin have become depressed. Some have attempted suicide or have committed suicide. Before you take ABSORICA LD, your doctor will assess you for mental health problems including depression. Tell your doctor if you are depressed, have ever been depressed, or if a family member is depressed. Stop taking ABSORICA LD and get immediate medical help if you have symptoms of depression. These include feeling sad, having crying spells, losing interest in your usual activities, changes in sleep patterns, losing your appetite or becoming unusually tired, having trouble concentrating, withdrawing from family and friends, having thoughts about taking your life (suicidal thoughts).

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

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# Consent Form

## Why do I have to sign a consent form before taking ABSORICA LD® (isotretinoin)?

The consent form is a policy requirement for taking ABSORICA LD. 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 ABSORICA LD.

If you are 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** and **Part III** 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.

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## 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.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**

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ABSORICA LD<sup>®</sup> (isotretinoin) Product Monograph. Sun Pharmaceutical Industries Limited; 22 June 2023.

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This patient information booklet does not contain all the information about ABSORICA LD. Talk to your doctor if you have questions about ABSORICA LD.

Do not get pregnant while taking ABSORICA LD and for 1 month after treatment (isotretinoin can cause serious birth defects).

**For confidential birth control information, call Sun Pharma at 1-833-388-0532.**

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