ABSORICA LD® (isotretinoin) Clinical Awareness Resource and Education C-A-R-E™ Program: Patient Informed Consent Form

Each patient of legal age, or parent or guardian of a patient under the legal age in his/her province of residence must read each item below, initial in the space provided, and sign this agreement ONLY if you have received ALL the information below from your doctor about ABSORICA LD and fully understand it all.

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.

PART I: FOR ALL PATIENTS (MALE AND FEMALE)	INITIAL _____
1	I understand that ABSORICA LD is a medicine used to treat severe acne (nodular and/or inflammatory, acne conglobata, and recalcitrant acne) that cannot be cleared up by other acne treatments, including systemic antibiotics. My doctor has told me about my choices for treating my acne.
2	I understand that there are serious side effects that may happen while I am taking ABSORICA LD. These have been explained in detail to me. These side effects include severe birth defects in a very high percentage of babies of pregnant females if isotretinoin is taken during pregnancy by the mother. I understand that the extent to which isotretinoin may be found in semen is not known; however, it is recommended that male patients being treated with ABSORICA LD use a condom or avoid reproductive sexual activity to avoid possible transmission to a female partner. **(Note: Female patients must complete PART II of this form; male patients must complete PART III of this form.)**
3	I understand that some patients, while taking isotretinoin or after stopping isotretinoin, have become depressed or experienced other serious mental health problems. Signs of these problems 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 own life (suicidal thoughts). I must tell my doctor immediately if I have or start having such feelings or thoughts.
4	Before I start taking ABSORICA LD, I agree to tell my doctor if I, or any member of my family, have ever had any mental illness including symptoms of depression **(see #5 below)**, mood disturbances, loss of contact with reality, aggression, attempted suicide, or take medicine for any of these problems.
5	Once I start taking ABSORICA LD, I agree to stop using ABSORICA LD and tell my doctor right away if I experience any of the following: • Mental health problems such as depression or psychosis: depression-related issues including deep sadness, crying spells, loss of interest in activities I once enjoyed, too much sleep or trouble sleeping; an increase in irritable, angry, or aggressive feelings (for example, temper outbursts, thoughts of violence); a change in appetite or body weight; trouble concentrating; withdrawal from friends or family; a feeling of no energy, or feelings of worthlessness or inappropriate guilt, and/or thoughts about hurting myself or taking my own life (suicidal thoughts) • Liver problems: nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching; yellowing of the skin and eyes; light-coloured bowel motions; dark-coloured urine • Pancreatitis: severe upper stomach pain, with nausea or vomiting • Intestinal (bowel) problems: fever, abdominal pain, diarrhea with blood and mucus, loss of weight, rectal bleeding • Bone and muscle problems: bone, joint, back, or difficulty moving; muscle pain or weakness especially after vigorous exercise; dark-coloured urine that is brown, red, or tea-coloured; or if I break a bone • Allergic reactions: hives, swollen face or mouth, trouble breathing, fever, rash (including rash with fever); red or inflamed eyes like "pink eye"; red patches; bruises; blisters on legs, arms, or face; and/or sores in your mouth, throat, nose, or eyes; or peeling skin • Benign intracranial hypertension: headaches, blurred vision, dizziness, nausea, vomiting, seizures (convulsions) • Hearing and vision problems: changes in hearing and/or vision • Heart problems: chest pain, heart palpitation, swelling in the leg or arm, seizures, slurred speech, problems moving, or any other serious unusual problems – Vascular thrombotic disease (formulation 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 mental state • Heart problems: sudden numbness or weakness of your arm, leg, or face; trouble walking or loss of balance (symptoms of stroke) • Pregnancy issues • Problems with blood sugar levels: fainting, become very thirsty, urinating a lot, feeling weak • Serious skin reactions: 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 the mouth, nose, eyes, and genitals)
6	I agree to return to see my doctor as scheduled (every month) to get a new prescription for ABSORICA LD and to monitor my body's response to ABSORICA LD.
7	ABSORICA LD will be prescribed just for me. I will not share ABSORICA LD with other people because it may cause severe side effects, including birth defects.
8	I will not give blood or blood products while taking ABSORICA LD or for 1 month after I stop taking ABSORICA LD.
9	I have read and understood the materials my doctor has given to me, including the **ABSORICA LD Clinical Awareness Resource and Education C-A-R-E Program: An Educational Guide for Patients.**

PART II: FOR FEMALE PATIENTS ONLY	INITIAL _____
1	I understand that there is a very high risk that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking ABSORICA LD in any amount, even for a short period of time.
2	I understand that I must not take ABSORICA LD if I am pregnant or become pregnant during treatment, or for up to 1 month after treatment. I am not pregnant now and do not plan to become pregnant during treatment with ABSORICA LD or up to 1 month after stopping ABSORICA LD.
3	I understand that I must avoid sexual intercourse completely, or I must use 2 separate, effective methods of birth control (contraception) at the same time, even if I think I cannot become pregnant or am not sexually active. I understand that at least one of my 2 methods of birth control must be a primary form. The only exception is if I have undergone a hysterectomy, bilateral oophorectomy, or have been medically confirmed to be postmenopausal.
4	I understand that the following are considered effective forms of birth control: • **Primary:** Tubal ligation (tying my tubes), partner's vasectomy, intrauterine devices, birth control pills, topical/injectable/implantable/insertable hormonal birth control • **Secondary:** Diaphragms, latex condoms, and cervical caps. Each must be used with spermicide, which is a special cream or jelly that kills sperm
5	I understand that any birth control method may fail and that no birth control method is absolutely safe. Therefore, I must use 2 different methods at the same time, every time I have sexual intercourse, even if one of the methods I choose is birth control pills or topical/injectable/implantable/insertable hormonal birth control.
6	I will talk with my doctor about any drugs or herbal products I plan to take during my isotretinoin treatment, because some hormonal birth control methods (for example, birth control pills) may not work if I am taking certain drugs or herbal products (for example, St. John's Wort).
7	I understand that I must begin using the birth control methods I have chosen as described above at least 1 month before I start taking ABSORICA LD.
8	I understand that I should not start taking ABSORICA LD unless I have had 2 negative pregnancy test results from a licensed laboratory. The first pregnancy test should be done when my doctor decides to prescribe ABSORICA LD. The second pregnancy test should be done within 11 days of starting to take ABSORICA LD. Treatment with ABSORICA LD should start after I've had 2 or 3 days of my next menstrual period or as instructed by my doctor. I will have one pregnancy test every month while taking ABSORICA LD.
9	I have read and understand the materials my doctor has given to me, including the **ABSORICA LD Clinical Awareness Resource and Education C-A-R-E Program: An Educational Guide for Patients.** I understand that there is a confidential counselling line that I may call for more information about birth control. I have received information on emergency contraception (birth control).
10	I understand that I must stop taking ABSORICA LD right away and inform my doctor if I get pregnant while taking ABSORICA LD, if I get pregnant during or within a month of stopping treatment, miss my menstrual period, or stop using birth control or have sexual intercourse without using my 2 methods of birth control at any time while taking ABSORICA LD.

PART III: FOR MALE PATIENTS ONLY	INITIAL _____
1	ABSORICA LD may be released into semen. I understand that I must avoid sexual intercourse or use a condom to avoid possible transmission to my female partner.
2	I understand that I cannot share my medication with anyone, particularly not with females.

(Please print)

Patient Name: _____ **Patient Address:** _____

Telephone: _____ **Patient, Parent, or Guardian Signature:** _____ **Date:** _____

FOR PHYSICIAN USE ONLY

I have:

- Fully explained to the patient the nature and purpose of ABSORICA LD treatment
- Fully outlined and explained its benefits with emphasis on the important risks involved
- Given the patient the appropriate educational materials, **ABSORICA LD Clinical Awareness Resource and Education C-A-R-E Program: An Educational Guide for Patients**, went through the materials with the patient and asked the patient if he/she has any questions regarding his/her treatment with ABSORICA LD
- Answered those questions to the best of my ability

Doctor Signature: _____ **Date:** _____

DOCTOR'S COPY (white) PATIENT'S COPY (yellow)