Please visit www.clarusclearprogram.ca to complete an online survey regarding the Clarus® CLEAR™ Program.

Clarus®
Isotretinoin Capsules, USP

PATIENT INFORMATION / CONSENT / AGREEMENT

VIATRIS®

Each patient, parent or guardian of a patient under age 18 (subject to provincial legislation) must read each item below, initial in the space provided and sign this agreement ONLY if you understand & have received ALL the information from your physician about CLARUS®.

PART I: FOR ALL PATIENTS (MALE AND FEMALE)

		Initial
1.	I understand that CLARUS® is a medicine used to treat severe acne that cannot be cleared up by any other acne treatments, including antibiotics. My physician has told me about my choices for treating my acne.	1
2.	I understand that serious side effects may happen while I am taking CLARUS®. These have been explained to me. These side effects include severe birth defects in babies of pregnant females if CLARUS® is taken during pregnancy. (Note: Female patients must complete PART II of this form.)	2
3.	I understand that some patients, while taking isotretinoin or after stopping isotretinoin, have become depressed or developed other serious mental health problems. Signs of these problems include feelings of sadness, irritability, unusual tiredness, trouble concentrating, and loss of appetite. Some patients taking isotretinoin have had thoughts about ending their own lives (suicidal thoughts), tried to end their own lives, and some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on isotretinoin becoming aggressive or violent. **I must tell my physician immediately if I have such feelings or thoughts.**	3
4.	Before I start taking CLARUS®, I agree to tell my prescriber if I, or any member of my family, have ever had symptoms of depression (see #5 below), been psychotic, attempted suicide, had any other mental problems, or take medicine for any of these problems.	4
5.	Once I start taking CLARUS®, I agree to stop using CLARUS® and tell my prescriber right away if any of the following happen. I: • Have changes in my mood such as becoming depressed, feeling sad, or having crying spells • Have trouble concentrating • Lose interest in my usual activities • Withdraw from family and friends • Have changes in my normal sleep patterns • Become more irritable or aggressive than usual (for example, temper outbursts, thoughts of violence) • Lose my appetite, become unusually tired • Have thoughts about taking my own life (suicidal thoughts)	5
6.	I agree to return to see my prescriber as scheduled (every month) to get a new prescription for CLARUS® and monitor my body's response to CLARUS®.	6
7.	CLARUS® will be prescribed just for me – I will not share CLARUS® with other people because it may cause serious side effects, including birth defects.	7
8.	I will not give blood while taking CLARUS® or for 1 month after I stop taking CLARUS®.	8
9.	I have read and understand the materials my prescriber has given to me, including the CLARUS® CLEAR™ program: A Guide For Patients.	9

PART II: ONLY FOR FEMALE PATIENTS

		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 isotretinoin capsules in any amount even for short periods of time.	1
2.	I understand that I must not take CLARUS® if I am pregnant or may become pregnant during treatment, or up to one month after treatment. I am not pregnant now and do not plan to become pregnant during treatment with CLARUS® , or up to one month after stopping CLARUS® .	2
3.	I understand that I must avoid sexual intercourse completely, or I must use 2 separate, effective forms of birth control (contraception) at the same time even if I think I cannot become pregnant. At least one of these forms must be a primary form. The only exception is if I have had surgery to remove the womb (a hysterectomy).	3
4.	I understand that the following are considered effective forms of birth control: Primary: Tubal ligation, partner's vasectomy, intrauterine devices, birth control pills, and topical/injectable/insertable hormonal birth control products. Secondary: Diaphragms, latex condoms, and cervical caps. A diaphragm and cervical cap must each be used with a spermicide. I understand that at least one of my 2 methods of birth control must be a primary method.	4
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/insertable hormonal birth control.	5
6.	I will talk with my prescriber about any drugs or herbal products I plan to take during my isotretinoin treatment because 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).	6
7.	I understand that I must begin using the birth control methods I have chosen as described above at least one month before I start taking CLARUS®.	7
8.	I understand that I should not take CLARUS® unless I have 2 negative pregnancy test results. The first pregnancy test should be done when my prescriber decides to prescribe CLARUS®. The second pregnancy test should be done within 11 days before starting therapy during the first 2 or 3 days of my menstrual period, or as instructed by my prescriber. I must then have one pregnancy test every month during my CLARUS® therapy.	8
9.	I have read and understand the materials my prescriber has given to me, including the CLARUS® CLEAR™ program: A 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).	9
10.	I understand that I must stop taking CLARUS® right away and inform my prescriber if I get pregnant during or within a month of stopping treatment, miss my menstrual period, stop using birth control, or have sexual intercourse without using my 2 methods of birth control at any time.	10

(Please print)

Patient Name: _____

Patient Address: _____ **Telephone:** (_____) _____ - _____

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

I have:
- fully explained to the patient, the nature and purpose of CLARUS® treatment, including its benefits and risks
- given the patient the appropriate educational materials, CLARUS® CLEAR™ program: A Guide For Patients, and asked the patient if he/she has any questions regarding his/her treatment with CLARUS®
- answered those questions to the best of my ability

Physician or Delegate Signature: _____ **Date:** _____

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