

Informed Consent Form for Patients Taking Hanzema™ (alitretinoin)

DO NOT sign this form or take Hanzema™ (alitretinoin) if there is any information about alitretinoin your doctor has given you that you do not understand.

For All Patients:

My doctor has provided me with verbal and written information about Hanzema™ (alitretinoin), and I understand the following: INITIAL

- Hanzema™ (alitretinoin) may cause serious birth defects, effective birth control must be used _____
 - Females of reproductive potential - please see below
 - Males must use a latex or synthetic condom every time when engaging in sexual intercourse with a female of reproductive potential
- Hanzema™ (alitretinoin) may cause serious side effects including: depression and mental changes, vision problems, bone disorders, dry hair or skin, muscle pain, raised blood fats, anemia, thyroid problems _____
- I must not donate blood during treatment and for 4 weeks after stopping treatment _____
- I must not share Hanzema™ (alitretinoin) with any other person _____
- I must return all unused Hanzema™ (alitretinoin) to my doctor/pharmacist at the end of treatment _____

Patient name (print) _____ Telephone: _____

Address: _____

For Females of Reproductive Potential:

I have reviewed the information that my doctor has given me about pregnancy prevention and Hanzema™ (alitretinoin), and I understand the following: INITIAL

- Hanzema™ (alitretinoin) may cause serious birth defects _____
- I must not take Hanzema™ (alitretinoin) if I am pregnant, may become pregnant during treatment, up to 4 weeks after treatment, or during breastfeeding _____
- I must return to the doctor for scheduled pregnancy tests and new/subsequent prescriptions _____
- I must use two effective and complementary birth control methods without interruption including a barrier method for at least 4 weeks before starting therapy, during, and 4 weeks after stopping treatment _____
- I understand that effective birth control means using one primary (highly effective) method and one additional method simultaneously _____
 - Primary (highly effective) methods: tubal ligation, IUD, hormonal (birth control, patches, injections, vaginal rings, implants), or patient vasectomy
 - Additional methods (Secondary): male latex/synthetic condom, diaphragm, or cervical cap
- I understand that birth control methods may fail. No birth control method is completely reliable _____
- I must tell my doctor about any medications/herbal products I plan to take during my treatment with Hanzema™ (alitretinoin). Hormonal contraceptive methods (i.e. the pill) may not work as effectively if I take certain products (i.e. St. John's Wort) _____
- I must stop taking Hanzema™ (alitretinoin) if I become pregnant, and I must discuss with my doctor the risks of continuing pregnancy _____

I acknowledge that my doctor has explained all of the above statements that are applicable to me, and I fully understand them.

For patients <18 years of age, parent or legal guardian must read the Hanzema™ (alitretinoin) Pregnancy Prevention Program (PPP) education resources and agree to ensure compliance.

Patient signature: _____ Date: _____

This material was developed by Dr. Reddy's Laboratories Canada Inc., as part of the risk minimization plan for Hanzema™. This material is not intended for promotional use. For more information about Hanzema™ (alitretinoin) and the Hanzema™ (alitretinoin) Pregnancy Prevention Program (PPP), please visit our website www.hanzema.ca or call Dr. Reddy's Laboratories Canada Inc., at **1(877)767-2260**.

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This Informed Consent form is downloaded from www.hanzema.ca, where more information about Hanzema™ (alitretinoin) and the Hanzema™ (alitretinoin) Pregnancy Prevention Program can be found.