Cipla

REYDIN

Dolutegravir 50 mg, Lamivudine 300 mg, Tenofovir disoproxil 300 mg

RISK ACKNOWLEDGEMENT FORM FOR WOMEN OF CHILDBEARING POTENTIAL.

PART A: TO BE COMPLETED AND SIGNED BY THE PATIENT [PARENT OR GUARDIAN]

Dolutegravir-based antiretroviral medicines such as **Reydin** can cause severe birth defects to your unborn baby if it is taken during pregnancy and there is a risk that you will have a severely deformed baby if:

- You are pregnant when you start taking **Reydin**.[1]
- You become pregnant while you are taking **Reydin**.[1]

Do not sign this acknowledgement form and do not take **Reydin** if there is anything that you do not understand about the information you have received about using **Reydin**.

My treatment with **Reydin** has been personally explained to me by my healthcare professional (HCP).
The following points of information, among others, have been specifically discussed and made clear to me:

1. I understand that severe birth defects have occurred in babies of females who took dolutegravir-based antiretroviral therapy such as **Reydin** during pregnancy.
2. I understand that I must not take **Reydin** if I am pregnant.
3. I understand that I must use at least 1 and preferably 2 separate, effective forms of contraception throughout the treatment period and for at least 1 month of stopping treatment.
4. I am fully aware of the risks of possible contraceptive failure, as explained to me by my doctor.
5. I agree to talk to my doctor about any medicines or herbal products I am taking or plan to take during my **Reydin** treatment, because hormonal contraception methods (for example, the pill) may not work if I am taking certain medicines or herbal products such as St. John's wort.
6. I understand that I should not start taking **Reydin** until I am sure that I am not pregnant and have had a negative pregnancy test if I am at risk of becoming pregnant.
7. I understand that I may require regular pregnancy tests during my treatment with **Reydin** and that my HCP will discuss this with me during each follow up visit.
8. I understand that it may be deemed necessary to have a pregnancy test 5 weeks after stopping **Reydin** therapy if I am at risk of becoming pregnant.
9. Should I get pregnant, miss my period, stop using any contraception method, or have sex without using contraception during my treatment with **Reydin** or in the month after I have stopped taking **Reydin** understand that I should consult my HCP.
10. I understand that if I become pregnant, my doctor may refer me to a specialist experienced in managing birth defects for evaluation and advice.
11. My doctor has informed me that there is a pregnancy registry for women who take antiviral medicines during pregnancy. The doctor has told me the purpose of the registry, which is to collect information about my health and that of my baby. I am happy to take part in this registry.

MY DOCTOR HAS ANSWERED ALL MY QUESTIONS ABOUT REYDIN AND I UNDERSTAND THE RISKS AND PRECAUTIONARY MEASURES INVOLVED, WHICH HAVE BEEN FULLY EXPLAINED TO ME.

_____ _____

Patient Signature **Date**

_____ _____

Parent/Guardian Signature (if required) **Date**

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Patient Name (print)

PART B: TO BE COMPLETED AND SIGNED BY THE HEALTHCARE PROFESSIONAL

Please note that patients with irregular menses present a difficult management problem that may require specialist advice.

CRITERIA FOR PRESCRIBING REYDIN IN WOMEN OF CHILD-BEARING POTENTIAL

When considering prescribing **Reydin** in women of child-bearing potential, it is important to ensure that the following criteria are fulfilled. Please ensure that you tick all the boxes and the form is signed: this is to make sure all the risks and information related to the use of **Reydin** during pregnancy have been understood and communicated to the patient.

1.	Does the patient understand the teratogenic risks involved with the use of **Reydin**?	YES	NO
2.	Does the patient understand the need for rigorous follow-up, on a monthly basis?	YES	NO
3.	Does the patient understand and accept the need for effective contraception, without interruption, before starting treatment, throughout the duration of treatment?	YES	NO
4.	Does the patient understand that at least 1 and preferably 2 complementary forms of contraception including a barrier method should be used?	YES	NO
5.	Is the patient capable of complying with effective contraceptive measures?	YES	NO
6.	Does the patient understand the need and accepts to undergo pregnancy testing before, during and after the end of **Reydin** treatment?	YES	NO
7.	Has the patient been informed and does she understand the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy?	YES	NO
8.	Has the patient acknowledged that she has understood the hazards and necessary precautions associated with the use of **Reydin**?	YES	NO

CONTRACEPTION IN WOMEN OF CHILDBEARING POTENTIAL

An appropriately trained healthcare professional should give advice on adequate contraception methods. As a minimum precaution, female patients of childbearing potential must use at least one effective method of contraception.

The most highly effective methods include contraceptive injections, implants, intra-uterine devices with copper or hormone, combined contraceptive pills and patches when used carefully.

Preferably all patients should use two complementary forms of contraception including a barrier method. Barrier methods on their own are not recommended.

9.	Has the patient received advice on adequate contraception?	YES	NO
10.	Has the patient reported the use of effective contraception without interruption for at least one month?	YES	NO

ANTIRETROVIRAL PREGNANCY REGISTRY PARTICIPATION

The Antiretroviral Pregnancy Registry is intended to provide an early signal of any major teratogenic effect associated with a prenatal exposure to the products monitored through the Registry. The Registry is a voluntary prospective, exposure-registration, observational study designed to collect and evaluate data on the outcomes of pregnancy exposures to antiretroviral products.

The Registry is a primary source for evaluating the use of antiretroviral products in pregnancy. Your contribution to this collaborative monitoring of exposures to antiretrovirals during pregnancy enables you to obtain information on available data in the Antiretroviral Pregnancy Registry Interim Report printed and distributed semi-annually.

Health care providers should report all exposures to ARV medications, including exposures for all women who were pregnant or conceived and used ARV medicines, to the Antiretroviral Pregnancy Registry via the following avenues:

Tel: +1 800 258 4263, **Fax:** +1 800 800 1052 / +44 1628 789 666, **Email:** SM_APR@INCResearch.com

Alternatively contact Cipla for assistance:

Tel: +27 21 943 4200, **Fax:** +27 21 914 1587, **Email:** drugsafetysa@Cipla.com

11.	Have you discussed the pregnancy registry with the patient, and have you informed her of participating in this registry?	YES	NO
12.	Is the patient willing to take part in the pregnancy registry?	YES	NO

ACKNOWLEDGEMENT FORM

All female patients who are of childbearing potential should sign the risk acknowledgement form indicating that they fully understand the risks of pregnancy whilst on Reydin, that they are not currently pregnant and have been using appropriate contraception for one month before starting treatment, and that the responsibilities of the patient and physician have been discussed. This should include the responsibility of the patient to consult their healthcare professional if they have knowingly had unprotected intercourse so that the possibility of using emergency contraception can be considered.

13.	Has the patient signed the acknowledgement form	YES	NO

I ACKNOWLEDGE THAT I HAVE INFORMED THE PATIENT ON THE RISKS INVOLVED WITH THE USE OF REYDIN AND HAVE ANSWERED ALL QUESTIONS ABOUT REYDIN TO THE PATIENT.

_____ _____

Healthcare Professional Signature **Date**

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Role of Healthcare Professional

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Healthcare Professional Name (print)

References:
1. AIDSinfo. The Panel on Antiretroviral Guidelines for Adults and Adolescents: Guidelines for the use of Antiretroviral Agents in Adults & Adolescents living with HIV. Available at: https://aidsinfo.nih.gov/news/2109/recommendations-regarding-the-use-of-dolutegravir-in-adults-and-adolescents-with-hiv-who-are-pregnant-or-of-child-bearing-potential. Accessed [24 January 2019].

S4 Reydin Reg. No. 52/20.2.8/0451.450. Each film coated tablet contains Dolutegravir 50 mg, Lamivudine 300 mg, Tenofovir disoproxil 300 mg. For full prescribing information refer to the package insert as approved by the medicines regulatory authority.

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