ACKNOWLEDGEMENT OF RISK INFORMATION FORM

Treatment with Dolutegravir for female patients

Patient ID:													

A copy of this form completed and signed shall be kept on record by the prescriber and a copy of this form shall also be kept by the patient. Form to be completed at initiation of treatment; annual visit or during or before pregnancy. Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

REVIEW OF FERTILITY INTENTION

If you are woman of childbearing age who has been initiated / started on or are taking Dolutegravir (DTG) and If you wish to conceive / become pregnant, please note the following:

1. If you take DTG at the time of becoming pregnant and during the first 3 months of pregnancy, there is a small risk that your baby may develop neural tube defects (birth defects involving the brain, spine, and spinal cord). Neural tube defects happen early in pregnancy, before many women even know they are pregnant. For this reason, women of childbearing age should talk to their healthcare professional about other non-dolutegravir containing antiretroviral medicines.
2. If you are planning to become pregnant, please seek guidance from your healthcare provider who may discuss changing you to other medicines instead of DTG (non-dolutegravir containing anti-HIV medicines).
3. You are most welcome to seek guidance again whenever you plan to conceive / become pregnant in future.
4. Please inform your healthcare provider if you are planning to become pregnant. Your healthcare provider may discuss other treatment options with you.

Part 1 and 2 must be completed: All boxes must be ticked, and the form signed once the risks of treatment are explained to the patient/carer and the patient/carer understands them.

PART 1: PRESCRIBER CHECKLIST **I have discussed the following with the above patient/carer/legal representative:**	**Tick once discussed**
1. That pregnant women started on Tenofovir disoproxil fumarate 300 mg; Lamivudine 300 mg; Dolutegravir 50 mg (TLD) or DTG in very early pregnancy and women of childbearing potential who start TLD or DTG and become pregnant may have an increased risk of an infant with a neural tube defect.	
2. The need for effective contraception (if of child-bearing potential) when taking TLD or DTG	
3. The need for up-to-date information on the risks and benefits of TLD or DTG and alternative antiretroviral options so the woman can make an informed choice – whether or not she plans to fall pregnant.	
4. The need for regular pregnancy testing and review of contraception choices.	
5. The need for urgent review if the patient is planning a pregnancy or if pregnancy occurs.	
6. Mothers who are breastfeeding their infants might not wish to use TLD or DTG as TLD or DTG is expected to be excreted in breast milk.	
7. I have discussed the alternative options if the woman plans to get pregnant.	
8. I have given the patient/carer a copy of this acknowledgement of risk form.	
9. I have advised the patient/carer that she should receive a patient information leaflet (PIL) either inside the box of TLD or DTG, or from the healthcare provider dispensing TLD or DTG.	
10. I have explained that the patient has the opportunity to be part of the National Antiretroviral Pregnancy Registry (APR) and am familiar with the procedures of registering her pregnancy onto the APR.	

TLD - tenofovir disoproxil fumarate 300 mg; lamivudine 300 mg; dolutegravir 50 mg

PART 2: PATIENT/CARER CHECKLIST I the undersigned understand:		Tick once discussed
1.	That I should avoid falling pregnant while receiving TLD or DTG until I discuss this with my healthcare provider.	
2.	That there might be a slightly greater risk to an unborn baby whose mother falls pregnant while taking TLD or DTG. One study found a higher rate of neural tube defects than normal in babies whose mothers became pregnant on DTG. Importantly, this was BEFORE the babies were conceived. Women who started DTG later in pregnancy showed no problems. The neural tube in a developing baby is what becomes the brain, spinal cord, skull and spine. The neural tube closes in the first 28 days of pregnancy – that is before most women know they are pregnant. If it does not fully close for some reason, the baby is said to have a neural tube defect. Neural tube defects vary, from very minor ones that are easily fixed, to ones that give severe disability and even death. So, the risk is taken very seriously by the Department of Health, healthcare providers and patients.	
3.	That I am advised to use reliable contraception during my treatment with TLD or DTG.	
4.	That my treatment, pregnancy status and contraception should be reviewed regularly.	
5.	That I should request an urgent review of my treatment if planning a pregnancy BEFORE attempting to conceive/ fall pregnant.	
6.	That if I am planning to become pregnant or am breastfeeding that there are other treatment options available that may be better suited to me.	
7.	That I have been informed of and understand the risks and benefits of TLD or DTG if I decide that TLD or DTG is the better option for me, even though I am planning to become pregnant or am breastfeeding.	
8.	I have been advised to receive a copy of the patient information leaflet inside the box of TLD or DTG, or from my healthcare provider dispensing TLD or DTG.	
9.	That I should visit my healthcare provider as soon as possible if I do fall pregnant while taking TLD or DTG. In this case I should not stop taking TLD or DTG until I have spoken to my healthcare provider.	
10.	Should I fall pregnant, I have been informed that there is a TLD or DTG pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of the registry is to collect information about my health and the health of my baby. I will talk to my healthcare professional about taking part in this registry.	

PATIENT/CARER signature indicating the above has been discussed and fully understood	**PRESCRIBER signature indicating that the above has been adequately discussed and explained to patient**
Date:	**Date:**
Place:	**Place:**

FOLLOW UP ACTIONS

- Prescriber to complete and submit the Adverse Drug Reaction (ADR) and Antiretroviral Pregnancy Register (APR) forms within 24 hours.
- Submit the ADR and APR forms to the Southern African HIV Clinicians Society (SAHCS) email address: sahivcs@sahivcs.org

BIRTH OUTCOME:

- Prescriber to complete the relevant section in the Acknowledgement of risk form available at https//www.APRegistry.com/
- Pharmaceutical companies will follow-up (2 attempts) with the prescriber at the time of delivery to determine the birth outcome and ensure that the relevant APR forms have been completed accordingly.

REPORTING STOCKOUTS:

Whether you are a patient, acquaintance or a healthcare worker and you have knowledge of a medication shortage or stockout, you can to report this through the Stop Stockouts Project (SSP).

TO REPORT MEDICINE STOCKOUTS AND SHORTAGES:
Send a Please Call Me, SMS or Phone 084 855 STOP (7867)
Email: report@stockouts.org
Go to: www.stockouts.org/report
Follow SSP on: Twitter@Stop_Stock_Outs
Like us on: www.facebook/stopstockouts

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