834/NDA/DPS/11/2017

CIRCULAR NO. 006/PS/11/2017

Dear Healthcare Provider,

RISK OF ABORTION AND BIRTH DEFECTS WITH FLUCONAZOLE

Fluconazole is used in the treatment and prevention of specified fungal infections in adults and children. Management of opportunistic fungal infections among HIV infected mothers, and the inherent increased risk of fungal infections during pregnancy may call for Fluconazole use.

Review of current literature has shown evidence to suggest an increased risk of spontaneous abortion in women taking fluconazole in the first trimester of pregnancy. Previous studies have also linked high dose and long term treatment to birth defects.

National Drug Authority therefore reminds all Health care professionals that fluconazole in high doses and/ or in prolonged regimens should not be used during pregnancy except for life threatening infections.

Advice to healthcare providers

Where Fluconazole is used during pregnancy,

- Monitor patients for any signs of threatened abortion and any other adverse effects.
- Sensitize patients to report back any signs of threatened abortion and or other adverse effects.
- To report all other adverse drug reactions and any other drug related concerns using the ADR forms or by email: druginfo@nda.or.ug . Tel: 256 -417-788100 or on Whatsapp: 0791415555.

Thank you for your continued cooperation.

Victoria Nambasa

For: DIRECTOR PRODUCT SAFETY