«Salutation» «Initials» «Surname» 3104
«JobTitle»
«M_Address1»
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«M_Address4»
«M_Address5»
«Town»
«PostCode»

HRA PHARMA
15 RUE BERANGER
75 003 PARIS
FRANCE

TEL : +33(0) 1 40 33 11 30
FAX : +33(0) 1 40 33 12 31

2nd February 2018

PREGNANCY REGISTRY
ellaOne® (ulipristal acetate 30 mg) post-marketing surveillance

Dear Doctor,

ellaOne® (ulipristal acetate 30 mg) is an emergency contraception indicated within 120 hours of unprotected sexual intercourse or contraceptive failure. Since early 2015, ellaOne is available without prescription.

Although ellaOne® significantly reduces the risk of pregnancy (from 5.5 to 0.9% when taken in the first 24 hours in Glasier *et al., 2010*) it cannot prevent all pregnancies. This is why a pregnancy registry was implemented since product launch in order to facilitate the collection of information on pregnancies exposed to ellaOne® for any reason: this was a mandatory requirement from the EMA. When granting a non-prescription status to ellaOne®, the EMA requested that the pregnancy registry be continued and extended to all Healthcare Providers (HCP) who manage the care of pregnant women.

So far, data collected via this pregnancy registry, together with other post-marketing surveillance data, has allowed to collect 1119 cases of pregnancies exposed to ellaOne® : they provide reassuring data in terms of safety and pregnancy outcome.

We need your input to monitor cases of pregnancy in women who used ellaOne® and we would like to ask you to please report these cases in the dedicated registry (www.hra-pregnancy-registry.com).

In the particular case of abortion clinics, please ensure that every pregnant woman is asked whether she has taken emergency contraception and if yes, to identify precisely which product.

You will find the link below and in the ellaOne® Product Information.

"Any woman who inadvertently took ellaOne® during her pregnancy or have become pregnant despite having taken ellaOne® can directly report safety information through the website. Alternatively, any health care professional can also access the website and report safety data through this secured tool.

To access the on-line questionnaire to be filled in, please go to:

www.hra-pregnancy-registry.com

select your language in the drop-down menu on the right side of the screen and follow the instructions."

Yours sincerely,

Delphine Cossard, EU QPPV

Laboratoire HRA-Pharma

Suna Horner, Associate Medical Manager

HRA Pharma UK & Ireland Limited