

ellaOne[®] Pregnancy Registry

What is the Registry?

A pregnancy registry is an important program aimed at collecting medical information on women exposed to a pharmaceutical product during their pregnancy.

This registry is designed to collect information about pregnancy outcomes in women who have taken ellaOne[®] while they were already pregnant, or who have become pregnant after ellaOne[®] intake. The existence of a registry does not mean that there is a risk for you or your baby if you have taken ellaOne[®] while you were pregnant.

The information collected from the pregnancy registry will allow to gain more experience on exposure to ellaOne[®] during pregnancy. In the long-term, other pregnant women could therefore benefit from your participation through the data collected via this registry.

What is ellaOne[®]?

ellaOne[®] is a female emergency contraceptive to be taken within five days of unprotected sex or contraceptive failure (such as a tear in a condom during sex).

Should you need more information on ellaOne[®] or the registry, please contact your physician.

How can you participate?

If you have inadvertently taken ellaOne[®] during your pregnancy or have become pregnant despite having taken ellaOne[®] we are very interested in receiving more information about your pregnancy. Any information would strictly be handled in an anonymous manner in order to preserve your confidentiality. You can directly report information through this website or ask your physician who could do it for you. **In any case, you are strongly advised to contact your physician as early as possible during your pregnancy.**

If you wish to participate, you or your physician may report any medical information regarding your own health, your pregnancy and whenever necessary, your baby's birth and health. Your participation will not generate extra doctors' visits nor lead to you having to take any medication.

If someone you know has taken ellaOne[®] during her pregnancy or just before her pregnancy, we would strongly advise you to inform her about this registry.

Your participation in this registry is really important to gain more experience on pregnancies exposed to ellaOne[®]. Your experience could benefit other pregnant women.

HRA Pharma does not recommend the use of ellaOne[®] in any manner other than as described in the **Package Leaflet.**

How is your confidentiality ensured ?

The information you will enter in this on-line questionnaire will be directly reported to HRA Pharma via a highly secured process.

Your identity will remain strictly confidential. Personal data are limited to your initials and date of birth to allow a correct follow-up of your data. Your personal data will be encrypted by the system in such a way that your identity will not be known to HRA Pharma. Information on initials and date of birth are only asked for to facilitate the follow-up of the pregnancies. The information collected in the registry will not be sufficient to identify patients.

However, if, and only if, you have entered your e-mail address, the electronic system will allow HRA Pharma to send you a first e-mail, without knowing your e-mail address and name, in order to collect additional information regarding your pregnancy. If you are willing to respond to this e-mail, provide additional information and be contacted for follow-up, then your e-mail address will be known by HRA Pharma. However, your personal data will always remain strictly confidential and will solely be used by the HRA Pharma Pharmacovigilance department.

If you have also agreed to provide your physician's contact details, he or she may be contacted by HRA Pharma's Pharmacovigilance department in case relevant or significant data were missing or inconsistent.

Warning: to be read before starting filling in the questionnaire

Filling in this questionnaire will only take you a couple of minutes. You will be able to print it out or save it after having submitted it. You will have to fill it all in in one go. Therefore we advise you to complete it **only once you will know the outcome of your pregnancy** (for example, if your baby was born, or if you have chosen to have an abortion, or if you had a miscarriage...). In fact, for confidentiality reasons, you will not be able to interrupt the completion of the form and continue it later. For some of the questions, there will be a Help text on the right side to help you to fill it in.

For information about how to sign up for this web-based registry, go to:

www.hra-pregnancy-registry.com