

### **Annex III**

**Amendments to the relevant sections of the Product information**

## Amendments to the relevant sections of the Product Information

### A. Summary of Product Characteristics

[...]

#### Section 4.2 Posology and method of administration

[The wording below should be inserted in this section]

[...]

Women who have used enzyme-inducing drugs during the last 4 weeks and need emergency contraception are recommended to use a non-hormonal EC, i.e. Cu-IUD or take a double dose of levonorgestrel (i.e. 2 tablets taken together) for those women unable or unwilling to use Cu-IUD (see section 4.5).

[...]

#### Section 4.5 Interaction with other medicinal products and other forms of interaction

[The wording in this section should be amended as below]

The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers, mainly CYP3A4 enzyme inducers. Concomitant administration of efavirenz has been found to reduce plasma levels of levonorgestrel (AUC) by around 50%.

~~Drugs suspected of having the similar capacity to reduce the efficacy of levonorgestrel containing medication due to similar effects on plasma levels of levonorgestrel include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, and griseofulvin.~~

For women who need levonorgestrel emergency contraception whilst using or and who have used enzyme-inducing drugs in the past 4 weeks and need emergency contraception, the use of non-hormonal emergency contraception (i.e. a Cu-IUD) should be considered. Taking a double dose of levonorgestrel (i.e. 3000 mcg within 72 hours after the unprotected intercourse) is an option for women who are unable or unwilling to use a Cu-IUD, although this specific combination (a double dose of levonorgestrel during concomitant use of an enzyme inducer) has not been studied.

Medicines containing levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism.

[...]

### B. Labelling (outer carton)

[...]

#### 7. OTHER SPECIAL WARNING(S), IF NECESSARY

[The wording below should be inserted in this section]

"If you have used certain other medicines in the last 4 weeks, in particular treatment for epilepsy, tuberculosis, for HIV infection or herbal medicines containing St. John's wort (see leaflet), <product name> may work less effectively. If you use these medicines take [number of] tablets of <product name>. If you are unsure or to ask for an alternative treatment speak to your doctor or pharmacist before using <product name>."

[...]

### C. Package leaflet

[...]

#### 2. What you need to know before you take Levonelle 1500

[...]

##### Other medicines and Levonelle 1500

*[The wording below should be amended in this section]*

Tell your pharmacist or doctor if you are taking or have recently taken ~~or might take~~ any other medicines, including medicines obtained without a prescription or herbal medicines.

Some medicines may prevent <product name> from working ~~properly effectively these include.~~ If you have used any of the medicines below during the last 4 weeks, <product name> may be less suitable for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of <product name>.

- barbiturates and other medicines (used to treat epilepsy (for example, primidone, phenytoin, and carbamazepine)
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin)
- a treatment for HIV ~~infection~~ (ritonavir, efavirenz)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's wort (Hypericum perforatum)
- ~~a medicine called cyclosporin (suppresses the immune system).~~

Speak to your pharmacist or doctor if you need further advice on the correct dose for you.

Consult your doctor as soon as possible after taking the tablets for further advice on a reliable form of regular contraception and to exclude a pregnancy before using Levonelle 1500 if you use any of the above mentioned medicines. (See section also 3 "How to take <product name>" for further advice).

~~Speak to your pharmacist or doctor if you need further advice.~~

<product name> may also affect how well other medicines work  
- a medicine called cyclosporin (suppresses the immune system).

[...]

#### 3. How to take Levonelle 1500

*[The wording below should be amended in this section]*

Always use this medicine exactly as described in the leaflet or as your pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Take the tablet as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after you have had unprotected sex. <product name> can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant. Do not chew but swallow the tablet whole with water. Do not delay taking the tablet. The tablet works ~~best better~~ the sooner you take it after having unprotected sex.

- If you are using one of the medicines that may prevent <product name> from working properly (see section above “Other medicines and <product name>”) or if you have used one of these medicines in the past 4 weeks, <product name> may work less effectively for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of <product name> (i.e. 2 tablets taken together at the same time).
- If you are already using a regular method of contraception such as the contraceptive pill, you can continue to take this at your regular times.

[...]