

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Oral contraception

Almost all women are at risk of unintended pregnancy throughout their reproductive years. Birth control and ensurance of access to preferred contraceptive methods for women and couples – is essential to securing the well-being and autonomy of women, while supporting the health and development of communities.

A woman's ability to choose if and when to become pregnant has a direct impact on her health and well-being. Birth control allows spacing of pregnancies and can delay pregnancies in young women at increased risk of health problems and death from early childbearing, and can prevent pregnancies among older women who also face increased risks. Family planning enables women who wish to limit the size of their families to do so. Evidence suggests that women who have more than four children are at increased risk of maternal mortality¹.

Levonorgestrel

The practice of contraception is as old as human existence. There have been numerous attempts to control fertility after unprotected sexual intercourse. So far, hormonal methods preventing or delaying ovulation have proved to be the most popular.

Levonorgestrel is one method of oral emergency contraception, which prevents fertilization and does not disrupt an already established pregnancy. Its limitations are the non - optimal efficacy which is decreasing the later the drug is taken and the fact that it is only approved for up to 72 hours after unprotected sexual intercourse².

VI.2.2 Summary of treatment benefits

Levonorgestrel is a well-known substance and has been studied extensively in the preclinical stage. Levonorgestrel is indicated for emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method. Emergency contraception is used as an emergency procedure to prevent pregnancy following unprotected coitus and is not a routine approach to contraception. Emergency contraceptives are not effective if the woman is already pregnant. Results from a study (Ho and Kwan; WHO/HRP 1998 - Study 92908) sponsored by Programme of Research, Development and Research Training in Human Reproduction (HRP) of WHO proved that LNG was an effective emergency contraceptive with a favourable safety profile³.

VI.2.3 Unknowns relating to treatment benefits

None.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Pregnancy outside the uterus (ectopic pregnancy)	If pregnancy occurs after using levonorgestrel, the possibility of a pregnancy outside the uterus (ectopic pregnancy) should be considered. The risk of ectopic pregnancy is likely to be low, as levonorgestrel prevents ovulation and fertilisation. Ectopic pregnancy may continue, even if uterine bleeding occurs.	There is no specific measure to prevent the occurrence of ectopic pregnancy. The risk can be reduced by not allowing levonorgestrel to be used in patients who are at risk of ectopic pregnancy (previous history of infection of the fallopian tube or ectopic pregnancy).
Bleeding not related to menstruation	This side effect is very common. Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected date.	There is no specific measure to prevent the occurrence of bleeding not related to menstruation.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Use in patients with severe hepatic dysfunction	No formal studies have evaluated the effect of hepatic insufficiency and levonorgestrel intake. Levonorgestrol 1.5 mg is not recommended in patients with severe hepatic dysfunction.
Use in patients with severe malabsorption syndromes, such as Crohn's disease	Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of levonorgestrel.

Missing information

None.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PIL). The measures in these documents are known as routine risk minimisation measures.

Levonorgestrel 1.5 mg tablet has no additional risk minimisation measures.

VI.2.6 *Planned post authorisation development plan*

None.

VI.2.7 *Summary of changes to the Risk Management Plan over time*

Not applicable as this is the initial risk management plan.