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RMP section VI.2 Elements for Public Summary

Product: Zarelle 75 microgram filmcoated tablet

RMP: Version 1.0

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MAH: Stragen Nordic A/S

VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Hormonal contraception refers to birth control methods that act on the endocrine system. There are two methods of birth control: hormonal and non-hormonal (intrauterine device and system). Among hormonal methods, there are two main types of hormonal contraceptive formulations: combined methods containing an estrogen and a progestin, and progestogen-only methods containing only progestin. These tablets act to inhibit ovulation. Ovulation occurs when a mature egg is released from the ovary and is the phase of the female menstrual cycle where she can become pregnant. The tablets also alter the mucus or fluid in the cervix making it impassable to sperm. This prevents implantation of the fertilized egg and prevents pregnancy.
According to the World Contraceptive Use 2011 (United Nations publication), contraceptive prevalence among women of reproductive age is globally estimated at 63 %: it is somewhat higher in the more developed regions (72 %) than in the less developed regions (61 %). In developed countries as a whole, the most commonly used methods are the pill (18 % of women) and the male condom (18 % prevalence). Those two methods accounted for half of all contraceptive use in the developed countries. The pill is the third most widely used contraceptive method in the world, with 9 % of women. Use of the pill has the widest geographic distribution of any method.

VI.2.2 Summary of treatment benefits

Treatment benefits of desogestrel depend mainly on its ability to adequately suppress ovulation. Several studies have been conducted on the efficacy of desogestrel,
including several trials indicating that desogestrel-containing contraceptives are as effective in preventing pregnancy as those containing any other traditional progestogens. Most studies show a method failure of one or less per 100 women-years of use.
It is then safe to assume that the contraceptive efficacy of desogestrel is comparable to that of other oral contraceptives.

VI.2.3 Unknowns relating to treatment benefits

The failure rate per method is always lower than the user's failure rate, which is generally in the 1% per year range. Patient failure will depend on other factors, such as motivation, level of education, type of support available, and varies with the different population studied.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Pregnancy outside the womb (Ectopic pregnancy)	The protection with desogestrel-only pill against pregnancy outside the womb is not as good as with combined oral contraceptives	None

Risk	What is known	Preventability
Vaginal bleeding at irregular intervals (Disturbances of the vaginal bleeding pattern)	Administration of desogestrel commonly causes vaginal bleeding at irregular intervals	As mentioned in the PIL and the SmPC, desogestrel must not be used in patients with unexplained vaginal bleeding
Liver disorder (Severe liver impairment or use in patients with severe hepatic disease)	Administration of desogestrel may lead to liver disorder	As mentioned in the PIL and the SmPC, desogestrel must not be used in patients with liver disorder
Allergy to peanut or soya (Allergy to peanut or soya)	Administration of desogestrel may lead to allergic reaction to peanut or soya	As mentioned in the PIL and the SmPC, desogestrel must not be used in patients with allergy to peanut or soya
Unintended pregnancies (Unintended pregnancies)	The Pearl-Index (most common technique for assessment of the efficacy of a birth control method) for desogestrel is comparable to the one historically found for combined oral contraceptives. However, contraceptive protection may be reduced if more than 36 hours have elapsed between two tablets.	Yes, by complying with the posology and method of administration and by following the management of missed tablets described in the SmPC
Drug interactions leading to vaginal bleeding or unintended pregnancies (Drug interactions leading to breakthrough bleeding or contraceptive failure)	Some medicines may stop <invented name> from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate and Phenobarbital) or tuberculosis (e.g. rifampicin), HIV infections (e.g. ritonavir) or other infectious diseases (e.g. griseofulvin), stomach upset (medical charcoal), depressive moods (the herbal remedy St John's wort). <invented name> may also interfere with how certain medicines work, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect.	As mentioned in the PIL and the SmPC, desogestrel must not be used in association with these medicines

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Venous or arterial blood clots (Thromboembolic events)	The risk of thromboembolic events is identified with combined contraceptives, however, with progestogen-only contraceptives, the evidence is less conclusive. Therefore, this risk was considered as potential for desogestrel. To be noted that the risk with progestogen-only contraceptives is believed to be lower than in users of combined contraceptives.
Liver and breast cancers (Hormone-dependent tumours, liver and breast)	The risk of hormone-dependent tumours is identified with combined contraceptives, however, with progestogen-only contraceptives, the evidence is less conclusive. Therefore, this risk was considered as potential for desogestrel. The risk of breast cancer in users of progestogen-only contraceptives is believed to be similar to that in women who use the combined contraceptives, but the evidence is less conclusive.
Masculinisation of female foetuses if exposure during pregnancy, animal studies (Masculinisation of female foetuses if exposure during pregnancy, animal studies)	Animal studies have shown that very high doses of progestagenic substances might cause masculinisation of female foetuses.

Important missing information

Risk	What is known
Limited information on effect on bone mineral density	Treatment with desogestrel leads to decreased estradiol serum levels. It is as yet unknown whether this decrease has any clinically relevant effect on bone mineral density.
Limited information on interactions with laboratory tests	Data obtained with Combined Oral Contraceptives have been shown that contraceptive steroids may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, serum levels of (carrier) proteins, e.g. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis. The changes generally remain within normal range. To what extent this also applies to progestogen-only contraceptives is not known.

VI.2.5 Summary of risk minimisation measures by safety concern

This medicine 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

Major changes to the Risk Management Plan over time: not applicable