



ISSUE

Emergency contraception drug brands available in Canada claim their drug prevents ovulation for the individual to not pregnant; however, monographs are unclear and inconsistent on their ability to perform as claimed for individuals with higher weight and Body Mass Index (BMI). View the attachments of a summary table and individual monographs for specific consumer information.

PURPOSE

- Drug information on the monographs should provide clear information on their ability to perform to appropriately inform consumers.

RECOMMENDATION

- Health Canada must require emergency contraception drug companies to conduct more conclusive research that measures the risk of drug failure for individuals based on BMIs and weights.
- Health Canada must require these companies to clearly indicate the conclusive risk of failure based on BMI and weight on their product monographs.
- Health Canada must also require conclusive research and information on the monographs regarding efficacy when increasing dosage for individuals with higher weight and BMI.

RATIONALE

- The Canadian population weight has been steadily increasing, meaning more individuals require conclusive information on how their weight changes the efficacy of the drug.
 - In 2019-2020, 27.4% of women in Canada had a BMI of 30 and over (Canadian Institute for Health Information [CIHI]).
 - From 1985 to 2020, self-reported obesity has quadrupled for Canadian adults (CIHI).
- At present, as indicated in the summary table, the information is:
 - inconsistent between the brands of the same levonorgestrel drug. The information should be the same for the same drug, regardless of the brand.
 - stating the research is limited and inconclusive on the effect of high body weight/high BMI in the contraceptive efficacy. There should be conclusive research to appropriately inform the consumer.
 - does not provide a comparison pregnancy rate of not taking the drug with one act of unprotected intercourse. For example, in one study the pregnancy rate, on the most fertile day with unprotected intercourse, has a pregnancy rate of less than 10% (Daniel et al., 2015). Some monographs state that the pregnancy rate increased to 6.4% for higher weights and in the summary “not effective for women who weigh more than 80 kg”. Without the comparison of not taking the drug, the pregnancy rates by weight do not provide context for the consumer to understand their risk of drug failure.
- Frequently these drugs are available over the counter, indicating consumers may not speak with a physician or pharmacist and are relying solely on product monographs for information.
- Anecdotally, double dosing is occurring as an intervention to improve outcomes for individuals with higher BMIs and weights. Limited research is available to confirm the efficacy of this strategy. One small study of 70 participants reports results that double dosing does not appear effective at improving the failure rate (Edelman et al., 2022). The monographs must include conclusive information on increasing dosage.

BACKGROUND

- Emergency contraception is a way to prevent pregnancy if an individual had sex without using birth control or a birth control method failed. It is not intended for routine use as a contraceptive.
- Emergency contraception of levonorgestrel and ulipristal acetate, when taken immediately before ovulation is to occur, postpone follicular rupture. The likely primary mechanism of action is inhibition or delay of ovulation.

FINANCIAL IMPLICATIONS

- The cost of one tablet of Plan B is approximately \$30, and \$20 for the generic brands. For some individuals this is expensive, especially for a medication that has unclear and inconsistent information on the risk of failure.

ATTACHMENTS

Summary Table of Emergency Contraception Drug Monograph Weight Information
Product Monograph Plan B
Product Monograph Contingency One
Product Monograph Backup Plan Onestep
Product Monograph Norvelo
Product Monograph Ella

CONTACT

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REFERENCES

- Canadian Institute of Health Information. (n.d.) *Obesity (Age 18 and Older)*.
[https://yourhealthsystem.cihi.ca/hsp/inbrief?lang=en&_gl=1*1y8dpjt*_ga*MTM0MDAzNzk1Ny4xNjgyMTE0MDg4*_ga_44X3CK377B*MTY5NjQ1Mzc1OS42LjEuMTY5NjQ1Mzg4Mi4wLjAuMA..&_ga=2.14494576.63811073.1696453759-1340037957.1682114088#!/indicators/076/obesity-age-18-and-older/;mapC1;mapLevel2;sex\(F\);/](https://yourhealthsystem.cihi.ca/hsp/inbrief?lang=en&_gl=1*1y8dpjt*_ga*MTM0MDAzNzk1Ny4xNjgyMTE0MDg4*_ga_44X3CK377B*MTY5NjQ1Mzc1OS42LjEuMTY5NjQ1Mzg4Mi4wLjAuMA..&_ga=2.14494576.63811073.1696453759-1340037957.1682114088#!/indicators/076/obesity-age-18-and-older/;mapC1;mapLevel2;sex(F);/)
- Li, D., Wilcox, A.J. and Dunson D.B. (2015). Benchmark Pregnancy Rates and the Assessment of Post-coital Contraceptives: An Update. *Contraception*, 91 (4), 344-349.
[https://www.contraceptionjournal.org/article/S0010-7824\(15\)00003-7/fulltext](https://www.contraceptionjournal.org/article/S0010-7824(15)00003-7/fulltext)
- Edelman, A. B., Hennebold, J. D., Bond, K., Lim, J., Cherala, G., Archer, D. F., Jensen, J. T. (2022). Double Dosing Levonorgestrel-Based Emergency Contraception for Individuals With Obesity: A Randomized Control Trail. *Obstetrics & Gynecology*, 140 (1), 48-54.
https://journals.lww.com/greenjournal/Fulltext/2022/07000/Double_Dosing_Levonorgestrel_Based_Emergency.8.aspx

ATTACHMENT:
Summary Table of Emergency Contraception Drug Monograph Weight Information

Drug Identification	Brand	Monograph information																																																		
DIN 2293854	Plan B	<p>Year: 2018 Dosage: One tablet of 1.5 mg levonorgestrel Page 23 “There is limited and inconclusive data on the effect of high body weight/high BMI in the contraceptive efficacy. In three WHO studies (1, 19, 23) no trend for a reduced efficacy with increasing body weight/BMI was observed (Table 8), whereas in the two other studies (21, 22) a reduced contraceptive efficacy was observed with increasing body weight or BMI (Table 9). Both meta-analyses excluded intake later than 72 hours after unprotected intercourse and women who had further acts of unprotected intercourse.” Table 8: Meta-analyses on three WHO studies ^{1, 19, 23}</p> <table border="1"> <thead> <tr> <th>BMI (kg/m²)</th> <th>Underweight 0 – 18.5</th> <th>Normal 18.5 - 25</th> <th>Overweight 25 – 30</th> <th>Obese ≥ 30</th> </tr> </thead> <tbody> <tr> <td>N total</td> <td>600</td> <td>3952</td> <td>1051</td> <td>256</td> </tr> <tr> <td>N pregnancies</td> <td>11</td> <td>39</td> <td>6</td> <td>3</td> </tr> <tr> <td>Pregnancy rate</td> <td>1.83%</td> <td>0.99%</td> <td>0.57%</td> <td>1.17%</td> </tr> <tr> <td>Confidence Interval</td> <td>0.92 – 3.26</td> <td>0.70 – 1.35</td> <td>0.21 – 1.24</td> <td>0.24 – 3.39</td> </tr> </tbody> </table> <p>Table 9: Meta-analyses on two studies ^{21, 22}</p> <table border="1"> <thead> <tr> <th>BMI (kg/m²)</th> <th>Underweight 0 – 18.5</th> <th>Normal 18.5 - 25</th> <th>Overweight 25 – 30</th> <th>Obese ≥ 30</th> </tr> </thead> <tbody> <tr> <td>N total</td> <td>64</td> <td>933</td> <td>339</td> <td>212</td> </tr> <tr> <td>N pregnancies</td> <td>1</td> <td>9</td> <td>8</td> <td>11</td> </tr> <tr> <td>Pregnancy rate</td> <td>1.56%</td> <td>0.96%</td> <td>2.36%</td> <td>5.19%</td> </tr> <tr> <td>Confidence Interval</td> <td>0.04 – 8.40</td> <td>0.44 – 1.82</td> <td>1.02 – 4.60</td> <td>2.62 – 9.09</td> </tr> </tbody> </table> <p>Page 33 “There is some data that levonorgestrel may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. If you have any questions regarding this, please consult with a health care professional.”</p>	BMI (kg/m ²)	Underweight 0 – 18.5	Normal 18.5 - 25	Overweight 25 – 30	Obese ≥ 30	N total	600	3952	1051	256	N pregnancies	11	39	6	3	Pregnancy rate	1.83%	0.99%	0.57%	1.17%	Confidence Interval	0.92 – 3.26	0.70 – 1.35	0.21 – 1.24	0.24 – 3.39	BMI (kg/m ²)	Underweight 0 – 18.5	Normal 18.5 - 25	Overweight 25 – 30	Obese ≥ 30	N total	64	933	339	212	N pregnancies	1	9	8	11	Pregnancy rate	1.56%	0.96%	2.36%	5.19%	Confidence Interval	0.04 – 8.40	0.44 – 1.82	1.02 – 4.60	2.62 – 9.09
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DIN 2425009	Contingency One	<p>Year: 2016 Dosage: One tablet of 1.5 mg of levonorgestrel Page 3, 7 and 16 “In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more and levonorgestrel was not effective in women who weighed more than 80 kg.” Page 23 Table 7: Pregnancy rate (95% Confidence Interval (CI) according to weight categories</p> <table border="1"> <thead> <tr> <th>Weight (kg)</th> <th>< 55</th> <th>[55-65]</th> <th>[65-75]</th> <th>[75-85]</th> <th>≥ 85</th> </tr> </thead> <tbody> <tr> <td>Total number of Women (N)</td> <td>349</td> <td>608</td> <td>426</td> <td>155</td> <td>193</td> </tr> <tr> <td>Number of Pregnancies (N)</td> <td>3</td> <td>8</td> <td>6</td> <td>10</td> <td>11</td> </tr> <tr> <td>Pregnancy rate</td> <td>0.9%</td> <td>1.3%</td> <td>1.4%</td> <td>6.4%</td> <td>5.7%</td> </tr> <tr> <td>Confidence interval (CI)</td> <td>[0.2-2.5]</td> <td>[0.6-2.6]</td> <td>[0.5-3.0]</td> <td>[3.1-11.5]</td> <td>[2.9-10.0]</td> </tr> </tbody> </table>	Weight (kg)	< 55	[55-65]	[65-75]	[75-85]	≥ 85	Total number of Women (N)	349	608	426	155	193	Number of Pregnancies (N)	3	8	6	10	11	Pregnancy rate	0.9%	1.3%	1.4%	6.4%	5.7%	Confidence interval (CI)	[0.2-2.5]	[0.6-2.6]	[0.5-3.0]	[3.1-11.5]	[2.9-10.0]																				
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DIN 2433532	Backup Plan Onestep	<p>Year: 2014 Dosage: One tablet of 30 mg ulipristal acetate Page 7, 16 “Body weight 75 kg and more: In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more, and levonorgestrel was not effective in women who weighed more than 80 kg (see <i>Clinical Trials</i> section).” Page 23 Table 7: Pregnancy rate (95% Confidence Interval (CI) according to weight categories</p> <table border="1"> <thead> <tr> <th>Weight (kg)</th> <th>< 55</th> <th>[55-65]</th> <th>[65-75]</th> <th>[75-85]</th> <th>≥ 85</th> </tr> </thead> <tbody> <tr> <td>Total number of Women (N)</td> <td>349</td> <td>608</td> <td>426</td> <td>155</td> <td>193</td> </tr> <tr> <td>Number of Pregnancies (N)</td> <td>3</td> <td>8</td> <td>6</td> <td>10</td> <td>11</td> </tr> <tr> <td>Pregnancy rate</td> <td>0.9%</td> <td>1.3%</td> <td>1.4%</td> <td>6.4%</td> <td>5.7%</td> </tr> <tr> <td>Confidence interval (CI)</td> <td>[0.2-2.5]</td> <td>[0.6-2.6]</td> <td>[0.5-3.0]</td> <td>[3.1-11.5]</td> <td>[2.9-10.0]</td> </tr> </tbody> </table> <p>Page 31 “Levonorgestrel tablet is less effective in women weighing 75 kg (165 lbs) or more and not effective in women weighing more than 80 kg (176 lbs). If your weight is 75 kg or more, ask your health professional for advice on alternative methods of emergency contraception.”</p>	Weight (kg)	< 55	[55-65]	[65-75]	[75-85]	≥ 85	Total number of Women (N)	349	608	426	155	193	Number of Pregnancies (N)	3	8	6	10	11	Pregnancy rate	0.9%	1.3%	1.4%	6.4%	5.7%	Confidence interval (CI)	[0.2-2.5]	[0.6-2.6]	[0.5-3.0]	[3.1-11.5]	[2.9-10.0]
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DIN 2285576	Norlevo	<p>Year: 2009 Dosage: One tablet of 1.5 mg of levonorgestrel N/A</p>																														
DIN 02436329	Ella	<p>Year: 2015, revised 2023 Dosage: One tablet of 30 mg ulipristal acetate Page 6 and 28 “The efficacy of ella in women with a body mass index (BMI) of ≥35 kg/m² has not been evaluated. Subgroup analysis of the pooled data by BMI showed that for women with BMI > 30 kg/m² (16% of all subjects), the observed pregnancy rate was 3.1% (95% CI: 1.7, 5.7), which was not significantly reduced compared to the expected pregnancy rate of 4.5% in the absence of emergency contraception taken within 120 hours after unprotected intercourse.”</p>																														