

Ectopic pregnancy fact sheet

Purpose

The purpose of this fact sheet is to detail the following:

- The efficacy of Jaydess[®] in the prevention of unplanned pregnancy
- The absolute and relative risks of ectopic pregnancy in women using Jaydess[®]
- The importance of contraceptive counselling in:
 - Evaluating the risk of ectopic pregnancy for individual women considering Jaydess[®] as their contraceptive method of choice
 - Educating women on how to recognise the signs and symptoms of ectopic pregnancy and the importance of contacting their healthcare provider immediately if they experience any of these signs or symptoms

Efficacy of Jaydess[®]

Jaydess[®] is highly effective in the prevention of unplanned pregnancy. In clinical trials the 1-year Pearl Index was 0.41 (95% confidence limits 0.13 – 0.96) and the 3-years Pearl Index was 0.33 (95% confidence limits 0.16 – 0.60). The failure rate was approximately 0.4% at 1 year and the cumulative failure rate was approximately 0.9% at 3 years. The failure rate also includes pregnancies occurring after undetected expulsions and perforations.

Importantly, efficacy is unaffected by the age, parity status or body mass index of the user.

Ectopic pregnancy in women using Jaydess[®]

The absolute rate of ectopic pregnancy observed in women using Jaydess is low since Jaydess has a high contraceptive efficacy. In the event that a woman becomes pregnant there is an up to 50% chance that the pregnancy will be ectopic.

The absolute rate of ectopic pregnancy with Jaydess in the Phase II and III clinical studies was ~0.11 per 100 woman-years.¹ In comparison, studies on the background incidence of ectopic pregnancy based on data from two large managed care databases in the US have estimated ectopic pregnancy rates in the range of **1.7–2.5%** of all pregnancies or **0.11 - 0.23** per 100 woman-years in women aged 20–39 in the general population (including contraceptive users and non-users).^{2,3,4}

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Signs and symptoms of ectopic pregnancy

It is important that the signs and symptoms of ectopic pregnancy are recognised at the earliest opportunity so that treatment can be prompt. It is therefore important to counsel the woman on the signs and symptoms of ectopic pregnancy which include:^{1,5-7}

- Pain on one side of the lower abdomen, which may be severe or persistent. The pain may develop suddenly and sharply or may gradually worsen over several days
- Vaginal bleeding. This may be different to that associated with menses (e.g. the blood may be darker)
- Persistent bleeding that occurs after a period of amenorrhea, particularly if the bleeding is associated with pain
- “Normal” symptoms of pregnancy but with bleeding and a feeling of dizziness
- Shoulder-tip pain (owing to blood leaking into the abdomen and irritating the diaphragm)
- Severe pain or collapse as a result of heavy internal bleeding associated with rupture
- General symptoms: diarrhoea, feeling faint or pain on passing faeces; these would only be cause for concern if they occurred in addition to any of the more specific symptoms above
- A positive pregnancy test

If a woman has a positive pregnancy test while using Jaydess[®], the possibility of ectopic pregnancy should be considered and further tests should be performed to either exclude or diagnose ectopic pregnancy.¹

Early diagnosis of ectopic pregnancy can be difficult and a series of investigations may be necessary. Ectopic pregnancy may be confirmed by transvaginal ultrasound scan and by aβhCG blood test.⁸

Impact of ectopic pregnancy on future fertility

Ectopic pregnancy can result in damage to, or the loss of, a reproductive organ (for example a fallopian tube) which in turn may have a detrimental impact on the woman's future fertility.

Ectopic pregnancy and contraceptive counselling

Women should be counselled on the benefits and risks of all contraceptive options available, including Jaydess[®], to allow them to make an informed choice. This includes counselling on their individual risk of ectopic pregnancy while using Jaydess[®]. Women who then choose Jaydess[®] should be educated on how to recognise the signs and symptoms of pregnancy and in particular ectopic pregnancy and the importance of seeking medical attention immediately if they experience any of these signs or symptoms. They should also be advised that in the unlikely event that they become pregnant while using Jaydess[®], they should contact a healthcare provider immediately in order to exclude or diagnose ectopic pregnancy.

The healthcare provider should evaluate the risk of ectopic pregnancy for each individual woman considering Jaydess[®] as their contraceptive method of choice. Risk factors for ectopic pregnancy include:

- Prior ectopic pregnancy⁹
- Age (risk increases with advancing age)⁹
- Smoking (risk increases with increasing consumption)⁹
- Prior spontaneous abortion or induced abortion⁹(although another study showed no association, see footnote † to Table 1)
- Prior sexually transmitted disease⁹
- Prior tubal surgery⁹
- History of infertility⁹
- Multiple sexual partners⁹
- Endometriosis⁵

A case-control study for the assessment of risk factors associated with ectopic pregnancy was conducted based on data from the ectopic pregnancy register of Auvergne (France) and associated case-controlled studies.⁹Overall, 803 cases of ectopic pregnancy and 1,683 deliveries were included in the analysis; this provided sufficient power to comprehensively investigate all ectopic pregnancy risk factors. The main statistically significant risk factors for ectopic pregnancy by logistic regression analysis are shown in Table 1.

Table 1. Statistically significant risk factors for ectopic pregnancy by final logistic regression analysis (random effects model), register of Auvergne, France, 1993–⁸

Variables	Adjusted OR	95% CI	p value
Woman's age (years)			
<20	0.6	0.2, 2.1	
20–24	0.9	0.7, 1.3	
25–29	1		0.01
30–34	1.3	1.0, 1.7	
35–39	1.4	1.0, 2.0	
≥40	2.9	1.4, 6.1	
Smoking			
Never	1		<0.001
Past smoker	1.5	1.1, 2.2	
1–9 cigarettes/day	1.7	1.2, 2.4	
10–19 cigarettes/day	3.1	2.2, 4.3	
≥20 cigarettes/day	3.9	2.6, 5.9	
Prior spontaneous abortions†			
None	1		0.02
1 -2	1.2	0.9, 1.6	
≥3	3.0	1.3, 6.9	
Prior induced abortions			
None	1		0.05
Surgical only	1.1	0.8, 1.6	
Medical (medical or surgical)	2.8	1.1, 7.2	
Prior sexually transmitted disease			
None	1		<0.001
Yes, without salpingitis	1.0	0.8, 1.3	

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Yes, with probable PID†	2.1	0.8, 5.4
Yes, with confirmed PID§	3.4	2.4, 5.0

Variables	Adjusted OR	95% CI	p value*
Prior tubal surgery			
No	1		<0.001
Yes	4.0	2.6, 6.1	
Previous oral contraceptive use			
No	1		0.03
Yes	0.7	0.5, 1.0	
History of infertility			
No	1		<0.001
<1 year	2.1	1.2, 3.6	
1–2 years	2.6	1.6, 4.2	
>2 years	2.7	1.8, 4.2	

Note: Only risk factors associated with a significant trend (p value) for ectopic pregnancy by logistic regression are shown.

Note: Prior ectopic pregnancy and multiple sexual partners were NOT included in the final logistic regression analysis. However, in univariate analysis: for women with 1 prior ectopic pregnancy the crude OR=12.5; for women with ≥2 prior ectopic pregnancies the crude OR=76.6, (for $p < 0.001$ for trend); for a lifelong number of sexual partners >5, the crude OR=1.6, for a lifelong number of sexual partners 2–5, the crude OR= 1.0 ($p = 0.003$ for trend)

† No significant association with ectopic pregnancy was demonstrated for prior spontaneous abortion in another case-controlled study¹⁰

‡ Probable pelvic inflammatory disease, association with fever, abdominal pain, and vaginal discharge
§ Pelvic inflammatory disease confirmed by laparoscopy and/or positive serologic tests for Chlamydia Trachomatis

CI, confidence interval; OR, odds ratio; PID, pelvic inflammatory disease

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare Professionals are asked to report any suspected adverse reactions. See section 4.8 of the attached SmPC how to report adverse events.

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References

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