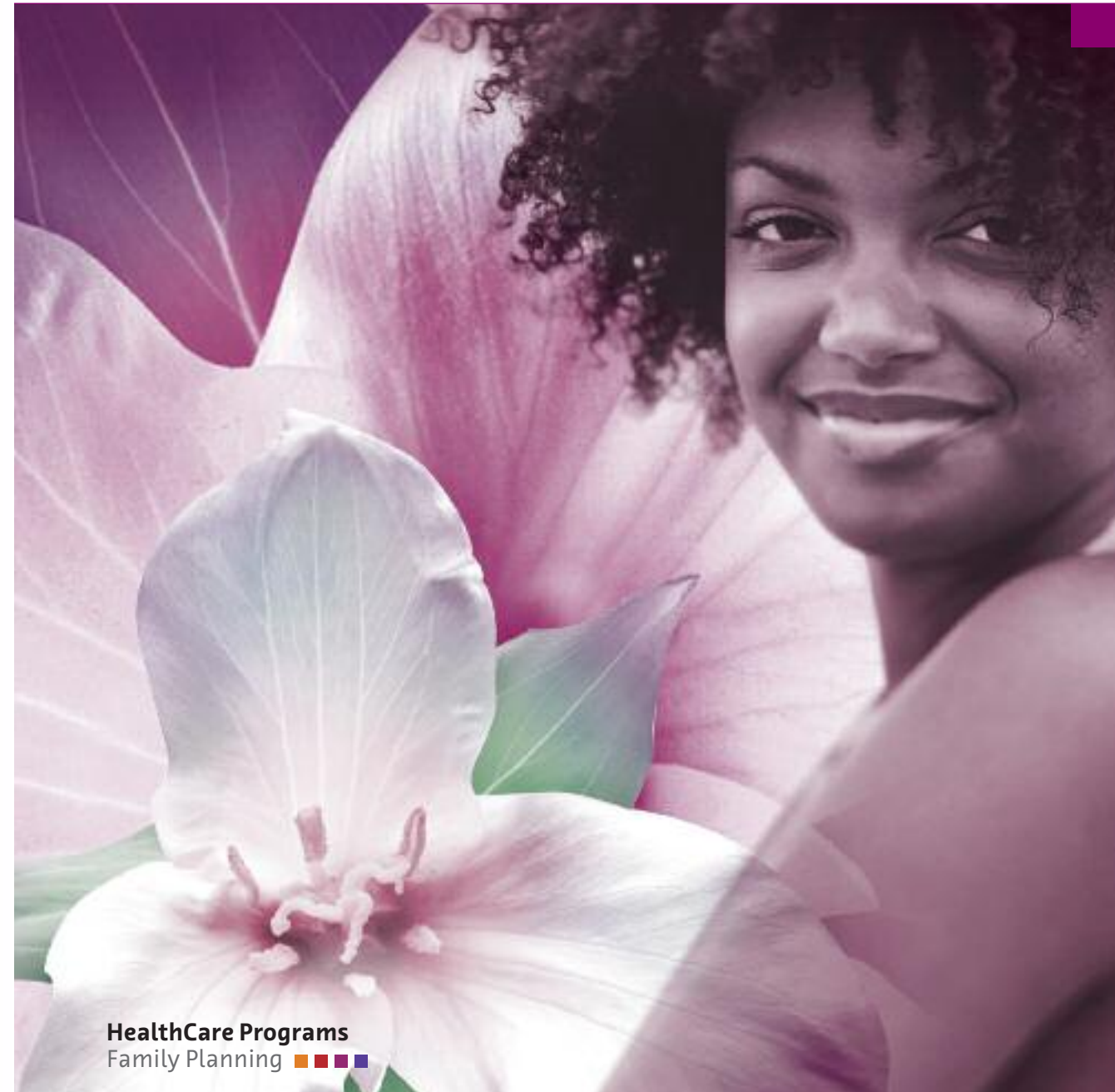


Jadelle®

Contraceptive Independence



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Family Planning 



Bayer HealthCare
Pharmaceuticals

Bayer HealthCare Pharmaceuticals
Health Care Programs
Family Planning
13342 Berlin, Germany

www.bayerpharma.com
www.jadelle.com

September 2013

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Contraceptive Independence

up to 5 years

www.jadelle.com

First Implants WHO-prequalified*

2 x 75mg Implants



* September 2009



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Introduction

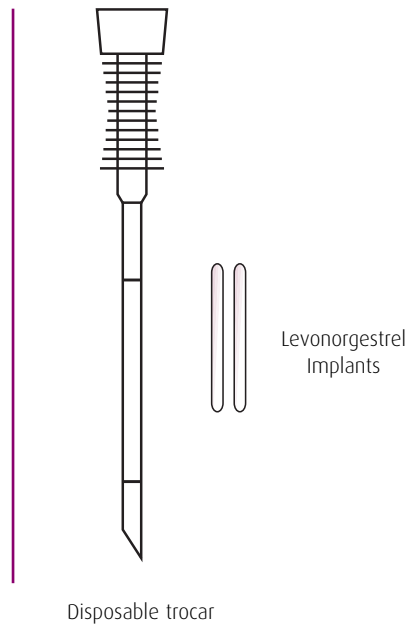
- »» Long-acting reversible method: up to 5 years usage with one single administration not requiring daily, weekly, monthly or quarterly remembering or action
- »» Effective: as reliable as sterilization but reversible
- »» Convenient and discreet: Jadelle goes wherever she goes unnoticeably
- »» Cost-effective in long term use¹

Advanced contraceptive technology

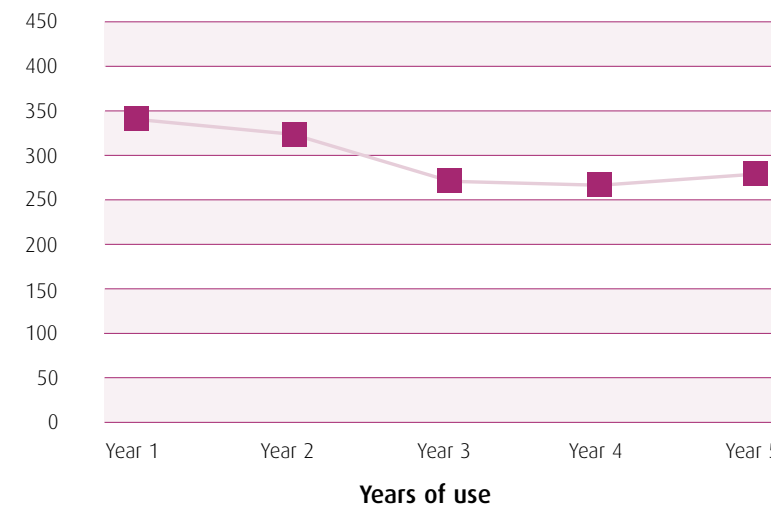
Jadelle is a progestin-only contraceptive system to be inserted just under the skin of the non-dominant upper arm in the shape of a narrow V. It consists of two sterile, flexible silicone-based rods. Each rod is 43 mm long, 2.5 mm in diameter and contains 75 mg of levonorgestrel.

The insertion is done under local anesthesia through a disposable trocar with CE mark. After insertion Jadelle continuously releases levonorgestrel and provides contraception for up to 5 years.

Jadelle – Product components



Mean levonorgestrel (pg/ml)



Mean serum levels of levonorgestrel²

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Mode of action

Jadelle is one of the most effective reversible contraceptive methods. One set of rods provides contraceptive protection for up to 5 years, with annual pregnancy rates of 0–0.8% (cumulative pregnancy rate 1.1% over 5 years), which is comparable to sterilization.

However, fertility rapidly returns following removal of the rods. Pregnancy rate of less than 1 per 1000 woman-years is lower than the rate in women using no contraception³.

The high contraceptive efficacy of Jadelle is based on the following mechanisms:

- » Thickening of the cervical mucus
- » Inhibition of ovulation (in about 45–85% of menstrual cycles)
- » Suppression of endometrial maturation
- » Decreased natural progesterone production from the ovary during the post ovulatory phase

The mean estradiol levels during the 5 years of use do not differ from those in control patients^{4,5}, which is reflected, for instance, in unchanged bone health⁶.

Percentage of women experiencing an unintended pregnancy within the first year of use (Pearl Index).

Less than 1 pregnancy
per 100 women in year

2–8 pregnancies
per 100 women in 1 year

15–25 pregnancies
per 100 women in 1 year

30 or more pregnancies
per 100 women in 1 year

More effective

Less effective

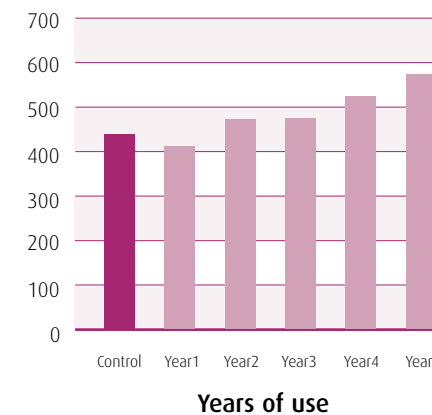
- Implant
- IUS
- IUD
- Sterilization

- Injection
- Pill
- Ring
- Patch

- Condom
- Diaphragm
- Cervical cap

- Spermicide
- Withdrawal

1 Mean estradiol (pmol/l)



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Well tolerated method

Jadelle is a well tolerated method with high annual continuation rates (over 80% per year in the key clinical studies) and low annual rates of removal because of adverse effects (3–9%)³.

As with other progestin-only methods, bleeding irregularities are the most common reasons for discontinuation.

The prospective Jadelle user

Jadelle is an ideal contraceptive for a young, active nulliparous woman who for example:

- » Needs a highly effective but promptly reversible true long-acting contraceptive method
- » Lives a busy life with a lot of other things to think about besides contraception and compliance
- » Cannot use intrauterine devices or estrogen containing methods

Proper times for insertion are:

- » Within 7 days from the onset of menstrual bleeding
- » Immediately or within 7 days postabortion
- » Immediately or within 3 weeks postpartum if the woman is not breastfeeding
- » From 6 weeks postpartum if the woman is breastfeeding.

Our goal: a satisfied user

For the woman to become a satisfied Jadelle user, it is important that

- » She is properly counseled about all contraceptive methods and the features of Jadelle
- » She is informed that the implants may be removed at her request at any time
- » The provider is familiar with the correct insertion and removal technique.

For additional information, please see the full national prescribing information.

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Contraceptive Independence

References:

1. Trussel J, in Hatcher R.A: Contraceptive Technology 17th Ed. NY, Ardent media Inc.,1998
2. Sivin I, Wan L, Ranta S et al. Contraception 2001; 64(1): 43-49
3. Sivin I, Campodonico I, Kiriwat O et al. Hum Reprod. 1998; 13(12): 3371-78
4. Croxatto H, Diaz S, Pavez M et al. Contraception 1988a; 38(4): 465-475
5. Brache V, Alvarez-Sanchez F, Faundes A et al. Contraception 1990; 41(2): 169-177
6. Cromer BA, Blair JM, Mahan JD et al. Journal of Pediatrics 1996; 129: 671-676
7. Finnish Pharmaceutical Data Ltd., Norwegian Medicines Agency, General Spanish Council of Pharmacists, The Swedish Association of the Pharmaceutical Industry and Pharmaceutical Benefits Board

Abbreviated Prescribing Information:

This section is intended as general reference source on Jadelle for the international reader. For detailed information, please refer to the prescribing Information of your national regulatory authority.

Jadelle 2x75mg implants

Composition: The product consists of two implants to be inserted subdermally. Each implant contains 75 mg levonorgestrel. The release rate of levonorgestrel is about 100 microgram/day at one month after insertion, declining to about 40 microgram/day within one year, to about 30 microgram/day within 3 years, and to about 25 microgram/day within five years. **Indication:** Contraception. **Method of administration:** For subcutaneous use for long-term (up to five years) contraception. The user must be informed that Jadelle can be removed at her request at any time. Training is required for the insertion and removal procedures, which should be done by a health care professional and the insertion instructions must be closely followed. Jadelle should be inserted within 7 days from the onset of menstrual bleeding. If the implants are inserted at any other time, pregnancy must be reliably excluded before insertion and an additional non-hormonal contraceptive method used for at least 7 days after the insertion. **Contraindications:** Hypersensitivity to levonorgestrel or any other component of Jadelle, Undiagnosed abnormal vaginal bleeding, Diagnosed or suspected sex hormone dependent neoplasia, Acute liver disease, Benign or malignant liver tumor, Thromboembolic disease. **Special precautions:** See full prescribing information. **Most common undesirable effects:** Headache, nervousness, dizziness, nausea, changed menstrual bleeding (frequent, irregular or prolonged menstrual bleeding, spotting amenorrhea), cervicitis, vaginal discharge, genital pruritus, pelvic pain, breast pain, weight gain. For further details see the full prescribing information. **Marketing authorization holder:** Bayer Pharma AG (local subsidiary).

www.jadelle.com



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