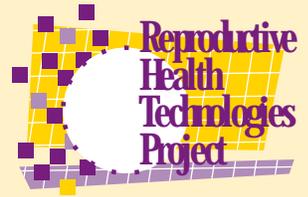




What You Need to Know About Nonoxynol-9



OVERVIEW

This fact sheet presents current data on the spermicide nonoxynol-9 (N-9) for contraception and for preventing HIV and other sexually transmitted infections (STIs). The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) agree on the following recommendations:

- N-9 is a safe, effective contraceptive option for women at low risk for HIV/STIs who do not use the product more than once a day;
- N-9 should not be used to prevent HIV/STIs; and
- N-9 should not be used rectally.

N-9 is the active ingredient in all of the over-the-counter (OTC) spermicidal products available in the U.S. and has been used for pregnancy prevention since the 1950s. An Advisory Review Panel of the Food and Drug Administration (FDA) has deemed N-9 a safe and effective contraceptive,¹ and a small number of American women currently use N-9 products alone or with barrier methods to prevent pregnancy. N-9 is an important contraceptive option for these women and their partners.

The need for a female-controlled method for preventing HIV/STIs led to more than a decade of research on whether N-9 would be an effective vaginal microbicide (defined as a topical method that prevents HIV/STIs).² An international panel of scientists, convened by the WHO in 2001, reviewed available published studies and concluded that N-9 should not be used for HIV/STI prevention.

WHAT IS N-9?

Mechanism of Action

N-9 is the active ingredient in all OTC spermicidal products in the U.S. N-9 is a chemical detergent that damages sperm cell membranes, killing the cells.

Products Containing N-9

N-9 is marketed and sold as a spermicidal contraceptive product in several different formulations, including:

- Suppositories - Foam - Film - Gel - Cream

Diaphragms and cervical caps are FDA approved for use in conjunction with spermicidal gels and creams. Also, some condoms include a spermicidal lubricant.

N-9 Users

Excluding condom use, about 3.1% of American women at risk of an unintended pregnancy used a spermicide alone or with a barrier method in 1995 (the most recent year for which data are available).³

SAFETY OF N-9

- N-9 has long been considered a safe and effective contraceptive method. It is still considered safe for women at low risk for HIV/STIs who do not use the product more than once a day.
 - Recent studies indicate that N-9 may potentially damage both vaginal and rectal cells, which could facilitate transmission of HIV/STIs under certain conditions.⁴
 - Frequent vaginal doses of N-9 consistently cause some damage to cells in the vagina, but small, infrequent vaginal doses (<150 mg once a day or less) of N-9 appear to cause little or no damage.^{5,6,7,8}
- When used rectally, even low doses or infrequent use of N-9 causes damage and likely increases susceptibility to HIV/STIs.^{9,10,11}
- The FDA recently proposed a change in labeling for N-9 products to inform consumers that N-9 does not offer protection against HIV/STIs.¹² The FDA has received public comments and is currently working on revised labeling for products containing N-9.

EFFECTIVENESS OF N-9 FOR PREGNANCY PREVENTION

- N-9 used alone is a moderately effective contraceptive. The contraceptive failure rates for spermicides range from 29% for typical users during the first year of use to about 18% for perfect users (used correctly and consistently).¹³ This means that of 100 women using N-9 alone for contraception over the course of one year, between 18 and 29 of them will experience an unintended pregnancy.
- A recent study on whether N-9 dosing levels (amount of N-9 in the product) and formulations (e.g., gel vs. film) affect pregnancy risk found that formulations do not affect risk, but dosing may. The lowest dose product that is commercially available (52.5 mg) is less effective at preventing pregnancy than higher dose products.¹⁴
- There is no evidence that condoms lubricated with N-9 are more effective in preventing pregnancy than lubricated condoms without N-9.¹⁵
- Limited evidence suggests that the contraceptive effectiveness of the diaphragm and cap may be moderately higher when used with a spermicide than without.¹⁶

EFFECTIVENESS OF N-9 AT PREVENTING HIV/STIs¹⁷

- Most clinical evidence on risk of HIV/STI infection with use of N-9 comes from studies conducted among women who were sex workers or women attending STI clinics. This research indicates that N-9 does not reduce the risk of HIV/STIs among these women.
- There is some evidence to suggest that, when used more than once per day in the vagina, N-9 may cause cell damage or inflammation, which could potentially increase the risk of contracting HIV/STIs during vaginal sex. Evidence also suggests that N-9 is considerably more damaging when used in the rectum, and even infrequent use might increase risk of infection during anal sex.
- There is no published scientific evidence that N-9-lubricated condoms provide any additional protection against STIs compared with condoms lubricated with other products.

N-9 USE RECOMMENDATIONS FROM WHO¹⁸ AND CDC¹⁹

- N-9 **can be used** as a contraceptive, alone or in combination with a cervical barrier method, among women at low risk of HIV/STI infection who use the product no more than once daily.
- N-9 **should not be used** for the purpose of HIV/STI prevention.
- N-9 **should not be used** for contraception by women at high risk of HIV infection.
- Condoms with N-9 **should not be promoted** for disease prevention. (However, it is better to use N-9-lubricated condoms than no condoms at all.)
- N-9 **should not be used** rectally.

RESEARCH & DEVELOPMENT

- In the U.S., there are only two OTC female-controlled contraceptive options available – the female condom and N-9 spermicides. There is a need to expand OTC contraceptive options available to women, including the development of alternative spermicides.
- Research must continue on the development of a safe and effective microbicide. More than 60 compounds are currently being studied, including 11 that are being studied in humans. A microbicide could be available in five to seven years.²⁰ Most studies, however, are evaluating products for HIV/STI prevention (and not pregnancy prevention).
- Research is needed on whether cervical barrier methods, when used with a non-spermicidal lubricant, are effective contraceptives or offer any HIV/STI protection. One such study is underway. The Methods for Improving Reproductive Health in Africa (MIRA) trial is testing the diaphragm used with Replens® gel for HIV/STI prevention and results are expected in 2007. For more information on this trial and on cervical barriers generally, visit www.cervicalbarriers.org.

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Ibis Reproductive Health

A non-profit organization based in Cambridge, MA that aims to improve women's reproductive health, choices, and autonomy. Ibis' work includes clinical and social science research, policy analysis, and evidence-based advocacy. www.ibisreproductivehealth.org

Reproductive Health Technologies Project

A DC-based non-profit organization working to advance the ability of every woman to achieve full reproductive freedom with access to the safest, most effective, and preferred methods for controlling her fertility and protecting her health. www.rhttp.org