

Gynol II[®] Vaginal Jelly

Nonoxinol 9

Patient Information Leaflet

What is in this leaflet

This leaflet answers some of the common questions about GYNOL II. It does not contain all of the available information. It does not take the place of talking to your doctor, pharmacist or family planning clinician.

If you have any concerns about using GYNOL II, ask your doctor or pharmacist. Your doctor and pharmacist have more information.

Keep this leaflet with your GYNOL II vaginal jelly. You may need to read it again.

What GYNOL II is used for

GYNOL II is used along with a barrier method of contraception, such as a vaginal diaphragm, to prevent pregnancy.

By using a vaginal diaphragm, access to the cervix is blocked, preventing the passage of sperm into the womb. Spermicides, such as GYNOL II, will kill sperm that may reach the diaphragm.

GYNOL II does not provide a high degree of protection when used alone.

GYNOL II is for vaginal use only. This product should not be used rectally.

Before you use GYNOL II

When you must not use it

Do not use Gynol II:

- if you are, or think you may be, pregnant;
- if you know you are allergic to any of its ingredients (signs of allergy include skin rash, itching, shortness of breath, and/or swollen face - see the last section of this leaflet for a list of ingredients);
- if you are paraplegic, quadriplegic or have no sensation in the vagina for any other reason;
- if the packaging is torn or shows signs of being tampered with.

Before you start to use it

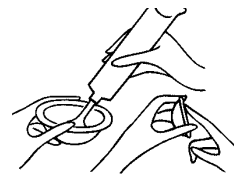
- If you are breast-feeding, discuss the use of this product with your doctor or pharmacist.

- Where avoidance of pregnancy is essential, you should see your doctor or family planning clinic about the most appropriate method of contraception for you.
- **Sexually transmitted diseases (STDs) alert:** This product does **not** protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs).
- **Ask a doctor before use if you have** a new sex partner, multiple sex partners, or unprotected sex. Frequent use (more than once a day) of this product may increase vaginal irritation, which may increase the risk of becoming infected with the AIDS virus (HIV) or other STDs from infected partners. Ask a doctor or other health professional for your best birth control method.

Using GYNOL II

How to use it

1. For your personal comfort and correct fitting, empty your bladder and bowel. Wash your hands with soap and water before you use GYNOL II or handle the diaphragm.
2. Place 5 g (one teaspoon) of contraceptive jelly into the dome of the diaphragm. Spread small amount around the rim with your fingertip. The spermicide on the rim makes the diaphragm easier to insert and helps seal the diaphragm in place. The diaphragm is now ready for insertion.



3. The diaphragm should be put in place inside the vagina before intercourse and **left there for at least 6 hours after intercourse** to prevent pregnancy.
4. More GYNOL II jelly must be applied before each act of intercourse. The jelly must be applied **without** removing the diaphragm using an ORTHO™ Vaginal Applicator (available separately).
5. Screw the applicator to the tube. Squeeze the tube gently until the applicator plunger is fully extended. Then unscrew the applicator from the tube.



6. Hold the filled applicator by the cylinder and gently insert it into the vagina as far as comfortably possible.
7. Press the plunger to apply the jelly. Remove the applicator with the plunger still depressed.
8. After each use, wash the applicator with mild soap and warm water and rinse thoroughly. Do not boil the applicator.

If you forget to use it

GYNOL II is only effective if used with a diaphragm every time you have intercourse. Failure to apply GYNOL II before each act of intercourse will reduce the effectiveness of the diaphragm as a contraceptive. If no other effective method of contraceptive is used, you may fall pregnant.

Overdose

If you think you or somebody else has swallowed GYNOL II, contact your doctor or pharmacist or the Poisons Information Centre in your state who will advise you what to do.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Keep these telephone numbers handy.

While you are using GYNOL II

Things you must do:

- Always follow these instructions carefully.
- **Stop use and ask a doctor** if you or your partner get burning, itching, a rash, or other irritation of the vagina or penis.

Things you must not do:

- Petroleum jelly, mineral oil and cold cream lubricants should NOT be used at the same time as the diaphragm as they may damage the diaphragm.
- Do not leave the diaphragm in your vagina for longer than 24 hours. Continuous wearing of a diaphragm for more than 24 hours may encourage the growth of bacteria in the vagina.
- Do not use GYNOL II beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly. Medicines cannot be stored indefinitely.

Things to be careful of

- Some vaginal medications and lubricating agents may contain ingredients that can damage or reduce the effectiveness of a contraceptive diaphragm. You should

discuss the use of any such vaginal preparation with your doctor, pharmacist or family planning clinic.

- Washing your vagina (douching) after intercourse is not required. However, if you wish to do so, you must wait for at least 6 hours after intercourse.

Side Effects

GYNOL II is usually well tolerated, but tell your doctor as soon as possible if you do not feel well while you are using GYNOL II.

GYNOL II may occasionally cause irritation of the vagina or penis. If this occurs, stop using it immediately. If the symptoms get worse or have not cleared within 48 hours, contact your doctor.

After using GYNOL II

Storage

- Keep your GYNOL II in a cool, dry place where the temperature stays below 25°C.
- Do not store it or any medicines in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Product Description

What it looks like

GYNOL II is a translucent odourless jelly. It is supplied in a 108 g plastic tube. An ORTHO™ Vaginal Applicator is available separately.

Ingredients

GYNOL II contains the active ingredient nonoxinol 9 (20 mg/g). Other ingredients include propylene glycol, sorbitol solution, carmellose sodium, povidone, methyl hydroxybenzoate, sorbic acid, lactic acid and purified water.

Sponsor

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