

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Gygel Contraceptive Jelly Nonoxinol-9

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or family planning clinic if you need more information.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Gygel Contraceptive Jelly. Throughout the rest of this leaflet, it will be referred to as Gygel.

In this leaflet:

1. What Gygel is and what it is used for
2. Before you use Gygel
3. How to use Gygel
4. Possible side effects
5. How to store Gygel
6. Further information

1. WHAT GYGEL IS AND WHAT IT IS USED FOR

Gygel is called a spermicidal contraceptive since it kills sperm. It should be used along with a barrier method of contraception, such as a vaginal diaphragm or cap, in order to prevent pregnancy.

How does Gygel work?

Following sex, pregnancy may occur if a sperm travels up the vagina and through the entrance to the womb (cervix) and beyond, where it might fertilise an egg. By using a vaginal diaphragm or cap, access to the cervix is blocked, preventing the passage of sperm into the womb.

Spermicidal contraceptives such as Gygel will kill any sperm that may get round a diaphragm, and so will provide more effective contraception.

2. BEFORE YOU USE GYGEL

Do not use Gygel if you:

- have ever experienced an allergic reaction to nonoxinol-9 or to any of the other ingredients in Gygel (see 'What Gygel contains')
- are paraplegic, quadriplegic or have no sensation in your vagina for any other reason
- are pregnant or think you may be pregnant.

Speak to your doctor or family planning clinic before using Gygel if:

- it is important that you do not get pregnant. Spermicidal contraceptives such as Gygel are intended for use with a barrier method of contraception, but they may not be the most appropriate method of contraception for you.
- you have sex more than three times a day since the nonoxinol-9 present in Gygel may cause genital skin problems and increase the chance of you getting HIV (AIDS) infection.
- you are at risk of getting HIV (AIDS) or another sexually transmitted disease since Gygel does not protect against HIV (AIDS) or other sexually transmitted diseases. You should use a latex condom to protect against the spread of sexually transmitted diseases (STD's).

If you have any doubts about whether you should use Gygel then discuss things more fully with your doctor, family planning clinic or pharmacist.

Taking other medicines

Always tell your doctor, family planning clinic or pharmacist if you are taking any other medicines because using some medicines together can be harmful.

Gygel is not known to react with other medicines. However, some vaginal products and lubricating agents may contain ingredients that can damage contraceptive diaphragms/caps made from latex rubber. As a result these may be less effective as a barrier against pregnancy and as a protection from sexually transmitted diseases including HIV. If you are in doubt you should discuss the use of any such vaginal preparation with your doctor, pharmacist or family planning clinic.

The following products should **NOT** be used at the same time as your vaginal diaphragm or cap.

- Petroleum jelly (Vaseline);
- Mineral oil (baby oil);
- Oil-based vaginal and rectal preparations.

Gygel need not be used with a condom.

Pregnancy and breast-feeding

You should not use Gygel if you are pregnant or think you may be pregnant.

Do not use Gygel if you are breast-feeding without talking to your doctor or family planning clinic first.

Driving and using machines

Gygel has not been reported to affect your ability to drive or operate machinery.

Important skin allergy information

Gygel contains propylene glycol which may cause skin irritation.

Gygel also contains Sorbic acid (E200) which may cause local skin reactions, (e.g. contact dermatitis).

3. HOW TO USE GYDEL

- Extra gel may be inserted into the vagina using a Vaginal Applicator.

Use with a diaphragm

- With clean hands put about two 2cm strips of gel on each side of your diaphragm. Make sure you also spread it along the outside rim of your diaphragm to prevent any sperm from getting past the edge.

Use with a cap

- Fill one third of the cap with spermicide. Silicone caps have a groove between the dome and the rim and some gel should be placed there also. Do not put any spermicide around the rim as this will stop the cap from staying in place.
- If using a diaphragm/cap this should be put in place inside the vagina before sex and left there for at least **six hours after sex**.
- If you have sex again during this time, you must apply more Gydel or another spermicide without **removing the diaphragm or cap**.
- If you have sex 3 hours or more after inserting your diaphragm or cap you will need to insert some extra gel.

Warning: your diaphragm should not be left in your vagina for longer than 24 hours.

There is no need to wash your vagina (douching) after sex. However, if you wish to do so, you must wait for at least six hours after intercourse.

Missed dose

If you forget to use Gydel or another form of contraception when you have sex you will not be protected against pregnancy and you should see your doctor if necessary. Ensure that you use Gydel on future occasions.

If you have any further questions on the use of this product, ask your doctor, family planning clinic or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Gydel can cause side effects, although not everybody gets them.

- Gydel may cause irritation of the vagina or penis. If this occurs, you should **stop using it immediately**. If the irritation gets worse or carries on for more than 48 hours, contact your doctor or family planning clinic for advice.
- Other symptoms suggesting an allergy to Gydel include pain, discomfort, a burning sensation, itching, dryness, redness or rashes of the vagina or penis.
- If this product affects you in any other way, you should tell your doctor, family planning clinic or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What if Gydel Contraceptive Jelly is swallowed?

Gydel should only be used in the vagina. If put in the mouth, it is likely to taste unpleasant. However, if large quantities are accidentally swallowed, it may cause stomach irritation. In this case you should seek **immediate** help from the nearest hospital casualty department.

5. HOW TO STORE GYDEL

Keep out of the sight and reach of children.

- Do not use Gydel after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- Do not use Gydel if you notice that the container has been damaged.
- Do not store above 25°C.
- Store in the original package in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Gydel contains

The active ingredient in Gydel is nonoxinol-9 2.0% w/w. The other ingredients are: methyl parahydroxybenzoate (E 218), Sorbitol solution (E 420), lactic acid, Povidone K30, propylene glycol, sodium carboxymethylcellulose, Sorbic acid (E 200) and purified water.

What Gydel looks like and the contents of the pack

Gydel is available in an aluminium tube containing a clear odourless vaginal gel. A Vaginal Applicator is available separately.

Gydel is available in a 30g or 81g tube.

Marketing Authorisation holder:

Marlborough Pharmaceuticals Ltd, 35A High Street, Marlborough, Wilts, SN8 1LW, UK
Tel 01672 514187

Manufacturer: PHARBIL Waltrop GmbH, Im Wirrigen 25, D-45731, Waltrop, Germany

For information in large print, tape, CD or Braille, telephone 01672 514187

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