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GLOVAN

VAGINAL OVULES

Composition

Each vaginal ovule contains:

Active Ingredient

| | |
|-----------------|--------|
| Nonoxynol 9 | 140 mg |
| Ricinoleic acid | 25 mg |

Other Ingredients

Witepsol W-35, polysorbate 61, lactic acid.

Mechanism of Action

Glovan is a topical spermicide. Nonoxynol-9 is responsible for cell membrane breakage; it decreases surface tension and kills epithelial cells. Following insertion into the vagina, the Glovan ovule dissolves and provides protective contraceptive coverage of the vaginal vault. Glovan is not 100% effective in contraception.

Glovan is used either in conjunction with a vaginal diaphragm or as the sole method of contraception.

Indications

Spermicide contraceptive.

Contraindications

Known hypersensitivity to either of the components of the preparation.

Vaginal anesthesia, as in spinal cord injuries.

Pregnancy.

Warnings

Before using Glovan, pregnancy should be ruled out (see Contraindications).

Use of Glovan does not preclude the possibility of contraception. Patients should be advised to report if a menstrual period is missed.

Vaginal contraceptives containing nonoxynol 9 do not protect against infection from HIV (human immunodeficiency virus, the AIDS virus) or other sexually transmitted diseases (STDs). Use of vaginal contraceptives containing nonoxynol 9 can increase vaginal irritation, which may actually increase the possibility of transmitting the AIDS virus and other STDs from infected partners.

Use in Pregnancy and Lactation

There is no evidence from animal and human studies that nonoxynol 9 is teratogenic. Human epidemiological studies have not shown any firm evidence of adverse effects on the foetus, however some studies have shown that nonoxynol 9 may be embryotoxic in animals. This product should not be used if pregnancy is suspected or confirmed. Animal studies have detected nonoxynol 9 in milk after intravaginal administration. Use by lactating women has not been studied.

Adverse Reactions

Some local irritation (allergic vaginitis, contact dermatitis) to the female or male genitalia may occur occasionally. Urinary tract infection in females may also occur.

Precautions

When pregnancy must be avoided on medical grounds, the patient should be advised to use alternative methods of contraception, or use Glovan in conjunction with barrier methods (diaphragm, condom).

Dosage and Administration

1 Glovan ovule should be inserted 15-30 minutes prior to intercourse, as deep as possible into the vagina. If intercourse is repeated, another Glovan ovule should be inserted, in the same way.

If vaginal douching is desired, it should be delayed for 6 hours following intercourse, to avoid washing out the spermicidal protection.

If intercourse is delayed for more than an hour after insertion of the ovule, a new one should be used.

The ovule may be wetted with a little water to ease insertion and prevent irritation

Overdosage

If taken orally, the surfactant properties of this preparation may cause gastric irritation. General supportive therapy should be carried out. Hepatic and renal function should be monitored if medically indicated.

Storage

Store in a cool place.

Manufacturer

Teva Pharmaceutical Industries Ltd
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