

GYNOL II EXTRA STRENGTH- nonoxynol gel
Caldwell Consumer Health LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Nonoxynol-9 (3%) (100 mg per applicatorful).....Vaginal Contraceptive

Uses

For the prevention of pregnancy.

With condom or alone.

For vaginal use only.

Not for rectal (anal) use.

Sexually transmitted diseases (STDs) alert:

This product does not protect against HIV/AIDS or other STDs and may increase the risk of getting HIV from an infected partner.

Do not use if you or your sex partner has HIV/AIDS. If you do not know if your sex partner is infected, choose another form of birth control.

Stop use and ask a doctor if you or your partner gets burning, itching, a rash, or other irritation or the vagina or penis.

Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.

Directions

For maximum protection against unwanted pregnancy, follow the enclosed directions exactly.

Each applicatorful is effective immediately and up to one hour after application.

Insert one applicatorful into the vagina prior to intercourse (see complete, illustrated directions on the package insert).

An additional applicatorful is required prior to each act of intercourse, regardless of time since last application.

Other Information

When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of catching or spreading HIV, the virus that causes AIDS.

Store at room temperature, 20° - 25° C (68° -77° F). Avoid exposure to extremes of hot or cold.

Inactive ingredients

Lactic acid, methylparaben, povidone, propylene glycol, purified water, sodium carboxymethylcellulose, sorbic acid, sorbitol solution.

EXTRA STRENGTH



Options

GYNOL II
VAGINAL CONTRACEPTIVE GEL

Adds sperm-killing power to diaphragms, condoms and can be used alone.

Safe

Hormone-Free

NET WT. 2.85 oz. (81g)



Directions for use with a diaphragm: Prior to inserting your diaphragm, put an applicatorful (about a teaspoonful) of Options Gynol II[®] Extra Strength Gel into the dome and spread a small amount around the edge with your fingertip. Then insert. If intercourse occurs more than 6 hours after insertion, or if repeated intercourse takes place, an additional application of Options Gynol II is necessary. **DO NOT REMOVE THE DIAPHRAGM** - simply add more Options Gynol II with the applicator, being careful not to dislodge the diaphragm.

Please read complete directions and precautions, including directions for use with a condom or as a use-alone product.

TAMPER-EVIDENT FEATURE: SEAL OVER TUBE OPENING. DO NOT USE IF SEAL HAS BEEN PUNCTURED OR DAMAGED.

TO OPEN: USE CAP TO PUNCTURE SEAL.

Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Active ingredient: Nonoxynol-9 (3%)
(150 mg of Nonoxynol-9 per applicatorful).

See tube crimp for lot number and expiration date.

Store at room temperature 20°-25°C (68°-77°F). Avoid exposure to extremes of hot and cold.

Distributed by: Revive Personal Products Company
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Madison, NJ 07940
www.reviveppc.com
Made in USA



GYNOL II EXTRA STRENGTH

nonoxynol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:34362-0302 |
| Route of Administration | VAGINAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| NONOXYNOL-9 (UNII: 48Q180SH9T) (NONOXYNOL-9 - UNII:48Q180SH9T) | NONOXYNOL-9 | 3.0 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |

| | |
|---|--|
| SORBIC ACID (UNII: X045WJ989B) | |
| METHYL PARABEN (UNII: A2I8C7H9T) | |
| LACTIC ACID (UNII: 33X04XA5AT) | |
| POVIDONE K29/32 (UNII: 390RMW2PEQ) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |

| Product Characteristics | | | |
|--------------------------------|-------|---------------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | | |
|------------------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:34362-0302-5 | 1 in 1 CARTON | 12/01/2020 | |
| 1 | NDC:34362-0302-1 | 81 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 05/01/2011 | |

Labeler - Caldwell Consumer Health LLC (828558713)

Registrant - Lornamead (126440440)

| Establishment | | | |
|----------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| DPT Laboratories | | 832224526 | manufacture(34362-0302) , pack(34362-0302) |

Revised: 12/2020

Caldwell Consumer Health LLC