

**CONCEPTROL OPTIONS- 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.*

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**Drug Facts**

**Active ingredient**

Nonoxynol-9 (4%) (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.

mm1.jpg



MM2.jpg



**CONCEPTROL OPTIONS**  
nonoxynol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:34362-0300
<b>Route of Administration</b>	VAGINAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
NONOXYNOL-9 (UNII: 48Q180SH9T) (NONOXYNOL-9 - UNII:48Q180SH9T)	NONOXYNOL-9	4.0 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBIC ACID (UNII: X045WJ989B)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
LACTIC ACID (UNII: 33X04XA5AT)	
POVIDONE K29/32 (UNII: 390RMW2PEQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:34362-0300-5	10 in 1 CARTON		
1	NDC:34362-0300-1	2.55 g in 1 APPLICATOR		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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(34362-0300) , pack(34362-0300)

Revised: 12/2013

Caldwell Consumer Health LLC