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.

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.

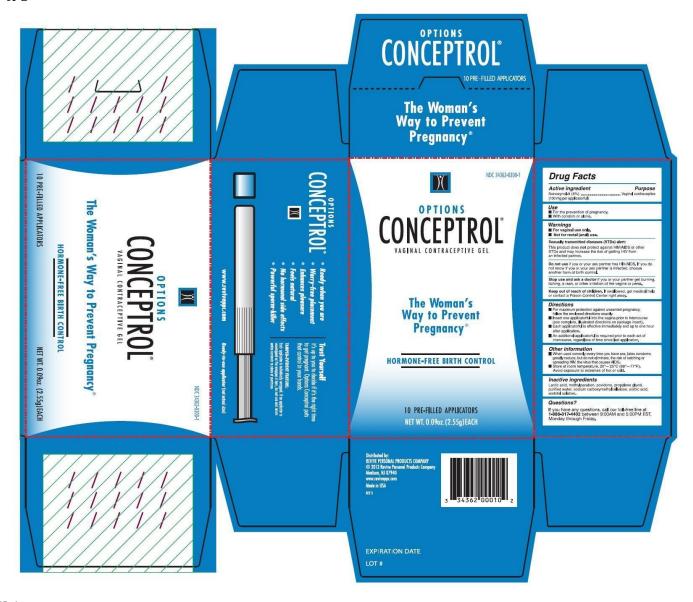
Other Information

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.



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CONCEPTROL OPTIONS

nonoxynol gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:34362-0300 Route of Administration VAGINAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
NONOXYNOL-9 (UNII: 48Q180SH9T) (NONOXYNOL-9 - UNII:48Q180SH9T)	NONOXYNOL-9	4.0 g in 100 g		

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SORBIC ACID (UNII: X045WJ989B)				
METHYLPARABEN (UNII: A218 C7HI9 T)				
LACTIC ACID (UNII: 33X04XA5AT)				
PO VIDO NE K29/32 (UNII: 390 RMW2PEQ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)				

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

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

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(34362-0300), pack(34362-0300)

Revised: 12/2013 Caldwell Consumer Health LLC