

**CVS PHARMACY SENSITIVE MEDICATED CREAM- benzocaine, benzalkonium chloride cream**

**CVS Pharmacy**

*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 Ingredients**

Benzocaine 5%

Benzalkonium Chloride 0.13%

**Purpose**

Topical Analgesic

First Aid Antiseptic

**Uses**

First aid temporary relief from the discomforts affecting the external area surrounding the vagina:

- Itching
- Burning
- Irritation
- Skin infections

**Warnings**

For external use only.

Do not use if you have unusual or abnormal vaginal discharge except under the supervision of your doctor.

**When using this product**

- Wash hand thoroughly with soap and water before and after use
- Avoid contact with eyes.
- If burning sensation occurs and lasts more than a few minutes remove the cream and discontinue use.
- Do not use more than 1 week unless directed by a doctor

**Stop use and ask a doctor if**

- condition worsens or symptoms persist for more than 7 days or clear up and occur again within a few days.
- side effect occur. You may report side effect to FDA at 1-800-FDA-1088

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center immediately. If in eyes, flush with water for 15 minutes and call a physician.

- Apply to the affected area.
- Because the area may already be irritated you could experience a slight burning sensation. If this persists more than a few minutes, remove cream and discontinue use.

- Wash hand thoroughly with soap and water before and after use.

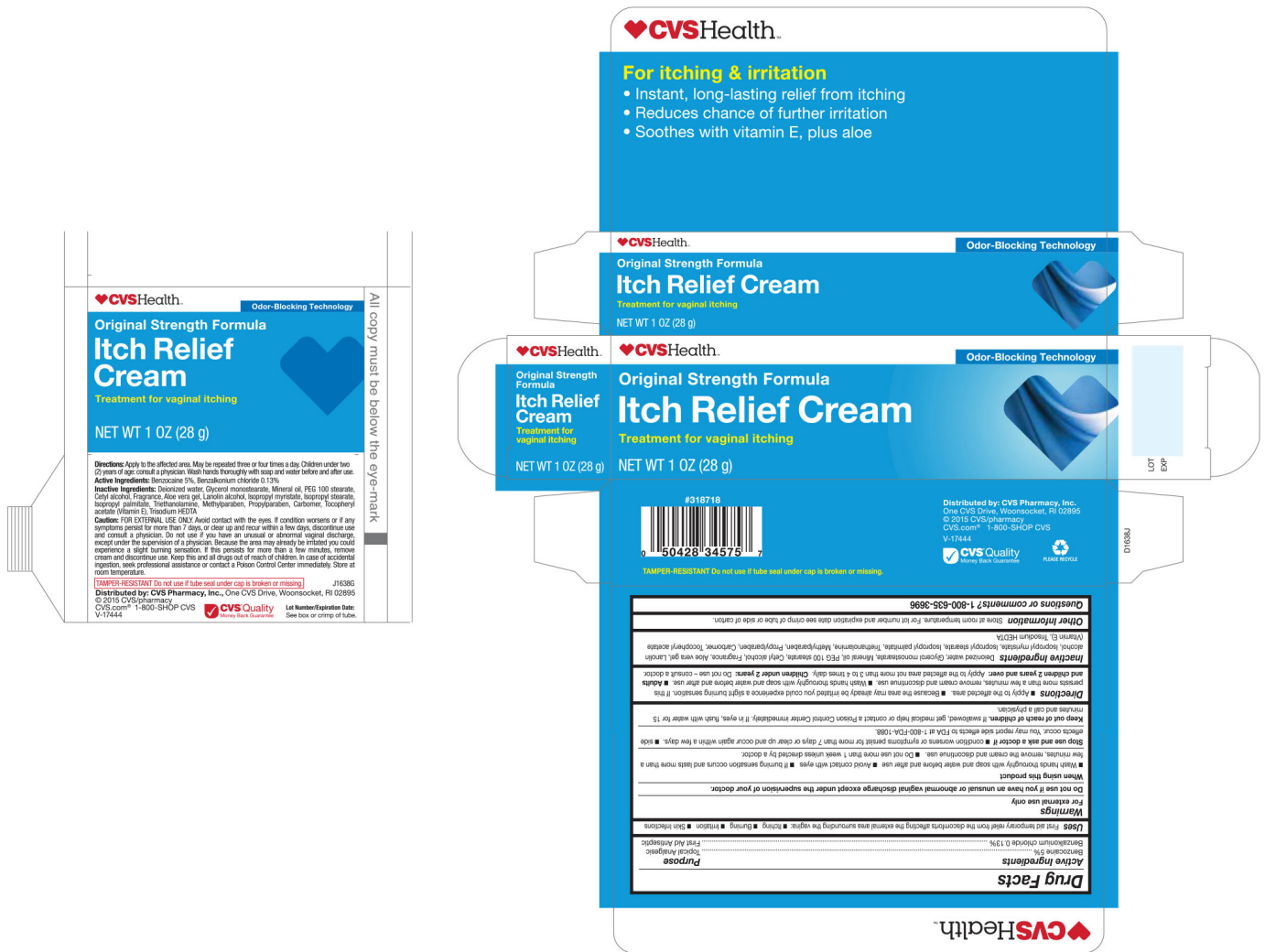
Store at room temperature. For lot number and expiration dates see crimp of tube or side of box.

Deionized Water, Glycerol Monostearate, Mineral Oil, PEG 100 Stearate, Cetyl Alcohol, Fragrance, Aloe Vera Gel, Lanolin Alcohol, Isopropyl Myristate, Isopropyl Stearate, Isopropyl Palmitate, Triethanolamine, Methylparaben, Propylparaben, Carbomer, Tocopheryl Acetate (Vitamin E), Trisodium HEDTA.

## Questions or Comments

1-800-635-3696

- **Adults and children 2 years and over:** Apply to the affected area not more than 3 to 4 times daily.
- **Children under 2 years:** Do not use-consult a doctor.



## CVS PHARMACY SENSITIVE MEDICATED CREAM

benzocaine, benzalkonium chloride cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-638
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.05 g in 1 g
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0013 g in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)	
<b>ISOPROPYL STEARATE</b> (UNII: 43253ZW1MZ)	
<b>LANOLIN ALCOHOLS</b> (UNII: 884C3FA9HE)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>TRISODIUM HEDTA</b> (UNII: K3E0U7O8KI)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-638-01	1 in 1 CARTON	05/01/2005	
1		42.5 g in 1 TUBE; 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	part348	05/01/2005	

**Labeler** - CVS Pharmacy (062312574)