BLACKWORK- numbing spray spray
Private Label Productions 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.

Blackwork Numbing Spray 60 mL

Active Ingredient(s)

Lidocaine HCl 5%

Purpose

Topical Anesthetic

Use

For temporary relief of pain, soreness or burning.

Warnings

■ For external use only. Do not use this product with a mechanical device. ■ Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase, discontinue use and consult a doctor. ■ Do not exceed the daily recommended dosage. ■ In case of any bleeding, discontinue use and consult a doctor. ■ Keep this and all drugs out of reach of children. In case of accidential overdose, seek medical help or call a Poison Control Center right away. ■ As with any drug, consult a health care professional if you are pregnant or nursing. Ask a health care professional before using this product.

Directions

■ Cleanse affected area with mild soap and water. Gently dry by palling or blotting with tissue or a soft cloth before application. ■ Apply externally to the affected area up to 6 times daily.

Keep out of reach of children.

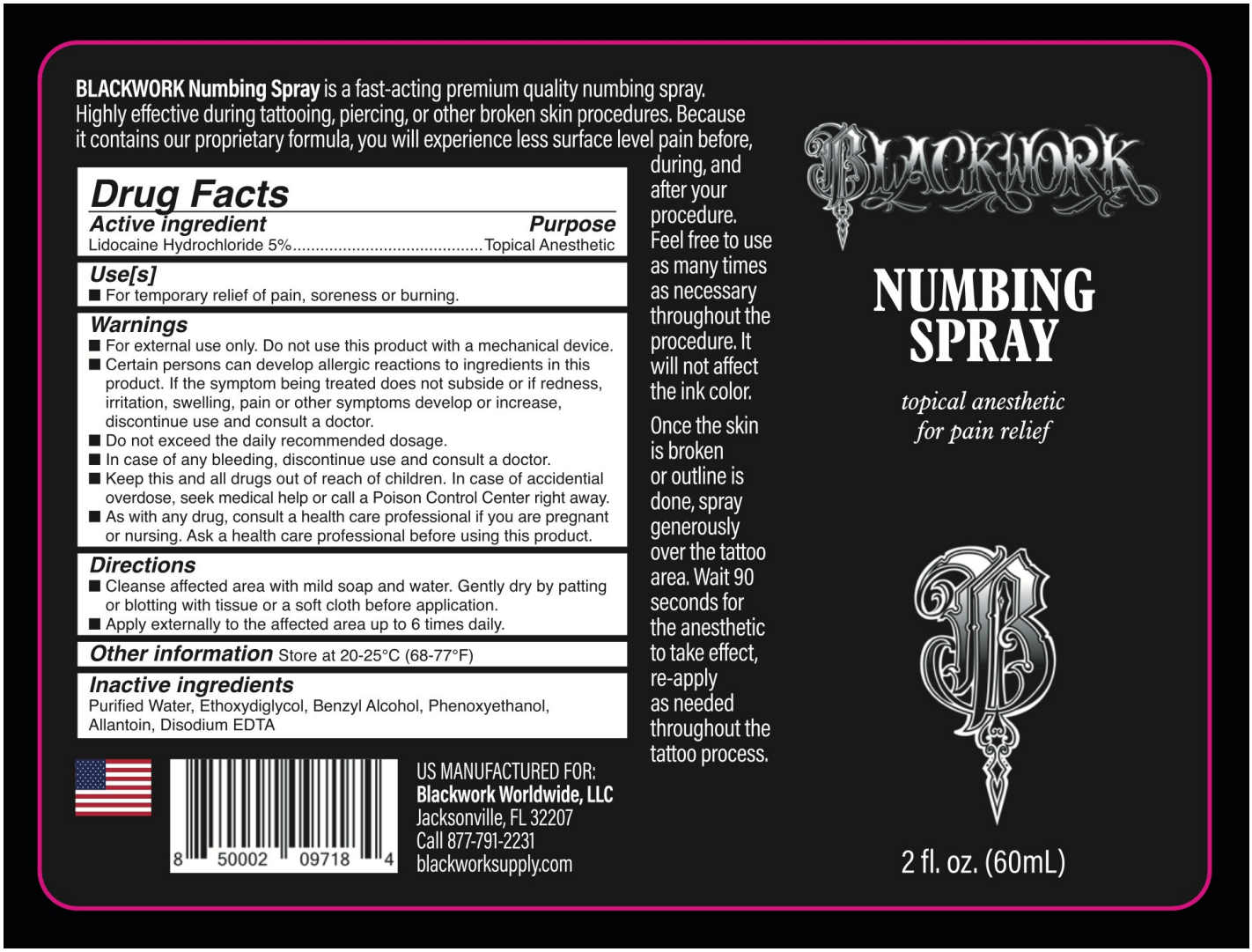
Other information

Store at 20-25°C (equals 68-77°F)

Inactive ingredients

Purified Water, Ethoxydiglycol, Benoy Alcohol, Phenoxyethanol, Allantoin, Disodium EDTA

Package Label - Principal Display Panel



60 mL: NDC: 77632-123-60

BLACKWORK

numbing spray spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77632-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77632-123-60	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/31/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/31/2023	

Labeler - Private Label Productions LLC (046278265)

Revised: 7/2023 Private Label Productions LLC