BURN FIRST AID- burn first aid cream
Dynarex Corporation

1165 First Aid Burn Cream NDC 67777-007-50
1165UB-10 First Aid Burn Cream NDC 67777-007-52
1165UB-25 First Aid Burn Cream NDC 67777-007-54

Active Ingredient

Lidocaine HCl 0.5%

Purpose

Topical analgesic

Active Ingredient

Benzalkonium chloride 0.13%

Purpose

Topical antiseptic

Uses

For the temporary relief of pain and itching associated with sunburn, minor burns, insect bites, minor skin irritation, cuts, scrapes

Warnings

For external use only

Do not use

- in the eyes
- over large areas of the body or on deep puncture wounds, animal bites, or serious burns
- in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask a doctor if

- the condition gets worse
- condition clears up and recurs within a few days
- condition persists for more than 7 days

If pregnant or breast feeding,

ask a health care professional before use.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 2 years and over:

- clean the affected area
- apply a small amount of this product on the area 3 to 4 times daily
- may be covered with a sterile bandage

Children under 2 years:

- consult a doctor

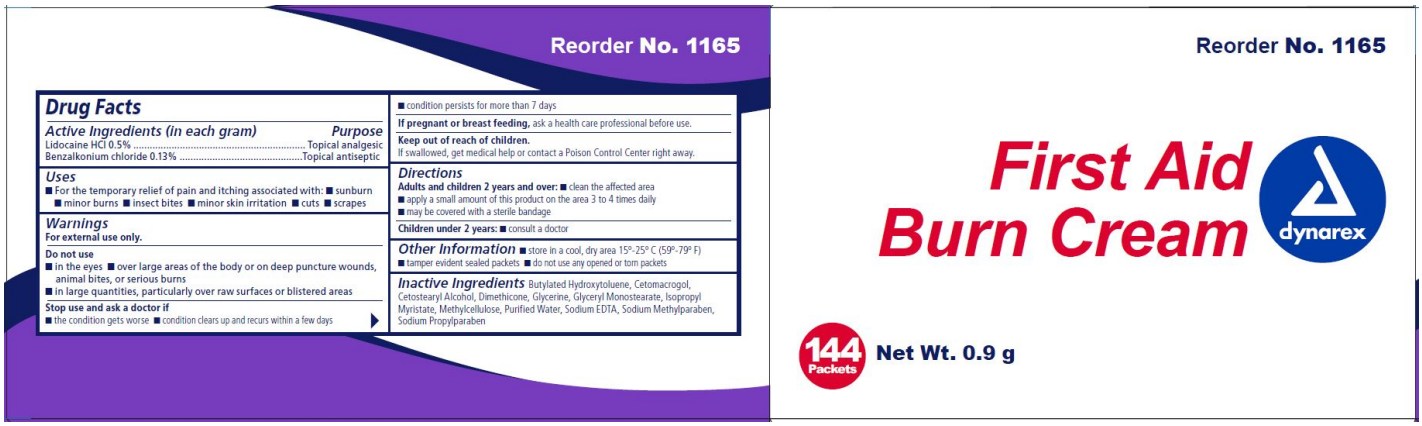
Other Information

- store in a cool, dry area 15°-25° C (59°-79° F)
- tamper evident sealed packets
- do not use any opened or torn packets

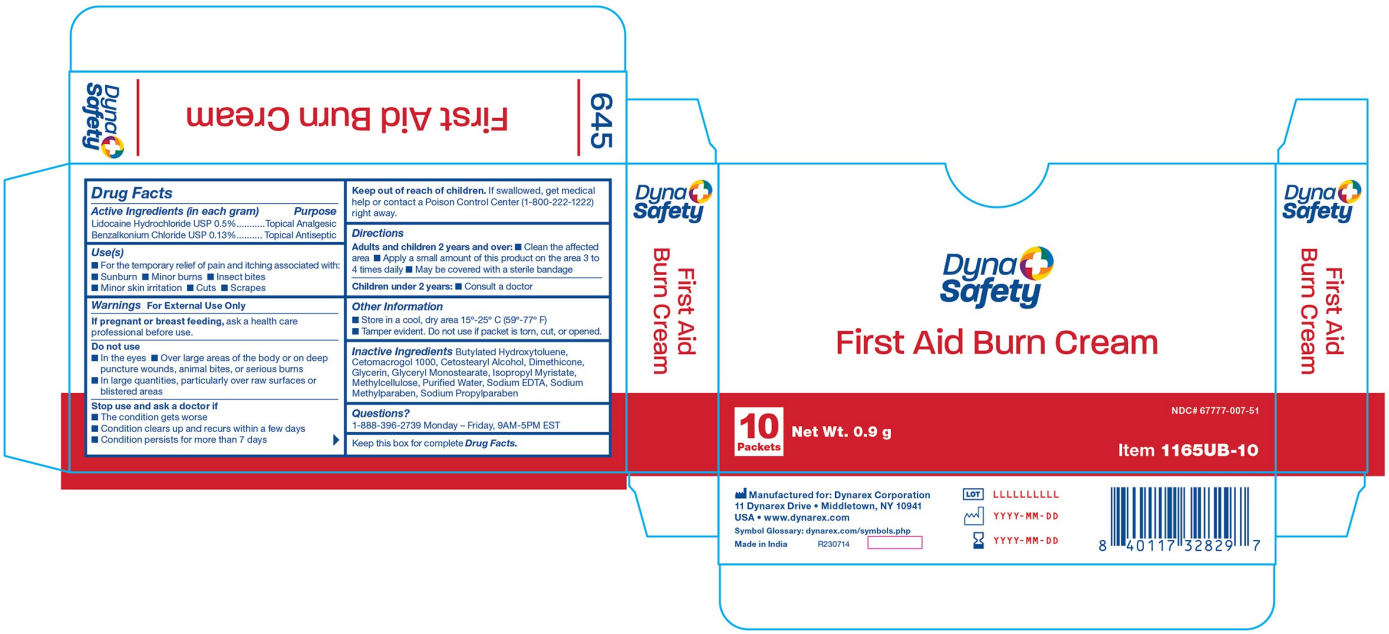
Inactive Ingredients

Butylated Hydroxytoluene, Cetomacrogol, Cetostearyl Alcohol, Dimethicone, Glycerine, Glyceryl Monostearate, Isopropyl Myristate, Methylcellulose, Purified Water, Sodium EDTA, Sodium Methylparaben, Sodium Propylparaben

1165 Label

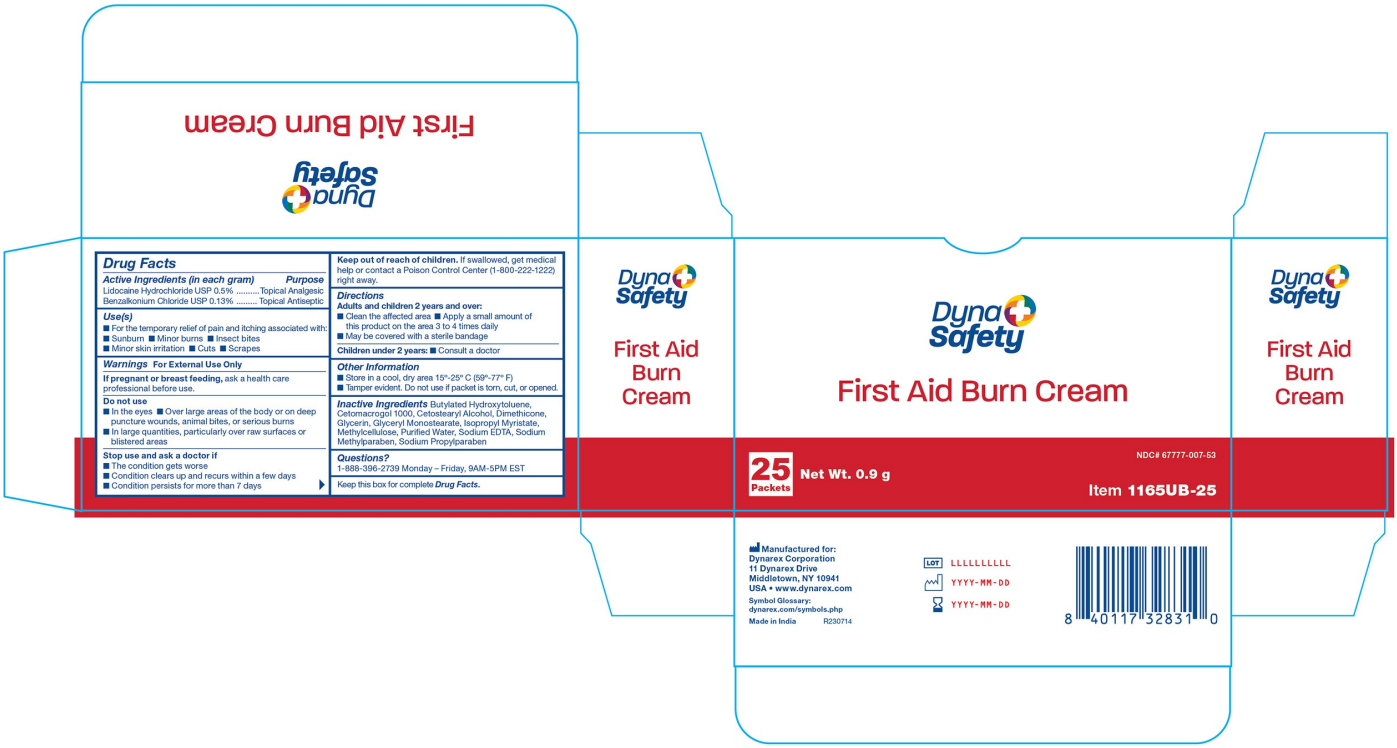


1165UB-10 Label



1165UB-10

1165UB-25 Label



BURN FIRST AID

burn first aid cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	50 mg in 10000 mg
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	13 mg in 10000 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
CETETH-20 (UNII: I835H2IHHX)	
METHYLCELLULOSE (4000 CPS) (UNII: MRJ667KA5E)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	

Product Characteristics

Color		**Score**	
Shape	FREEFORM	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-007-50	1728 in 1 CASE	09/17/2018	
1	NDC:67777-007-49	144 in 1 BOX		
1		900 mg in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:67777-007-52	1000 in 1 CASE	09/17/2018	
2	NDC:67777-007-51	10 in 1 BOX		
2		900 mg in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:67777-007-54	1800 in 1 CASE	09/17/2018	
3	NDC:67777-007-53	25 in 1 BOX		
3		900 mg in 1 PACKET; Type 0: Not a Combination		

3		Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/17/2018	

Labeler - Dynarex Corporation (008124539)

Revised: 1/2024

Dynarex Corporation