

WART REMOVER SET- wart remover set oil
RD2 GROUP, 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.

83436-001
Wart Remover set

Active Ingredient

Salycilic Acid 2%

Purpose

wart remover

Use

To remove warts such as plantar wart, flat wart, common wart

Warnings

For external use only. Keep out of reach of children. Avoid contact with eyes. If product gets into the eye, flush with water for 15 minutes. Avoid inhaling vapors.

Cap tightly and store at room temperature away from heat

Avoid long-term contact with air while using.

The liquid can get easily volatilized & crystallized, tighten the cap after use.

Do not use

on irritated skin or on any area that is infected or reddened

If you are allergic to any of the ingredients in this product.

WHEN USING

Only on the wart

STOP USE

if discomfort persists

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

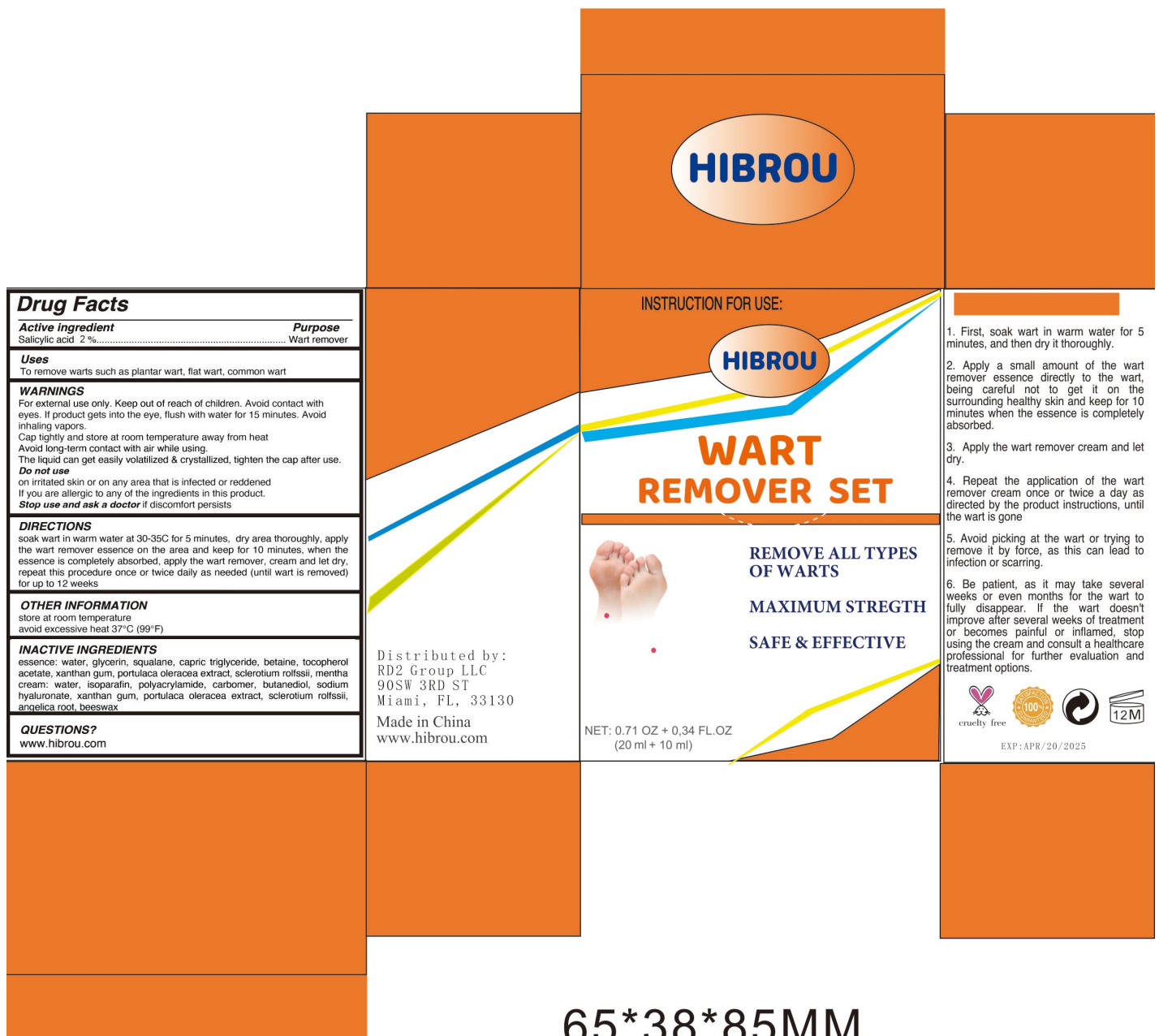
Directions

soak wart in warm water at 30-35C for 5 minutes, dry area thoroughly, apply the wart remover essence on the area and keep for 10 minutes, when the essence is completely absorbed, apply the wart remover, cream and let dry, repeat this procedure once or twice daily as needed (until wart is removed) for up to 12 weeks

Inactive ingredients

Water, Glycerin, Squalane, Caprylic Capric Triglyceride, Propylene Glycol, camellia sinensis leaf extract, Betaine, Cetearyl alcohol, Isononyl isononanoate, CHONDRUS CRISPUS, Hydroxyethyl urea, Polydimethylsiloxane, Trehalose, Erythritol, butyrospermum parkii extract, Isosorbide dimethyl ether, Glyceryl stearate, Tocopherol Acetate, 1,2-Hexanediol, P-hydroxyacetophenone, Cetearyl glucoside, Allantoin, Potassium cetyl phosphate, Carbomer, Hydroxypinacolone retinoate, Triethanolamine, portulaca oleracea l. Extract, Xanthan gum, Laureth-7

83436-001-01



WART REMOVER SET

wart remover set oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83436-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
BETAINE (UNII: 3SCV180C9W)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
HYDROXYETHYL UREA (UNII: MBQ7DDQ7AR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TREHALOSE (UNII: B8WCK70T7I)	
ERYTHRITOL (UNII: RA96B954X6)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
ALLANTOIN (UNII: 344S277G0Z)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
HYDROXYPINACOLONE RETINOATE (UNII: NJ3V2F02E1)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAURETH-7 (UNII: Z95S6G8201)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83436-001-01	30 mL in 1 BOX; Type 0: Not a Combination Product	05/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	05/04/2023	

Labeler - RD2 GROUP, LLC (942996682)

Establishment

Name	Address	ID/FEI	Business Operations
RD2 GROUP, LLC		942996682	label(83436-001) , manufacture(83436-001)

