

TRICLOTREX-B ANTIBACTERIAL (NEUTRAL)- triclosan gel
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS

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.

TRICLOTREX-B ANTIBACTERIAL GEL

THIS PRODUCT IS AN ANTIBACTERIAL GEL WHICH PRODUCES A SYNERGISTIC EFFECT BETWEEN THE TRICLOSAN IS THE ACTIVE INGREDIENT WITH A VOLATILE CARRIER SUCH AS ALCOHOL.

THIS PRODUCT ACT AS A PROTECTOR AGAINST FUNGI AND BACTERIA.

THIS PRODUCT MUST BE KEEP OUT REACH OF EYES CHILDREN.

THIS PRODUCT IS FOR TOPICAL APPLICATION,

IF THIS PRODUCT TO CONTACT WITH EYES RINSE IMMEDIATELY WITH WATER AND CONSULT YOUR DOCTOR

APPLY A MODERATE AMOUNT OF TRICLOTREX GEL ON THE PALM OF YOUR HAND AND RUB SPREADING IT EVENLY OVER BOTH HANDS.

TRICLOSAN, CETIOL AND ALOE VERA EXTRACTS BUILT A PROTECTIVE GLOVE FOR YOUR HANDS PREVENTING THE CONTAMINATION CAUSED BY FUNGI AND BACTERIA

IMAGE OF THE LABEL

SPAI SONS

Triclo Trex-B

Net Wt. 14,3 Oz (430g)

Gel Contra Bacterias
Antibacterial Gel

TRICLOTREX B GEL CONTRA BACTERIAS

Acción contra bacterias, causantes de diversas enfermedades infecciosas. Las cuales se contraen en los pasamanos, vidrios, buses, taxis, puertas, paredes, escaleras, etc. Son micro-organismos que de no eliminarlos pasan a través de las manos, boca, nariz o piel causando grandes problemas de salud.

Triclosan, cetiol y extracto de sábila forman un guante protector para sus manos, protegiéndolas de la contaminación por hongos o bacterias.

USO: Protector contra hongos y bacterias.

MODO DE EMPLEO: Aplicar cantidad moderada de gel en la palma de las manos y frotar.

INGREDIENTES: Alcohol, agua, propilén glicol, PEG-7 cocoato de glicerilo, carbomero, extracto de hojas de aloe barbadensis, fragancia, triclosan, trietanolamina, +/- CI 19140, CI 42090, CI 60730, CI 16035.

TRICLOTREX B ANTIBACTERIAL GEL

Active ingredient used to fight against bacteria that cause infectious diseases of diverse types and which can be contracted by simply touching or coming into contact with a myriad of different surfaces: handrails, glass objects, busses, taxis, doors, walls, stairs, public toilettes, pools, etc. These germs are micro-organisms that if not eliminated will pass on through contact with hands, mouth, nose or the skin causing serious and dangerous health problems.

Triclosan, cetiol and Aloe Vera extracts built a protective glove for your hands preventing the contamination caused by fungi and bacteria.

RECOMMENDED USE: As a protector against fungi and bacteria.

DIRECTIONS: Apply a moderate amount of Triclotrex Gel on the palm of your hand and rub spreading it evenly over both hands.

INGREDIENTS: Alcohol, water, propylene glycol, PEG-7 glyceryl cocoate, carbomer, aloe barbadensis leaf extract, fragrance, triclosan, triethanolamine, +/- CI 19140, CI 42090, CI 60730, CI 16035.

Manufactured by SPAI-SONS Pharmaceutical International Cosmetics

Notif Sanit. NSOC34319-09C

For American SPAI-SONS USA Corp. MIAMI, FL (305)2066008

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Lote N°



TRICLOTREX-B ANTIBACTERIAL (NEUTRAL)

triclosan gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66854-016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.3 g in 100 g
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Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C BLUE NO. 4 (UNII: 0KSY80VYS3)	

Product Characteristics

Color	purple (PURPLE)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66854-016-01	110 g in 1 JAR		
2	NDC:66854-016-02	430 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333E	04/16/2012	

Labeler - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Registrant - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Establishment

Name	Address	ID/FEI	Business Operations
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS		880172184	analysis, label, manufacture, pack