

**TOBCHARM- undecylenic acid liquid**  
**EUbizrival 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.*

-----

**Active ingredients**

Undecylenic Acid 10%

**Purpose**

Anti-Fungal

**Uses**

Hinder fungal and bacterial growth, reduce itching, cleanse skin tissue.

**Warnings**

**For external use only**

**Do not use**

- on irritated skin and any area that is infected or reddened
- if pregnant or if there is any allergic reaction to this product.

**When using this product**

- avoid contact with eyes.

**Stop use and ask a doctor if**

- if discomfort persists

**Keep out of reach of children.**

- if product get into eyes, flush with water for 15 minutes
- if swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Wash feet thoroughly with warm water, and gently file thickened part of the fungal nail with a nail file until its flat
- apply layer of the liquid to the surface of the fungal nail and allow it to be absorbed into the nail.
- after the liquid has been absorbed, apply a layer of the cream to the infected parts of the nail
- repeat the process if necessary once a day

## **Other information**

Store at room temperature and out of direct sunlight. Skin discoloration may occur during or after use.

## **Inactive ingredients**

mineral oil, apricot kernel oil, tea tree oil, tocopherol, peppermint oil, camphor oil, jojoba oil, bergamot oil, lavender oil

Questions ? Email at

service@Tobcharm.com

## **Product label**

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Undecylenic Acid 10% -----	Anti-Fungal
<b>Use</b> Hinder fungal and bacterial growth, reduce itching, cleanse skin tissue.	
<b>Warnings</b> For external use only.	
<b>Do not use</b> ■ on irritated skin and any area that is infected or reddened. ■ if pregnant or if there is any allergic reaction to this product.	
<b>When using this product</b> avoid contact with eyes.	
<b>Ask a doctor before you use</b> if you have diabetes or poor blood circulation.	
<b>Stop use and ask a doctor</b> if discomfort persists	
<b>Keep out of reach of children</b> ■ If product gets into eyes, flush with water for 15 minutes. ■ If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> ■ Wash feet thoroughly with warm water, and gently file thickened part of the fungal nail with a nail file until it's flat. ■ Apply a layer of the liquid	

to the surface of the fungal nail and allow it to be absorbed into the nail. ■ After the liquid has been absorbed, apply a layer of the cream to the infected parts of the nail. ■ Repeat the process if necessary, once a day

### **Other information**

■ Store at room temperature and out of direct sunlight. ■ Skin discoloration may occur during or after use.

### **Inactive ingredients**

Mineral oil, Apricot Kernel Oil, Tea Tree Oil, Tocopherol, Peppermint Oil, Camphor Oil, Jojoba Oil, Bergamot Oil, Lavender Oil

Questions ? Email at [service@Tobcharm.com](mailto:service@Tobcharm.com)

## **TOBCHARM**

undecylenic acid liquid

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83462-002
<b>Route of Administration</b>	TOPICAL		

### **Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>UNDECYLENIC ACID</b> (UNII: K3D86KJ24N) (UNDECYLENIC ACID - UNII:K3D86KJ24N)	UNDECYLENIC ACID	10 g in 100 mL

### **Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>APRICOT KERNEL OIL</b> (UNII: 54JB35T06A)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>CAMPHOR OIL</b> (UNII: 75IZZ8Y727)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>BERGAMOT OIL</b> (UNII: 39W1PKE3JI)	

**LAVENDER OIL** (UNII: ZBP1YXW0H8)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83462-002-01	30 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	09/05/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333C	09/05/2023	

**Labeler** - EUbizrival LLC (036572203)

### Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Pallas Cosmetics Co.,Ltd.		419564106	manufacture(83462-002)

Revised: 9/2023

EUbizrival LLC