

**DELICE- dimethicone solution**  
**Pella Pharmaceuticals Co. Ltd**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Delice**

**Active Ingredient**

Dimethicone (Blend) 92%

**Composition**

Mineral Oil, Caprylic/ Capric Triglyceride and Lemon Fragrance.

**Characteristics**

Delice<sup>®</sup> does not contain any harmful insecticides. The solution creeps deeply into the breathing system of lice, nymphs and eggs (nits) resulting in suffocation. Because this mechanism of action is physical, the development of resistance in lice is not possible.

**Indications**

Delice<sup>®</sup> is a physical treatment of scalp hair in case of infestation with head lice; if used as instructed it is also effective against nymphs and eggs (nits).

**Contraindications**

Delice<sup>®</sup> must not be used in people with known hypersensitivity to any of its ingredients.

If any allergic skin reactions should occur, treatment should be stopped immediately.

Delice<sup>®</sup> should not be used in children under the age of two years because there are no enough studies demonstrate the safety use on this group.

**Precautions**

Delice<sup>®</sup> is for external use only.

Avoid inhaling Delice<sup>®</sup>.

**Precaution**

Keep out of reach of children

## **Warnings**

When using Delice®, you should make sure that the solution does not come into contact with eyes or mucous membranes (nose and throat). If the solution gets into the eyes accidentally, rinse for 10 - 15 minutes with plenty of water. If irritation persists please consult your doctor or pharmacist.

Because some ingredients are flammable, Delice® must not be used near naked flames or heat sources, including hair dryers. Keep Delice® away from sources of ignition and do not smoke during using this product.

If Delice® spilled accidentally, there is danger of slipping. Spillage should therefore be cleaned up immediately.

## **Pregnancy**

Delice® should not be used in pregnant women because there is no enough studies demonstrate the safety use on these groups.

## **Lactation**

Delice® should not be used in breast-feeding women because there is no enough studies demonstrate the safety use on these groups.

## **Interactions**

Delice® could react with certain hair care and hair tinting products.

## **Side Effects**

In rare cases, allergic skin reactions can be triggered by one of the ingredients of Delice®. These occur as inflammation, swelling, redness or rashes.

## **Storage Conditions**

Store below 30°C.

## **Presentation**

Glass bottle 50 ml, dispensing pump and special comb.

## **Instructions**

Before Delice® is used for the first time; the enclosed dispensing pump must be screwed onto the glass bottle. To do this, remove the screw cap from the bottle and screw the dispensing pump on tight. Always hold the spray bottle upright or the pump will not be able to work properly. Please note that the pump will need to be primed, by pumping, when used for the first time and when used it has been unused for a long

period. Inspect all scalp hair of each family member with the Delice<sup>®</sup> comb. All affected family members must use Delice<sup>®</sup> on the same day to avoid re-infestation. Delice<sup>®</sup> comb should be cleaned thoroughly after use.

### **1. Spray Delice<sup>®</sup> on the hair and leave it for 30 minutes.**

Use Delice on a dry hair; spray the product on overall the hair with scalp massaging by using the inserted comb, to work effectively, whole hair should be wetted by Delice completely, so the product reaches all the lice, eggs and nits. The amount of used product depends on the hair length and density. Make sure that the hair near the scalp and behind the ears is covered by the product because the lice and nits are concentrated there. Leave Delice on hair for 30 minutes.

### **2. After 30 minutes, comb the hair carefully using the lice comb.**

After leaving Delice on hair for 30 minutes minimum, comb the hair by using the inserted comb to remove the strangled lice, Delice solution makes the hair combing easier, because it contains ingredients which make the combing hair regardless its length easier.

### **What is the right way to use the lice comb?**

Divide the hair into several parts, and each part in several smaller strands of hair, comb each strand separately with the hair roots and ending with spikes, attach each combed strand backwards, and clean the comb after each strand combing with tissues before resuming combing the other strands.

### **3. Do not wash out leave the hair to dry at least 8 hours (overnights).**

Lice eggs are more flexible and difficult to remove it, Lice makes lice eggs adhere with hair like small balls with white heads, in addition it secretes an adhesive material similar to the composition of hair, even good combing is not enough to remove all the eggs, so you should leave Delice on hair for 8 hours, even the most stubborn eggs will choke.

### **4. Wash out with normal commercial shampoo.**

You can wash Delice solution from hair after eight hours by using any normal shampoo, any traces of solution remains on the hair after the first washing can be easily removed by a second washing.

### **5. After 8-10 days, re-apply if necessary.**

To ensure that all lice and eggs are treated, you must re-apply using the solution by the same procedure which described above. Delice use is safe and you can reuse it many times if necessary.

## **Secondary Package**

**EN**

**Ingredients**  
92% Ipermethrine (lindane), Mineral Oil, Caprylic/Capric Triglyceride and Citron Parfum.

**Directions**  
Read Enclosed Instructions

**Warnings**

- Must not be used near naked flames or heat sources, including hair dryers.
- Do not smother during use of the product.
- Do not inhale.
- Avoid contact with eyes and mucous membranes.

Store Below 30°C.  
Keep out of Reach of Children.  
For External Use Only.

**FR**

**Ingredients**  
92% Ipermethrine, Huile minérale, triglycéride caprylique/caprique et parfum citron.

**Mode d'utilisation**  
Lire les instructions ci-joint.

**Mise en garde**

- Ne doit pas être utilisé près de flammes nues ou des sources de chaleur, y compris un sèche-cheveux.
- Ne pas fumer pendant l'utilisation du produit.
- Ne pas inhaler.
- Éviter tout contact avec les yeux et les muqueuses.

Conserver en dessous de 30° C.  
Conserver Hors de Portée des Enfants.  
À Usage Extérieur Uniquement.

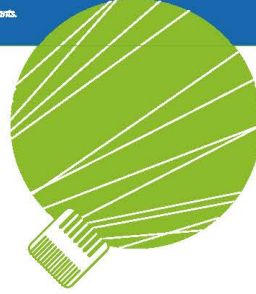
**CAUTION!**  
IRREFLECTIBLE

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**derma**

delice<sup>®</sup>  
solution



One Application is Effective  
Against Both Head Lice And Nits

Une application est efficace  
contre les poux et les lentes



**المكونات**  
٩٢٪ إبيرميثرين (أندروج)، زيت معدني، كابرليك/كابريك ثلاثي الجليسريد وطرير لللبون.

**التخزين**  
يحفظ في درجة حرارة أقل من ٣٠°م.

**طريقة الاستعمال**  
اقرأ النشرة المرفقة قبل الاستعمال.

**الاحتياطات**  
- للاستعمال الخارجي فقط.  
- يحفظ بعيداً عن متناول الأطفال.  
- يجب عدم استعمال المستحضر بالقرب من شعلة غاز، كما يجب إبعاد المستحضر عن مصادر الحرارة (مثل مجفف الشعر) كما يجب عدم التدخين أثناء استعمال المستحضر.

يجب تفادي استنشاق المستحضر.  
يجب التأكّد من عدم ملامسة المستحضر للعينين أو الأغشية المخاطية.  
صنع في الأردن

ديلايس<sup>®</sup>  
مخلول



مخلول للشعر يقضي على  
قمل الرأس ويبيضه معاً



Label



## DELICE

dimethicone solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82160-351
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIMETHICONE 100</b> (UNII: RO266O364U) (DIMETHICONE 100 - UNII:RO266O364U)	DIMETHICONE 100	25 g in 50 mL
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	21 g in 50 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>FRAGRANCE LEMON ORC2001060</b> (UNII: K1725A7G95)	

### Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82160-351-01	1 in 1 CARTON	09/19/2011	
1		50 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/19/2011	

**Labeler** - Pella Pharmaceuticals Co. Ltd (562370925)

Revised: 1/2022

Pella Pharmaceuticals Co. Ltd