

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

RESIDERM 1% GEL

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

1g of gel contains 10mg clindamycin (1% w/w) equivalent to 11.88mg clindamycin phosphate. RESIDERM 1% gel also contains 40% w/w propylene glycol.

For a full list of excipients see section 6.1.

### **3 PHARMACEUTICAL FORM**

Gel

A white translucent gel.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

RESIDERM is indicated for the treatment of mild to moderate acne vulgaris.

#### **4.2 Posology and method of administration**

##### **Adults and adolescents**

Apply a thin film of RESIDERM once daily to the affected area. Patient response should be reviewed after 6-8 weeks of treatment and the duration of treatment should be limited to 12 weeks.

##### **Children**

RESIDERM is not indicated for use in children below the age of 12 years.  
Cutaneous use.

#### **4.3 Contraindications**

RESIDERM is contra-indicated in patients with a hypersensitivity to the active substance clindamycin or to any of the excipients in the medicinal product. Although cross-sensitisation to lincomycin has not been demonstrated, it is recommended that

RESIDERM should not be used in patients who have demonstrated lincomycin sensitivity.

#### **4.4 Special warnings and precautions for use**

Oral and parenteral clindamycin, as well as most other antibiotics, have been associated with severe pseudomembranous colitis. Topical clindamycin has very rarely been associated with pseudomembranous colitis; however if diarrhoea occurs the product should be discontinued immediately.

Studies indicate a toxin(s) produced by *Clostridium difficile* is the major cause of antibiotic-associated colitis. Colitis is usually characterised by severe persistent diarrhoea and abdominal cramps. Should antibiotic associated colitis occur appropriate diagnostic and therapeutic measures (such as stopping RESIDERM and, if necessary, antibiotic treatment such as metronidazole or vancomycin treatment) should be taken immediately.

Responses may not be seen for 4-6 weeks.

Although the risk of systemic absorption following the administration of RESIDERM is low, the potential for the development of gastrointestinal adverse effects should be taken into account when considering treatment in patients with a previous history of antibiotic-associated colitis, enteritis, ulcerative colitis or Crohn's disease.

Prolonged use of clindamycin may cause resistance and/or overgrowth of non susceptible bacteria or fungi although this is a rare occurrence.

Cross resistance may occur with other antibiotics such as lincomycin and erythromycin. See section 4.5.

Contact with the eyes or the mucous membranes of the nose and mouth should be avoided. In the event of accidental contact with the eyes or mucous membranes bathe the affected area with copious amounts of cool water.

RESIDERM 1% Gel contains propylene glycol. May cause skin irritation.

The irritation potential of RESIDERM may be increased if the product is used under occlusion.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

*In vitro*, antagonism has been demonstrated between erythromycin and clindamycin, synergy has been shown with metronidazole and both antagonistic and synergistic effects have been observed with aminoglycosides.

#### **4.6 Pregnancy and lactation**

For clindamycin applied cutaneously no clinical data on exposed pregnancies are available. Data on a limited number of pregnancies exposed to clindamycin administered by other routes indicate no adverse effects on pregnancy or on the health of the fetus/newborn child. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant

women.

Orally and parenterally administered clindamycin has been reported to appear in breast milk. It is not known whether clindamycin is excreted in human milk following use of RESIDERM. As a general rule, patients should not breastfeed while taking a drug since many drugs are excreted in human milk.

For use during pregnancy and lactation, benefit and possible risks have to be weighed carefully against each other. Sensitisation and diarrhoea cannot be ruled out in nursed infants.

#### **4.7 Effects on ability to drive and use machines**

Not relevant.

#### **4.8 Undesirable effects**

Approximately 10% of patients can be expected to experience an adverse reaction. These reactions are typical of irritant dermatitis. The incidence of these is likely to increase if an excess of gel is used. Should irritation occur, the use of a moisturiser may be of benefit.

The table below shows all adverse reactions reported with RESIDERM in clinical trials. They are listed in decreasing order of incidence.

<b>Organ System</b>	<b>Common (&gt;1/100, &lt;1/10)</b>	<b>Uncommon (&gt;1/1000, &lt;1/100)</b>
Skin and subcutaneous tissue disorder	Dry skin Erythema Skin burning Irritation around eyes Acne exacerbation Pruritis	Painful skin Scaly rash

Whilst no case of severe diarrhoea or pseudomembranous colitis has been reported in clinical trials with RESIDERM, and only a small amount of clindamycin is absorbed percutaneously, pseudomembranous colitis has very rarely been reported with the use of other topical clindamycin products. Therefore a theoretical risk of pseudomembranous colitis with RESIDERM exists (please refer to Section 4.4).

#### **4.9 Overdose**

It is not expected that overdose would occur in normal use. Irritant dermatitis may occur when excessive quantities of RESIDERM are applied. The use of a suitable

moisturiser may be of benefit in these cases. In subsequent applications a thin film of RESIDERM should be applied in accordance with the dosage instructions (see section 4.2).

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Antiinfectives for treatment of acne

ATC code: D10A F01

RESIDERM contains clindamycin phosphate which is hydrolysed in the skin to the active constituent clindamycin. Clindamycin is a lincosamide antibiotic with primarily bacteriostatic action against Gram positive aerobes and wide range of anaerobic bacteria.

When clindamycin phosphate is applied cutaneously, clindamycin is found in comedone samples at sufficient levels to be active against most strains of *Propionibacterium* (*P. acnes*). It thus reduces the number of surface and follicular *P. acnes*, one of the aetiological factors of the disease.

As with all antibiotics, the long-term use of cutaneous clindamycin may lead to resistance.

### **5.2 Pharmacokinetic properties**

The RESIDERM formulation results in a reduction in the extent of systemic absorption of clindamycin. An *in vitro* study with RESIDERM with normal human skin has shown the *in vitro* absorption of radiolabelled clindamycin phosphate from the RESIDERM formulation to be less than 5% of the applied dose.

When RESIDERM is applied cutaneously, to patients with acne, at 8g/day for 5 days, i.e. levels well in excess of the maximum anticipated clinical dose a very small amount, (median less than 2ng/ml) of clindamycin was measured in plasma.

Clindamycin phosphate is metabolised to the parent drug in the skin and clindamycin itself is primarily metabolised in the liver via N-demethylation, sulfoxidation and hydrolysis and predominantly excreted in the bile.

### **5.3 Preclinical safety data**

Preclinical data for clindamycin reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or toxicity to reproduction.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Propylene glycol  
Purified water  
Ethanol 96%  
Zinc acetate dihydrate  
Hydroxyethylcellulose  
Sodium hydroxide 30% (w/w)

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

2 years.

### **6.4 Special precautions for storage**

No special precautions for storage.

### **6.5 Nature and contents of container**

RESIDERM is packaged in 15g, 30g or 60g laminate tubes with a high-density polyethylene inner layer and a peelable membrane laminate seal covering the orifice. The tube is fitted with a white opaque polypropylene screw cap. Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Crawford Healthcare Limited  
King Edward Court,  
King Edward Road,  
Knutsford,  
Cheshire,  
WA16 0BE

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 20074/0006

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

August 2001

**10     DATE OF REVISION OF THE TEXT**

29/04/2014