Once a day

Gets Used, Gets Results.

ZINDACLIN® is an effective topical therapy for mild to moderate acne[1]

Improved complexion... Improved confidence

Topical therapies for mild to moderate acne only work if they get used

Zindaclin® aids compliance[2]

Zindaclin's once a day formulation aids compliance by combining the 5 patient preferred attributes[2]:

- Once-a-day application
- Gel formulation
- Applied with fingers
- Stored at room temperature
- 2 year shelf life

Fannin
Caring for life

Zindaclin® is made with zinc which helps to improve skin healing[3]

Zindaclin is an effective topical therapy for mild to moderate acne[1].

- Improves skin healing[3]
- Reduces bacterial resistance[4]
- Regulates oil production in sebaceous glands to prevent clogging[5,6]
- Reduces inflammation and the appearance of acne[7, 8, 9, 10,11]

Additional information available on request.

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Caring for life

Zindaclin® is an effective topical therapy for mild to moderate acne [1]

ABBREVIATED PRESCRIBING INFORMATION

Name of the medicinal product: Zindaclin 1% gel, a white translucent gel. 1g of gel contains 10mg clindamycin (1% w/w) equivalent to 11.88 mg clindamycin phosphate. Zindaclin 1% Gel also contains 40% w/w propylene glycol.
(Please refer to the full Summary of Product Characteristics before prescribing)
Therapeutic Indications: Zindaclin is indicated for the treatment of mild to moderate acne vulgaris. **Posology and method of administration**: *Adults and adolescents:* Apply a thin film of ZINDACLIN 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:* ZINDACLIN is not indicated for use in children below the age of 12 years. **Contraindications:** Patients with 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 Zindaclin should not be used in patients who have demonstrated lincomycin sensitivity.
Special warnings and special 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.Colitis is usually characterised by severe persistent diarrhoea and abdominal cramps. Should antibiotic associated colitis occur appropriate diagnostic and therapeutic measures (such as stopping Zindaclin 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 Zindaclin 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.
- 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.
- Zindaclin 1% Gel contains propylene glycol. May cause skin irritation. The irritation potential of Zindaclin may be increased if the product is used under occlusion.

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. **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 foetus/newborn child. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal 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 Zindaclin. 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. **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. Adverse events are listed in decreasing order of incidence. **Organ System: Skin & Subcutaneous tissue disorder. Common (<1/100, <1/10)** dry skin, erythema, skin burning, irritation around eyes, acne exacerbation, Pruritus **Uncommon (>1/100, <1/100)** painful skin, scaly rash. Whilst no case of severe diarrhoea or pseudomembranous colitis has been reported in clinical trials with Zindaclin, 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 Zindaclin exists (please refer to Section 4.4 of SmPC, Special warnings and precautions for use). **Overdose:** It is not expected that overdose would occur in normal use. Irritant dermatitis may occur when excessive quantities of Zindaclin are applied. The use of a suitable moisturiser may be of benefit in these cases. In subsequent applications a thin film of Zindaclin should be applied in accordance with the dosage instructions **Pharmacodynamic properties:** Anti-infective for treatment of acne. Zindaclin 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. **Pharmacokinetic properties:** The Zindaclin formulation results in a reduction in the extent of systemic absorption of clindamycin. An in vitro study with ZINDACLIN with normal human skin has shown the in vitro absorption of radiolabelled clindamycin phosphate from the Zindaclin formulation to be less than 5% of the applied dose. When Zindaclin 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, sulphoxidation and hydrolysis and predominantly excreted in bile. **Preclinical safety data:** Reveals no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or toxicity to reproduction.
List of excipients: Propylene glycol; Purified water; Ethanol 96%; Zinc acetate dehydrate Hydroxyethylcellulose; Sodium hydroxide 30% (w/w) **Nature and contents of container:** ZINDACLIN 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. **MARKETING AUTHORISATION HOLDER** Crawford Healthcare Limited, King Edward Court, King Edward Road, Knutsford, Cheshire WA16 OBE, UK. **MARKETING AUTHORISATION NUMBER** PA 1098/001/001
Legal Category: POM
Reporting of suspected adverse reactions
Adverse events should be reported to Fannin Ltd, Pharmacovigilance at +353 868394447 or medical@dccvital.com
Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 (0)1 676 4971; Fax: +353 (0)1 676 2517. Website: www.hpra.ie; Email: medsafety@hprа.ie

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Distributed by:
Fannin Ltd.
Fannin House
South County Business Park
Leopardstown
Dublin 18
Ph: 00353 1 290 7000
Fax: 00353 1 290 7111

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References: 1. Kellet N. West F. Finlay AY. Br J Dermatol 2006 Mar ... n discontinued.) **2.** Bojar R *et al*. Br J Dermatol 1994: 130: 329-336.