Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zindaclin 1% Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of gel contains 10mg clindamycin (1% w/w) equivalent to 11.88mg of clindamycin phosphate.

Excipients with known effect:
This medicine contains propylene glycol (40% w/w) and ethanol (20% w/w).

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

Zindaclin 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 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.

Cutaneous use.

4.3 Contraindications

Zindaclin 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 Zindaclin 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 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. (See Section 4.5, Interaction with other medicinal products and other forms of interaction).

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 which may cause skin irritation.
ZINDACLIN 1% Gel contains ethanol which may cause burning sensation on damaged skin..

The irritation potential of Zindaclin 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 Fertility, 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.

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 Zindaclin in clinical trials.
They are listed in decreasing order of incidence.

Organ System	**Common (>1/100, <1/10)**	**Uncommon (>1/1000, <1/100)**
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 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, Special warnings and precautions for use*).

4.9 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 *(see section 4.2, Posology and method ofadministration*).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

*Pharmacotherapeutic grou*p: Anti-infectives for treatment of acne.
ATC code: D10A F01

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.

5.2 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 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

ZINDACLIN is packaged in 15g**,** 30g or 60g laminate tubes with a high-density polyethylene inner layer and a peelable membrane seal made of laminate or aluminium covering the orifice. The tube is fitted with a white opaque polypropylene screw cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA23142/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 November 2002

Date of last renewal: 16 August 2006

10 DATE OF REVISION OF THE TEXT

April 2025