

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

**MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007**

**(S.I. No.540 of 2007)**

**PA1142/012/001**

Case No: 2041147

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Transferred from PA0488/018/001.

**Amdipharm Limited**

**Temple Chambers, 3 Burlington Road, Dublin 4, Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Topicycline**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **19/12/2007** until **29/10/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Topicycline®

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One bottle of powder containing 154 mg of Tetracycline Hydrochloride.

One bottle containing 70 ml of solvent.

Once reconstituted, Topicycline contains tetracycline hydrochloride 2.2mg per ml.

For excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Powder and solvent for cutaneous solution.

Topicycline is presented in two separate bottles as a yellow powder and as a solvent.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

For the treatment of acne vulgaris.

##### 4.2 Posology and method of administration

Once reconstituted, Topicycline is applied topically, twice daily. It should be applied generously to the entire affected area, not just to the individual lesions, until the skin is thoroughly wet.

The average amount of Topicycline delivered to the skin by application to the face and neck twice a day is approximately 1.3 ml/day. This quantity of the medication contains approximately 2.9 mg of tetracycline hydrochloride. Twice-daily use of Topicycline on other acne-involved areas, in addition to the face and neck, has resulted in an average application of about 2.2 ml/day, or 4.8 mg of tetracycline hydrochloride.

##### 4.3 Contraindications

In patients who have shown hypersensitivity to any of its ingredients or to any of the other tetracyclines.

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

Cross resistance between tetracyclines may develop in micro-organisms and cross sensitisation in patients.

Prolonged use of an anti-infective may result in the development of infection due to micro-organisms resistant to the anti-infective.

Topicycline is for external use only, and care should be taken to keep it out of eyes, nose and other mucosal surfaces. Liver damage from Topicycline is highly unlikely because of the low levels of systemic absorption, however the

warnings and precautions associated with the use of oral tetracyclines should be considered before prescribing to patients with renal impairment.

Photosensitisation may occur in patients exposed to sunlight during use of tetracycline. Appropriate precautions should be taken. This is particularly important in fair skinned individuals.

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

None.

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

Reproduction studies in rats and rabbits have revealed no evidence of impaired fertility or harm to the foetus from Topicycline. There are no data on the use of this product in pregnant women. It is not known whether tetracycline or any other component of Topicycline, administered in this topical form, is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised if Topicycline is administered to nursing mothers.

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

None.

#### **4.8 Undesirable effects**

Some patients may experience stinging or tingling sensations, skin rashes and skin discolouration at the site of application. The stinging or tingling reaction normally occurs for no more than a few minutes, does not occur on every application and often diminishes with continued use.

Topicycline may leave a faint yellow colour on the skin which could result in the staining of clothing and bed linen. This can be avoided by advising the patient to wash lightly the affected area one hour after applying Topicycline.

#### **4.9 Overdose**

Not applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Topicycline is a topical antibiotic preparation containing the active ingredient tetracycline hydrochloride. It has a broad spectrum of antimicrobial activity against both gram positive and gram negative pathogenic bacteria and it is mainly bacteriostatic.

In this topical preparation, Topicycline delivers tetracycline hydrochloride to the pilosebaceous apparatus and the adjacent tissues. Topicycline reduces the inflammatory acne lesions but its mode of action is not fully understood.

#### **5.2 Pharmacokinetic properties**

Very small amounts of tetracycline hydrochloride are absorbed systemically after application of Topicycline to the skin, compared with oral dosing. The serum level of tetracycline resulting from the use of Topicycline is less than 0.1 µg/ml which is less than 7% of the level associated with an oral therapeutic dose of 500 mg/day.

#### **5.3 Preclinical safety data**

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### Powder

4-epitetracycline hydrochloride

Sodium bisulphite (E222)

#### Solvent

N-decyl methyl sulphoxide

Citric acid (E330)

Ethanol

Purified water

### 6.2 Incompatibilities

None known.

### 6.3 Shelf Life

Shelf life of unreconstituted product is 2 years.

Shelf life of reconstituted product is 8 weeks.

### 6.4 Special precautions for storage

Do not store above 25°C.

### 6.5 Nature and contents of container

A single carton containing a polyethylene bottle and polypropylene cap with an applicator and overcap supplied for the reconstituted product. On reconstitution of active powder and solvent the pack size is 70 ml.

### 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

At the time of dispensing the entire contents of the solvent - containing bottle are poured into the bottle containing the powder. The resultant mixture is then shaken well. Any unused material should be discarded.

## 7 MARKETING AUTHORISATION HOLDER

Amdipharm Limited  
Temple Chambers  
3 Burlington Road  
Dublin 4  
Ireland

## 8 MARKETING AUTHORISATION NUMBER

PA 1142/12/1

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

Date of first authorisation: 30<sup>th</sup> October 1998

Date of last renewal: 30<sup>th</sup> October 2003

**10 DATE OF REVISION OF THE TEXT**

December 2007