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### 1.3.2 Patient Information Leaflet (PIL)

### 1.3.1.2 PIL – Approved

References for the proposed PI for **XACLITEL 30 mg/5 ml, XACLITEL 100 mg/16,7 ml, XACLITEL 150 mg/25 ml & XACLITEL 300 mg/50 ml** are enclosed on pages.

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**Applicant/PHCR:** **AUROGEN SA (PTY) LTD**
**Product proprietary name: XACLITEL 30 mg/5 ml, XACLITEL 100 mg/16,7 ml, XACLITEL 150 mg/25 ml & 300 mg/50 ml**
**Dosage form and strength: Concentrate solution for injection containing 6 mg paclitaxel from per 1 ml solution.**

**Approved Patient Information Leaflet**

# PATIENT INFORMATION LEAFLET

**S4** **SCHEDULING STATUS**

**XACLITEL 30 mg/5 ml**;

**XACLITEL 100 mg/16,7 ml;**

**XACLITEL 150 mg/25 ml;**

**XACLITEL 300 mg/50 ml;**

**solution for infusion**

**Sugar free**

Contains sugar (lactose monohydrate): 44.60 mg.

**Read all of this leaflet carefully before you start taking XACLITEL**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

**What is in this leaflet**

## 1 What XACLITEL is and what it is used for

XACLITEL is used for the treatment of cancer. It can be cancer in the ovaries or breast cancer (advanced or spreading), after failure of other standardised prescribed treatment.

XACLITEL may also be used for a certain cancer in the lungs (advanced non-small cell lung cancer, NSCLC) in patients who cannot be treated with surgery and/or radiotherapy.

## 2. What you need to know before you take XACLITEL

**XACLITEL should not be administered to you:**

•You have had severe allergic reactions to paclitaxel, to any of the other ingredients of XACLITEL or other medicines formulated.

• You have an infection.

• You are pregnant or breastfeeding.

• You suffer from liver disease.

**Warnings and precautions**

Special care should be taken with XACLITEL :

• If you notice an allergic reaction which may cause shortness of breath, dizziness (caused by low blood pressure), swelling of the face or rash. Contact your healthcare provider immediately if you experience any of these symptoms.

• If you have heart disease or liver problems (if liver damage is severe, you should not be given XACLITEL .

• If your blood cell counts are abnormal.

Other precautions before or during treatment with XACLITEL :

It will be necessary for your doctor to carefully monitor you by performing regular blood tests to monitor blood counts, before or during treatment with XACLITEL .

**Other medicines and XACLITEL :**

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Caution is necessary if you receive other medication, especially the following:

When used in combination, XACLITEL should be given before cisplatin. XACLITEL should be given 24 hours after doxorubicin.

Special care should be observed if you are taking medicines which influence the metabolism of paclitaxel such as: ketoconazole (treats fungal infections), erythromycin (antibiotic), fluoxetine (anti-depressant), gemfibrozil (cholesterol medication), clopidogrel (to prevent blood clots), cimetidine (for treatment of stomach ulcers), rifampicin (TB medication), epilepsy treatment such as carbamazepine, phenytoin, phenobarbital, or HIV treatment such as efavirenz, and nevirapine and for HIV patients receiving protease inhibitors (ritonavir, nelfinavir) as concomitant therapy

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before you receive XACLITEL .

XACLITEL must not be given if you are pregnant unless clearly advised.

Do not use XACLITEL if you are breastfeeding or if you wish to start breastfeeding whilst you are receiving treatment with XACLITEL .

**Driving and using machines**

Immediately after a course of treatment, the amount of alcohol in XACLITEL may affect your ability to drive or use machines. In addition, some side effects such as nausea or tiredness may affect your ability to drive or operate machinery.

## 3. How to receive XACLITEL

Do not share medicines prescribed for you with any other person.

Patients receiving XACLITEL should be under the supervision of a doctor experienced in cancer chemotherapy.

You will not be expected to give yourself XACLITEL . It will be administered into a vein given to you by a person who is qualified to do so. Your doctor will determine the exact dosage that you will need. The dosage may vary according to your body mass.

**If you take more XACLITEL than you should**

Since a healthcare professional will administer XACLITEL , he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage

## 4. Possible side effects

If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

**XACLITEL can have side effects.**

Not all side effects reported for XACLITEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving XACLITEL , please consult your health care provider for advice.

If any of the following happens, stop receiving XACLITEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

• swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,

• rash or itching,

• fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to XACLITEL . You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe infection including sepsis (blood poisoning) with a state of shock,
- feeling unusually hot or cold (fever or chills),
- severe allergic reactions causing low or high blood pressure, chest pain, breathing problems, fast heart-beat (pulse), pain in your stomach or extremities, sweating, severe itching and/or back pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- joint or muscle weakness, pain, aching or loss of sensation in the limbs,
- bone marrow suppression, which can lead to decreased blood cell counts and may result in infections, anaemia with paleness and weakness, and bruising and bleeding,
- pain in the muscle or joints,
- hair loss,
- nausea, vomiting, diarrhoea, constipation,
- soreness of the mouth or tongue,
- loss of appetite,
- cough,
- shortness of breath,

- nerve problems – these may appear as pins and needles in the hands and feet,
- lack of energy.

Less frequent side-effects:

- headache,
- migraine,
- swelling,
- decreased weight,
- stomach pain,
- back pain,
- itching,
- injection site reactions,
- fever,
- disease of the nails,
- low blood pressure,
- slow heartbeat,
- chest pain,
- general pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via Med Safety APP (Medsafety X SAHPRA)and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store XACLITEL

Store all medicines out of reach of children.

Unopened vials must be stored at 2 - 8 °C in the original package.

Solutions for infusion prepared as recommended are stable for up to 30 hours at room temperature (15 – 30 °C). However, it is recommended that the infusion be initiated within 24 hours of reconstitution.

**STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. Toilets).

## 6. Contents of the pack and other information

The active substance is paclitaxel.

XACLITEL for injection contains 6 mg paclitaxel per 1 ml solution. The medicine contains 50 % v/v dehydrated alcohol.

Sugar free.

**HOLDER OF THE CERTIFICATE OF REGISTRATION**

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South Africa

**Registration numbers:**

**XACLITEL 30 mg/5 ml**: 57/26/0201

**XACLITEL 100 mg/16,7 ml**: 57/26/0202

**XACLITEL 150 mg/25 ml**: 57/26/0203

**XACLITEL 300 mg/50 ml**: 57/26/0204