

Zolasol (Powder for concentrate for solution for infusion)

Each vial contains 4 mg topotecan (as hydrochloride)

Application no.: 56/26/0642

SCHEDULING STATUS: S4

Read all of this leaflet carefully before you are given ZOLASOL

- 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 ZOLASOL is and what it is used for
2. What you need to know before you are given ZOLASOL
3. How ZOLASOL is used
4. Possible side effects
5. How to store ZOLASOL
6. Contents of the pack and other information

1. What ZOLASOL is and what it is used for

ZOLASOL belongs to a group of medicines called cytostatic or antineoplastic agents used to treat cancers. It acts on an enzyme (topoisomerase-I) to prevent the growth of tumour cells.

ZOLASOL is used to treat:

- ovarian cancer or small cell lung cancer that has come back after chemotherapy.
- advanced cervical cancer if surgery or radiotherapy treatment is not possible. When treating cervical cancer, ZOLASOL is combined with another medicine called cisplatin.

Your doctor will decide with you whether ZOLASOL therapy is better than further treatment with your initial chemotherapy.

A doctor or a nurse will give you ZOLASOL as an infusion into a vein in a hospital.

2. What you need to know before you are given ZOLASOL

ZOLASOL should not be administered to you:

- if you are hypersensitive (allergic) to topotecan or any of the other ingredients of ZOLASOL (listed in section 6).
- if you are pregnant or breastfeeding.
- if your blood cell counts are too low. Your doctor will tell you whether this is the case, based on the results of your last blood test.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- if you are aware of an existing problem with your blood (e.g., red cells, white cells, platelets) such as anaemia, a tendency to bleed and/or poor immune system.
- if you have a history of lung disease or lung cancer, have received radiation therapy to the lungs, are taking medicines that may damage your lungs (e.g., amiodarone used for irregular heart rhythm, blood pressure medicines called ACE inhibitors such as enalapril, other cancer medicines), or are taking medicines known as colony stimulating factors to promote the growth of certain blood cells. Your doctor may need to monitor your condition and discontinue your treatment with ZOLASOL if necessary. See section 4 Possible side effects.
- if you have any kidney or liver problems. Your dose of ZOLASOL may need to be adjusted.
- if you are being treated with cisplatin (a medicine used for cancer). Your dose of ZOLASOL or cisplatin may need to be adjusted.
- if you have not yet received or are not currently receiving any other treatment for cancer. Your doctor may need to also prescribe another cancer medicine in addition to ZOLASOL.

ZOLASOL can decrease certain white blood cells (needed to fight infections) and blood platelets (needed for blood to clot). This can lead to life-threatening conditions such as sepsis, severe inflammation of the bowel and severe bleeding (see section 4 Possible side effects). Your doctor will order a full blood count before starting treatment to determine the correct dose for you, and regularly monitor your blood counts (see section 3 How ZOLASOL is used).

Children and adolescents

ZOLASOL is not intended for use in children since it is unlikely to be safe.

Other medicines and ZOLASOL

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

Tell your doctor if you are taking any cancer medicines such as paclitaxel, etoposide, cisplatin or carboplatin.

Your doctor may need to adjust your dose of ZOLASOL or other medicines you are taking.

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 healthcare provider for advice before taking ZOLASOL.

You should not receive treatment with ZOLASOL if you are pregnant or think you may be pregnant. It may

harm a baby conceived before, during or soon after treatment. You should use an effective method of contraception. Ask your doctor for advice. Do not try to become pregnant until a doctor advises you it is safe to do so.

Do not breastfeed if you are being treated with ZOLASOL. Do not restart breastfeeding until the doctor tells you it is safe to do so.

Male patients who wish to father a child should ask their doctor for family planning advice or treatment. If your partner becomes pregnant during your treatment with ZOLASOL, tell your doctor immediately.

Driving and using machines

It is not always possible to predict to what extent ZOLASOL may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ZOLASOL affects you.

ZOLASOL can make you feel tired. If you feel tired or weak, do not drive or use machines.

ZOLASOL contains sodium

ZOLASOL contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium free”. If your doctor uses a solution of common salt to dilute ZOLASOL, the dose of sodium received would be larger.

3. How ZOLASOL is used

You will not be expected to give yourself ZOLASOL. It will be given to you by a person who is qualified to do so.

The dose of ZOLASOL you are given will be determined by your doctor, based on:

- your body size (surface area measured in square metres)
- the results of blood tests carried out before treatment
- the disease being treated.

The usual dose of ZOLASOL:

- for **ovarian and small cell lung cancer** is 1,5 mg per square metre of body surface area per day. You will have treatment once a day for 5 days. This treatment will normally be repeated every 3 weeks.
- for **cervical cancer** is 0,75 mg per square metre of body surface area per day. You will have treatment once a day for 3 days. This treatment will normally be repeated every 3 weeks. When treating cervical cancer, ZOLASOL is combined with another medicine, called cisplatin. Your doctor will determine the correct dose of cisplatin.

Your doctor will tell you how long your treatment with ZOLASOL will last.

You will be given a suitable dose of ZOLASOL in the form of an infusion, usually over a period of about 30 minutes. ZOLASOL is administered after reconstitution with water and further dilution with sodium chloride intravenous infusion or dextrose intravenous infusion.

If you receive more ZOLASOL than you should

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

If you forget to use ZOLASOL

Since a healthcare provider will administer ZOLASOL, it is unlikely that the dose will be missed.

4. Possible side effects

ZOLASOL can have side effects.

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

Tell your doctor immediately if experience any of the following side effects, you may need urgent medical attention or hospitalisation:

Signs of infections: ZOLASOL may reduce the number of white blood cells and lower your resistance to infection. This can even be life threatening. It occurs frequently; signs include:

- fever
- serious deterioration of your general condition
- local symptoms such as sore throat or urinary problems (for example, a burning sensation when urinating, which may be a urinary infection).

Severe allergic reaction: An anaphylactic reaction to ZOLASOL can even be life threatening. It occurs less frequently; signs include:

- raised and itchy rash (hives)
- swelling of the face or mouth (angioedema) causing difficulty in breathing
- fainting.

Lung inflammation (interstitial lung disease): You are most at risk if you have existing lung disease, have had radiation treatment to your lungs, or have previously taken medicines that caused lung damage. It occurs less frequently; signs include:

- difficulty breathing
- cough
- fever.

Bowel inflammation (neutropenic colitis): Occasionally severe stomach pain, fever and possibly diarrhoea (less frequently with blood) can be signs of bowel inflammation (colitis). It occurs less frequently.

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- unusual bruising or bleeding, caused by a decrease in the number of clotting cells in the blood; this can lead to severe bleeding from relatively small injuries such as a small cut
- feeling generally weak and tired (temporary anaemia); in some cases, you may need a blood transfusion
- allergic or hypersensitivity reactions (including rash)
- weight loss and loss of appetite (anorexia)
- feeling sick (nausea), being sick (vomiting), diarrhoea, stomach pain, constipation
- inflammation and ulcers of the mouth tongue or gums
- yellow skin (jaundice)
- hair loss (alopecia)
- itching sensation
- high body temperature (fever)
- tiredness, weakness, feeling unwell.

Less frequent side effects:

- mild pain and inflammation at the site of injection.

Side effects with unknown frequency:

- severe bleeding (haemorrhage) as a result of decreased blood platelets
- severe stomach pain, nausea, vomiting of blood, black or bloody stools (possible symptoms of gastrointestinal perforation)
- mouth sores, difficulty swallowing, abdominal pain, nausea, vomiting, diarrhoea, bloody stools (possible signs and symptoms of inflammation of the inner lining of the mouth, stomach and/or gut).

If you are being treated for cervical cancer, you may get side effects from the other medicine (cisplatin) that you will be given along with ZOLASOL. Those effects are described in the cisplatin patient information leaflet.

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. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ZOLASOL.

5. How to store ZOLASOL

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep the vial in the outer carton in order to protect from light.

Do not use after the expiry date stated on the label.

ZOLASOL is for single use only. After opening, ZOLASOL should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2-8 °C when reconstituted and diluted under aseptic conditions.

Any unused product or waste material should be disposed of in accordance with local requirements for cytotoxic material.

6. Contents of the pack and other information

What ZOLASOL contains

- The active substance is topotecan. Each vial contains 4 mg of topotecan (as hydrochloride).
- The other ingredients are mannitol (E421), tartaric acid (E334), hydrochloric acid (E507) and sodium hydroxide.

What ZOLASOL looks like and contents of the pack

ZOLASOL is a light yellow to greenish, freeze-dried powder in a colourless vial. It is available in packs containing 1 glass vial per outer carton. Each vial contains 4 mg of topotecan (as hydrochloride). The powder needs to be reconstituted and diluted before infusion. The clear, reconstituted solution is light yellow to greenish in colour and provides 1 mg of topotecan per ml when reconstituted as recommended.

Holder of Certificate of Registration

Ando Pharma (Pty) Ltd.

73 Keurboom Crescent

Platteklouf

Cape Town

This leaflet was last revised in

To be allocated

Registration number

56/26/0642