

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

COSMEGEN 0,5 mg powder for injection

Dactinomycin

Contains mannitol

Read all of this leaflet carefully before you are given COSMEGEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- COSMEGEN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What COSMEGEN is and what it is used for

COSMEGEN contains dactinomycin, an anticancer medicine which works by stopping the growth and spread of cancer cells.

Your doctor has prescribed COSMEGEN for you because you may suffer from one of the following conditions:

- Nephroblastoma (a type of kidney cancer which usually occurs in children.)
- Rhabdomyosarcoma (a rare cancer of the muscle).
- Ewing's sarcoma (a type of bone cancer).
- Cancer of the testis and uterus.
- Melanoma (a type of skin cancer).

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

COSMEGEN should not be administered to you:

- If you are allergic to dactinomycin or any of the other ingredients of COSMEGEN (listed in section 6).
- If you have chickenpox or shingles.
- If you are or think you may be pregnant.
- If you are planning to become pregnant.
- If you are breastfeeding.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you are receiving radiation therapy.
- If you are receiving COSMEGEN with radiation therapy your doctor will monitor you closely as there is an increased possibility of some other side effects.
- If you have kidney, liver or bone marrow problems.

COSMEGEN may cause kidney, liver or bone marrow problems. This can result in a lower number of red and white blood cells and a lower number of platelets.

Symptoms of lower red blood cells include tiredness, headaches, being short of breath when exercising, dizziness and looking pale. A lower number of white blood cells may make it harder for you to fight off infections.

Symptoms of lower platelet counts include excessive bruising or a harder time to stop bleeding if you have a cut. Your doctor will control these functions frequently.

Other medicines and COSMEGEN

Always tell your health care provider if you are taking any other medicine. This includes all complementary or traditional medicines.

Tell your doctor if you are taking or receiving any of the following medicines or treatment:

- X-rays: You should tell your doctor if you receive X-ray treatment at any time, as X-rays may affect, or may be affected by treatment with COSMEGEN.
- Antibacterial medicines: COSMEGEN may affect the concentration levels in your blood.

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 receiving COSMEGEN.

If you are pregnant or breastfeeding, you should not receive COSMEGEN.

Driving and using machines

COSMEGEN may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/ equipment (see 'Undesirable effects').

COSMEGEN contains mannitol

COSMEGEN contains mannitol and may have a laxative effect.

3. How to receive COSMEGEN

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

You will not be expected to give yourself COSMEGEN. You will be given your COSMEGEN injection by a doctor or nurse who is experienced in the use of cancer treatments.

Your doctor will determine the correct dose and duration of the treatment depending on your type of cancer. Your doctor will advise you of the method and number of injections and courses you require.

Method of administration

You may be given COSMEGEN either as an injection or mixed with another solution as an infusion (a 'drip') into your vein. It must not be taken by mouth.

If you have the impression that the effect of COSMEGEN is too strong or too weak, tell your doctor or pharmacist.

If you receive more COSMEGEN than you should

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

If you missed a dose of COSMEGEN

Since a health care provider will administer COSMEGEN, it is unlikely that the dose will be missed.

4. Possible side effects

COSMEGEN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to COSMEGEN. 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 especially in the first few hours after receiving COSMEGEN:

- Serious bacterial infection in the bloodstream or body tissues. Symptoms include shivering, hot and cold, a sudden chill, diarrhoea;
- blisters and/or a rash that join together to cover a large portion of the body resulting in severe peeling of the skin, flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, eventually causing the top layer

of skin to die, peel, and shed;

- difficulty swallowing, sore mouth or throat, mouth ulcers or sores, cracked lips, facial or tongue swelling, hives, skin pain that may be accompanied by fever, chills, aching muscles and generally feeling unwell;
- evenly distributed red patches and rash primarily on the arms and legs.

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

Tell your doctor if you notice any of the following:

Frequency unknown

- vomiting;
- nausea (feeling ill), fever; stomach ulcers, pains in stomach, diarrhoea;
- any leakage on the skin will cause soft tissue damage, generally feeling unwell.
- liver problems (such as liver failure, hepatitis (irritated liver caused by a virus), a painful enlarged liver, fluid retention when excess fluids build up inside the body);
- a lowering of the red blood cells which can cause tiredness;
- a lowering of white blood cells which can make you more sensitive to infections;
- a lowering of blood platelets which can make you more sensitive to bleeding;
- infections;
- kidney problems;
- slowing down of growth;
- inflammation of the rectum;
- fertility problems;
- muscle pain;
- tiredness, feeling generally unwell;
- inflammation of the lungs;
- spasm of the hands or feet and tingling around the mouth and vocal cords (due

to low calcium levels in the blood);

- loss of appetite;
- inflammation of the rectum;
- acne;
- increased darkness in skin which has previously been exposed to radiation treatment;
- hair loss.

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 COSMEGEN.

5. How to store COSMEGEN

Store all medicines out of reach of children.

- Store at or below 25 °C
- Do not freeze.
- Keep in original packaging until required for use, to protect from light.
- Although reconstituted COSMEGEN is chemically stable, the product does not contain a preservative and accidental contamination might result. Any unused portion of the solution should be discarded.
- Do not use after the expiry date stated on the label or carton.

- 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

What COSMEGEN contains

- The active substance is dactinomycin. Each 3 ml vial contains 500 µg of dactinomycin.
- The other ingredient is mannitol.

What COSMEGEN looks like and contents of the pack

COSMEGEN powder for injection is a yellow to orange lyophilized powder in the form of a plug. The product stored in a 3 ml amber Type I glass vial closed with a dark grey butyl rubber stopper and an aluminium cap with a light blue flip off seal. Pack size: 1 vial in an outer carton.

Holder of Certificate of Registration

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Key Oncologics (Pty) Ltd
COSMEGEN 0,5 mg

Powder for injection, 0,5 mg (500 µg) /3 ml
Dactinomycin
Approved PIL: 6 September 2022

Registration number

54/26/0380

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.