

COSMEGEN®

Dactinomycin (actinomycin D)
(pronounced dak-ti-noe-mye-sin di)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about COSMEGEN. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking COSMEGEN against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What COSMEGEN is used for

COSMEGEN is used alone, or in combination with other chemotherapy or radiotherapy, to treat certain types of cancers, including:

- Wilms' tumour, a type of kidney cancer
- Rhabdomyosarcoma, a cancer of the muscle
- Nonseminomatous testicular carcinoma, a cancer of the testis
- Choriocarcinoma, a cancer of the uterus
- Ewing's sarcoma, a type of bone cancer
- Sarcoma botryoides, a cancer of the female reproductive tract.

COSMEGEN may also be used to treat the symptoms of certain cancers, or to treat tumours that are

not responding to radiotherapy. It may also be used in people who are having a tumour surgically removed.

COSMEGEN belongs to a group of medicines called antineoplastics. It works by interfering with the growth of cancer cells, which are eventually killed.

Your doctor may have prescribed COSMEGEN for another reason. Ask your doctor if you have any questions about why COSMEGEN has been prescribed for you.

COSMEGEN is not addictive.

Before you are given COSMEGEN

When you must not be given COSMEGEN

Do not use COSMEGEN if you have an allergy to COSMEGEN or any of the ingredients listed at the end of this leaflet.

Do not use COSMEGEN if you have recently had or are currently infected with chicken pox or herpes zoster (shingles).

If you are not sure whether you should start receiving COSMEGEN, talk to your doctor.

Do not use COSMEGEN if you are breast-feeding or intend to breast-feed.

COSMEGEN is not recommended for use while breast-feeding. It is not known whether it passes into breast milk.

Before you are given COSMEGEN

Tell your doctor if:

1. you are pregnant

Like most medicines, COSMEGEN is generally not recommended during pregnancy. However, if there is a need to consider using COSMEGEN during pregnancy, your doctor will discuss the possible risks and benefits to you and your unborn baby.

2. you are currently receiving radiotherapy

3. you have Wilms' tumour and you are either currently receiving radiotherapy or you have had radiotherapy in the last two months

4. your child is to receive COSMEGEN and is less than 12 months of age

COSMEGEN is not recommended in infants less than 6 to 12 months of age as there is a higher risk of toxic effects.

5. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you are given COSMEGEN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and

COSMEGEN may interfere with each other. This includes:

- other chemotherapy
- live virus vaccines

These medicines may be affected by COSMEGEN, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given COSMEGEN.

How COSMEGEN is given

COSMEGEN is given as a slow injection into a vein. It may also be given by the isolation-perfusion technique.

COSMEGEN must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive COSMEGEN. This depends on several factors, such as your weight, the size and location of your cancer, whether you are receiving or have received other chemotherapy or radiotherapy, and how you tolerate COSMEGEN. It is usually given in short courses.

If you are being given COSMEGEN intravenously, a second course may be given after at least 3 weeks has passed since your last dose of COSMEGEN, and provided you have no signs of toxicity.

Side effects

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given COSMEGEN.

COSMEGEN helps most people, but it may have unwanted side-effects in a few people. All

medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- nausea, vomiting
- loss of appetite (anorexia)
- difficulty in swallowing, or discomfort when swallowing
- stomach pain
- tiredness, drowsiness, lack of energy, generally feeling unwell
- aching muscles, muscle tenderness or weakness, not caused by exercise
- cracked, dry lips
- hair loss
- acne

These side effects usually vary in severity.

Nausea and vomiting usually occur during the first few hours after being given COSMEGEN. Many of the other side effects do not occur until 2 to 4 days after a course of COSMEGEN has stopped, and may not be at their worst until after one or two weeks.

Tell your doctor or nurse immediately if you notice any of the following:

- local reactions at the injection site, including skin burning, redness or swelling
- a burning sensation in the chest (heartburn)
- swelling of the lungs causing coughing, difficulty breathing and wheezing
- bruising or bleeding more easily than normal
- signs of anaemia, such as headaches, being short of breath when exercising, dizziness and looking pale

- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- skin reactions, including blisters or increased pigmentation of skin that has previously been exposed to radiotherapy
- widespread peeling or sloughing off of skin
- sore back passage, sometimes with bleeding and discharge
- diarrhoea
- signs of liver problems, including yellowing of the skin and eyes, stomach swelling, and dark coloured urine
- signs of an allergic reaction, including rash, swelling of the face, tongue, lips, mouth or throat which may cause difficulty in swallowing or breathing

These may be serious side effects of COSMEGEN. You may need urgent medical attention.

Your doctor may ask you to have blood tests every day to monitor your blood cells and your kidney and liver function.

Growth retardation has been reported rarely with COSMEGEN.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using COSMEGEN

Storage

COSMEGEN will be stored in the pharmacy or on the ward.

It is kept in a cool, dry place where it is protected from light and where the temperature stays below 25°C.

Product description

What it looks like

COSMEGEN comes as a yellow powder in a glass vial.

Ingredients

Active ingredient:

- 500 microgram of Dactinomycin (actinomycin D) per vial

Inactive ingredients:

- mannitol

Supplier

COSMEGEN is supplied by:

Australia

Recordati Rare Diseases Australia,
Pty Ltd.

Level 6, 69 Reservoir Street, Surry
Hills,
Sydney NSW 2010, Australia

New Zealand

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