

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using COSMEGEN?

COSMEGEN contains the active ingredient dactinomycin. COSMEGEN is used alone, or in combination with chemotherapy or radiotherapy, to treat certain types of cancers. 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. For more information, see Section [1. Why am I using COSMEGEN?](#) in the full CMI.

### 2. What should I know before I use COSMEGEN?

Do not use if you have ever had an allergic reaction to COSMEGEN or any of the ingredients listed at the end of the CMI. **Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use COSMEGEN?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with COSMEGEN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use COSMEGEN?

COSMEGEN is given as a slow injection into a vein. It may also be given by the isolate-perfusion technique. COSMEGEN must only be given by a doctor or a 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.

More instructions can be found in Section [4. How do I use COSMEGEN?](#) in the full CMI.

### 5. What should I know while using COSMEGEN?

|                                    |  |
|------------------------------------|--|
| <b>Things you should do</b>        | <ul style="list-style-type: none"> <li>Remind any doctor, dentist or pharmacist you visit that you are using COSMEGEN.</li> <li>Tell your doctor if you are pregnant before you are given COSMEGEN.</li> <li>Tell your doctor if you are currently receiving radiotherapy, have a Wilms' tumour and are either currently receiving radiotherapy or have had radiotherapy in the last two months, or if your child is to receive COSMEGEN and is less than 12 months of age.</li> <li>Tell your doctor if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.</li> </ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"> <li>Do not use COSMEGEN if you are breast-feeding or intend to breast feed.</li> <li>Do not use COSMEGEN if you have recently had or are currently infected with chicken pox or herpes zoster (shingles).</li> </ul>  |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"> <li>There is no information regarding any warnings to consider before driving or operating machinery.</li> </ul>  |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"> <li>There is no information regarding drinking alcohol while using the medicine.</li> </ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>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.</li> </ul>   |

For more information, see Section [5. What should I know while using COSMEGEN?](#) in the full CMI.

### 6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Common side effects include nausea and vomiting. Serious side effects include blood related disorders (irregular bleeding, bruising), allergic reactions (rash, face swelling) and skin reactions (blisters, sloughing off of skin). For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# COSMEGEN\*

Active ingredient(s): *Dactinomycin* (*dak-ti-noe-mye-sin*)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using COSMEGEN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COSMEGEN.**

Where to find information in this leaflet:

- [1. Why am I using COSMEGEN?](#)
- [2. What should I know before I use COSMEGEN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use COSMEGEN?](#)
- [5. What should I know while using COSMEGEN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using COSMEGEN?

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

**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.**

**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.

## 2. What should I know before I use COSMEGEN?

### Warnings

**Do not use COSMEGEN if:**

- you are allergic to COSMEGEN or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not use COSMEGEN if you have recently had or are currently infected with chicken pox or herpes zoster (shingles).
- Do not use COSMEGEN if you are breast-feeding or intend to breast feed.

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

### Check with your doctor or pharmacist if you:

- Are currently receiving radiotherapy
- Have a Wilm's tumour and you are either currently receiving radiotherapy, or you have had radiotherapy in the last two months.
- 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.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

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

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.

It is recommended to use effective contraception during treatment with COSMEGEN, and for at least 7 months after the last dose for women, and 4 months for men.

**Please consult your doctor or pharmacist if you have any questions about the contraception methods to be used during this period.**

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COSMEGEN.**

### 4. How do I use COSMEGEN?

#### How much COSMEGEN is given

- 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.

#### When COSMEGEN is given

- COSMEGEN must only be given by a doctor or nurse.

#### How COSMEGEN is given

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

### 5. What should I know while using COSMEGEN?

#### Things you should do

**Tell your doctor straight away if:**

- You are pregnant
- You are currently receiving radiotherapy
- Have a Wilm's tumour and you are either currently receiving radiotherapy, or you have had radiotherapy in the last two months
- 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.

- You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Remind any doctor, dentist or pharmacist you visit that you are using COSMEGEN.

#### Things you should not do

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

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how COSMEGEN affects you.**

#### Drinking alcohol

**Tell your doctor or pharmacist if you drink alcohol.**

#### Looking after your medicine

- 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.

### 6. Are there any side effects?

All medicines can have side effects. COSMEGEN helps most people, but it may have unwanted side-effects in a few people. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

#### [Less serious/common] side effects

| Less serious side effects  | What to do   |
|--|--|
| <b>Gastrointestinal disorders:</b> <ul style="list-style-type: none"><li>• Nausea, vomiting</li><li>• Diarrhoea</li><li>• Loss of appetite</li><li>• Stomach pain</li><li>• Constipation</li><li>• Difficulty in swallowing, or discomfort when swallowing</li></ul> <b>Local reactions at the injection site:</b> <ul style="list-style-type: none"><li>• Including skin burning, redness or swelling</li></ul> | <b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b> |

|   |  |
|---|--|
| <b>General disorders:</b> <ul style="list-style-type: none"> <li>Tiredness, drowsiness, lack of energy</li> <li>Generally feeling unwell</li> </ul> <b>Musculoskeletal disorders:</b> <ul style="list-style-type: none"> <li>aching muscles, muscle tenderness or weakness, not caused by exercise</li> </ul> <b>Skin disorders:</b> <ul style="list-style-type: none"> <li>Acne</li> <li>Hair loss</li> <li>Cracked, dry lips</li> </ul> |  |
|---|--|

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.

### [Serious/rare] side effects

| Serious side effects   | What to do   |
|--|--|
| <b>Musculoskeletal disorders:</b> <ul style="list-style-type: none"> <li>Slowing down of growth</li> <li>Sore back passage, sometimes with bleeding and discharge</li> <li>Bruising or bleeding more easily than normal</li> </ul> <b>Reproductive disorders:</b> <ul style="list-style-type: none"> <li>Fertility problems</li> </ul> <b>Signs of anaemia:</b> <ul style="list-style-type: none"> <li>Such as headaches, being short of breath when exercising, dizziness and looking pale</li> </ul> <b>Frequent infections:</b> <ul style="list-style-type: none"> <li>Such as fever, severe chills, sore throat or mouth ulcers</li> </ul> <b>Skin reactions:</b> <ul style="list-style-type: none"> <li>Including blisters or increased pigmentation of skin that has previously been exposed to radiotherapy</li> <li>Widespread peeling or sloughing off of skin</li> </ul> <b>Signs of liver problems:</b> <ul style="list-style-type: none"> <li>Including yellowing of the skin and eyes, stomach swelling, and dark coloured urine, ascites, difficult breathing with thoracic pain, confusion with musty or sweet breath odour and seizures</li> </ul> <b>Signs of an allergic reaction:</b> <ul style="list-style-type: none"> <li>Including rash, swelling of the</li> </ul> | <b>Tell your doctor or nurse immediately if you notice any of these serious side effects. You may need urgent medical attention.</b> |

|  |  |
|--|--|
| face, tongue, lips, mouth or throat which may cause difficulty in swallowing or breathing<br><br><b>Tumour lysis syndrome:</b> <ul style="list-style-type: none"> <li>Symptoms include irregular heartbeat, tingling, muscle spasm and decreased urine flow</li> </ul> <b>Eye disorders:</b> <ul style="list-style-type: none"> <li>Decreased or blurry vision</li> </ul> <b>Other:</b> <ul style="list-style-type: none"> <li>Sharp, stabbing pains</li> <li>Severe bleeding or inflamed blood vessel walls (phlebitis) caused by irregular clotting (disseminated intravascular coagulation)</li> <li>Swelling of the lungs, causing coughing, difficulty breathing and wheezing</li> <li>A burning sensation in the chest (heart burn)</li> </ul> |  |
|--|--|

### Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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 here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What COSMEGEN contains

|   |   |
|---|---|
| <b>Active ingredient (main ingredient)</b>      | <ul style="list-style-type: none"> <li>Dactinomycin (actinomycin D) per vial</li> </ul> |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"> <li>mannitol</li> </ul>                              |
| <b>Potential allergens</b>                      | N/A   |

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What COSMEGEN looks like**

COSMEGEN comes as a yellow powder in a glass vial.

### **Who distributes COSMEGEN**

#### Australia

Recordati Rare Diseases Australia, Pty Ltd  
Suite 1802, Level 18, 233 Castlereagh Street, Sydney, NSW,  
2000 Australia  
Phone: +61 (0) 408 061 403  
[rrdaustrialinfo@recordati.com](mailto:rrdaustrialinfo@recordati.com)

#### New Zealand

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics  
58 Richard Pearse Drive,  
Airport Oaks, Mangere,  
Mt. Wellington, New Zealand  
Phone: (09) 918 5100

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