

PART III: CONSUMER INFORMATION

Pr Cosmegen® dactinomycin for injection

This leaflet is part III of a three-part “Product Monograph” and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about COSMEGEN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

COSMEGEN in a combination therapy is used in the treatment of the following:

- Wilms’ tumor
- Childhood rhabdomyosarcoma
- Ewing’s sarcoma

COSMEGEN alone or in a combination therapy is used in the treatment of gestational trophoblastic neoplasia.

What it does:

COSMEGEN is a chemotherapy drug often used in combinations with other drugs to kill cancer cells. Most chemotherapy agents (including COSMEGEN) work by killing rapidly dividing cells, such as cancer cells. This action can affect normal cells as well.

When it should not be used:

- If you are hypersensitive or allergic to dactinomycin or to any ingredient in the formulation or component of the container.
- If you have the chickenpox or herpes zoster because of the risk of severe generalized disease which may result in death.

What the medicinal ingredient is:

Dactinomycin is the active ingredient.

What the important non-medicinal ingredients are:

- Mannitol

For a full listing of nonmedicinal ingredients, see Part 1 of the product monograph.

What dosage forms it comes in:

COSMEGEN is yellow to orange sterile powder to be given intravenously after reconstitution with sterile water for injection. COSMEGEN is supplied in vials containing 0.5 mg (500 micrograms) of dactinomycin and 20.0 mg of mannitol.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

COSMEGEN should only be given under the care of a doctor who is experienced in the use of cancer drugs.

COSMEGEN is highly toxic, the following are possible serious side effects:

- a decrease in the production of blood cells (myelosuppression)
- severe skin damage, including redness and blistering, (vesicant), which can be life-threatening in some cases

Before you use COSMEGEN, tell your doctor if the following conditions apply to you:

- **have chickenpox or herpes zoster (shingles)**
- **receive live vaccines**
- **are pregnant or plan to get pregnant. COSMEGEN may cause harm to an unborn child. Effective birth control methods should be used. Tell your doctor right away if you become pregnant during treatment.**
- **are breast feeding or plan to breast feed. COSMEGEN should not be used if you breast feed a child.**
- **have radiation therapy**
- **plan to have surgery**

Treatment with cancer drugs, such as COSMEGEN may result in having a second cancer, including leukemia.

Little information has been reported on whether or not COSMEGEN causes infertility, although decreased fertility has been suggested following treatment with other cancer drug.

Your doctor will monitor you closely for side effects and check your blood frequently while you are receiving COSMEGEN. COSMEGEN can affect any part of the body, and commonly causes suppression of the bone marrow, resulting in fewer red blood cells, white blood cells and platelets. Your doctor may discontinue COSMEGEN if your blood counts drop too low, if you have diarrhea, or if you develop sores and irritation inside of your mouth.

INTERACTIONS WITH THIS MEDICATION

When COSMEGEN is given in combination with radiation therapy, halogenated inhalation general anesthesia, live vaccines, or in people who have previously received radiation therapy, halogenated inhalation general anesthesia, live vaccines, more frequent and severe reactions involving the bone marrow, gastrointestinal tract and lining of the mouth may occur. When this combination is used for Wilms’ tumor, an enlarged liver and elevated blood levels of AST (a blood test that indicates liver injury) may occur. You should tell your doctor or pharmacist about your medicines, including the ones you bought without prescription, natural health products, and supplements

PROPER USE OF THIS MEDICATION

How is COSMEGEN given?

You will receive COSMEGEN through a vein in the arm (“intravenously” or “IV”). It is given in the hospital, outpatient department or clinic.

If you are getting many injections, for your convenience, your doctor may insert a catheter (thin tube) or port into a large vein in your body that is placed there as long as it is needed. Medicines get injected through the catheter or port rather than directly into a vein.

What is the dose of COSMEGEN I will receive?

The dose of COSMEGEN will be calculated based on how much you weigh and other factors your doctor will consider, such as your blood count.

What happens if I receive too much COSMEGEN?

If you are given too large a dose of COSMEGEN, you could develop serious problems including sores in the mouth and gastrointestinal tract, a serious bacterial infection in the bloodstream or body tissues (sepsis, including neutropenic sepsis) which can lead to death, critically low blood counts, blockage of veins in the liver, kidney failure and death.

Is treatment with COSMEGEN painful?

COSMEGEN is given through a vein. If the drug leaks into the area outside the vein, painful swelling will result. If this should happen, or if COSMEGEN should leak out of the IV and contact your skin, tell your doctor or nurse right away.

Overdose:

If you think you have taken too much COSMEGEN, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

COSMEGEN’s side effects (except nausea and vomiting) do not usually start until 2-4 days after therapy has stopped, and may not peak until 1 or 2 weeks have gone by. Most side effects are reversible after treatment has stopped, however deaths have occurred.

Hair loss

Infection

The signs of infection include:

- fever over 38° C (100° F),
- chills or sweating,
- sore throat or coughing,

- redness or swelling around a cut, wound or catheter site,
- a burning feeling when you urinate,
- unusual vaginal itching or discharge.

Nausea and vomiting

Fatigue

Anemia

Allergic reactions

Kidney or liver damage

Your doctor will do blood tests to check for problems with your kidneys or liver. There have been reports of liver problems including hepatitis, liver failure and death in people being treated with COSMEGEN.

Soft Tissues

COSMEGEN causes severe soft tissue damage if it escapes from the vein into the surrounding tissues. If you start to have pain, redness, or swelling where the intravenous injection is given tell your doctor or nurse right away.

Rare, serious skin disorders, which may start with redness and blistering and can include flu-like symptoms, possible shedding or sloughing off of skin, have been reported.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Very Common			
Anemia		X	
Decrease in cells that fight infections and prevent bleeding		X	
Fatigue	X		
Hair loss	X		
Inflammation of the inside lining of the mouth and throat		X	
Nausea	X		
Vomiting	X		
Common			
Diarrhea	X		
Infection		X	
Infertility		X	
Injection site reaction		X	
Uncommon			
Liver damage		X	
Rare			
Allergic reactions (hypersensitivity)		X	
Toxic Epidermal Necrolysis (TEN)		X	
Stevens Johnson Syndrome (SJS)		X	

A serious bacterial infection in the bloodstream or body tissues (sepsis, including neutropenic sepsis) which can lead to death		X	
Very Rare			
Small blood clots or excessive bleeding due to depleted clotting factors (disseminated intravascular coagulation)		X	
Vision loss (optic neuropathy)		X	
Constipation	X		
Brain dysfunction related to liver failure (hepatic encephalopathy)		X	
Fluid in the chest (pleural effusion)		X	
Nerve disorder of the hands and feet (peripheral neuropathy)		X	
Collapsed lung (pneumothorax)		X	
Vein inflammation (thrombophlebitis)		X	
Bleeding (hemorrhage)		X	

This is not a complete list of side effects. If you experience any unexpected side effects while taking COSMEGEN, contact your doctor or pharmacist

HOW TO STORE IT

COSMEGEN should be stored in a dry place at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from light and humidity.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals, may be found by contacting the sponsor, Recordati Rare Diseases Canada Inc., at: 905-827-1300.

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