

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

DACOGEN (Decitabine) 50 mg for Injection

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse .

In this leaflet:

1. What Dacogen is and what it is used for
2. Before you use Dacogen
3. How to use Dacogen
4. Possible side effects
5. How to store Dacogen
6. Contents of the pack and other information

1. WHAT DACOGEN IS AND WHAT IT IS USED FOR

What Dacogen is

Dacogen contains the active substance ‘decitabine’. It is an anti-cancer medicine.

What Dacogen is used for

Dacogen is used to treat patients with:

- myelodysplastic syndromes (MDS), a bone marrow disease in which the marrow may not produce adequate numbers of blood cells, or the blood cells may not function normally, and in which the development of leukemia is a risk.
- acute myeloid leukemia (AML). This is a type of cancer that affects your blood cells. You will use Dacogen when you are first diagnosed with AML. It is used in adults only.

How Dacogen works

Dacogen works by stopping cancer cells from growing. It also kills cancer cells.

Talk to your doctor or nurse if you have any questions about how Dacogen works or why this medicine has been prescribed for you.

2. BEFORE YOU USE DACOGEN

Ask your doctor or nurse for advice before taking any medicine.

Do not use Dacogen if:

- you are allergic (hypersensitive) to decitabine or any of the other ingredients of Dacogen.
- you are breast feeding.

Do not use Dacogen if any of the above apply to you. If you are not sure, talk to your doctor or nurse before using Dacogen.

Take special care with Dacogen if:

- you have low numbers of platelets, red blood cells or white blood cells
- you have an infection
- you have a liver disease
- you have a serious kidney disorder

- you have a heart disorder

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before using Dacogen.

Dacogen can cause a serious immune reaction called differentiation syndrome. Tell your doctor or nurse if you experience fever, cough, difficulty breathing, rash, decreased urine, dizziness, swelling of the arms or legs, and rapid weight increase (see also section 4, Possible Side Effects).

Children

Dacogen is not for use in children or adolescents under the age of 18.

Using other medicines

Please tell your doctor or nurse if you are using or have recently used any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Dacogen can affect the way some other medicines work. Also, some other medicines can affect the way Dacogen works.

Tests

You will have blood tests before you start treatment with Dacogen and at the start of each treatment cycle. These tests are to check that:

- you have enough blood cells
- your liver and kidneys are working properly.

Talk to your doctor about what your blood test results mean.

What if I am pregnant (or think I might be pregnant) or breast-feeding?

- You should not use Dacogen if you are pregnant as it may harm your baby.
- Tell your doctor **immediately** if you become pregnant during treatment with Dacogen.
- Do not breast-feed if you are using Dacogen. This is because it is not known if the medicine passes into the mother's milk.

Male and Female fertility and contraception

- Men should not father a child while using Dacogen.
- Men must use effective contraception during treatment and for up to 3 months after treatment has stopped.
- Talk to your doctor if you wish to conserve your sperm before starting treatment.
- Women who are able to become pregnant must use an effective method of contraception during treatment with Dacogen.
- It is unknown when it is safe for women to become pregnant after treatment has stopped. Women who are able to become pregnant must use an effective method of contraception for at least 6 months following completion of treatment with Dacogen.
- Talk to your doctor if you wish to freeze your eggs before starting treatment.

Driving and using machines

You may feel tired or weak after using Dacogen. If this happens, do not drive or use any tools or machines.

3. HOW TO USE DACOGEN

Dacogen will be given to you by a doctor or nurse who is trained in giving this type of medicine. The solution is given into a vein (as an infusion).

How much to use

- Your doctor will work out your dose of Dacogen. This depends on your height and weight (body surface area).

5-Day Treatment Regimen

Dacogen is given by intravenous infusion over 1 hour, repeated daily for 5 days. This is one treatment cycle. There is a gap between treatment cycles of about 4 weeks.

3-Day Treatment Regimen

Dacogen is given by intravenous infusion over 3 hours, three-times daily for 3 days. This is one treatment cycle. There is a gap between treatment cycles of about 6 weeks.

Before each treatment cycle for either the 5-Day or 3-Day treatment regimens, you will have a blood test to see if you are well enough for treatment.

You will usually receive at least 4 treatment cycles. Your doctor may change or delay your dose and change the total number of cycles, depending on how you respond to the treatment.

If you have any further questions on the use of this product ask your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dacogen can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

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

- fever - this may be a sign of an infection caused by low levels of white blood cells
- chest pain or shortness of breath (with or without fever or cough) - these may be signs of an infection of the lung called “pneumonia”.
- bleeding – including blood in the stools. This may be a sign of bleeding in the stomach or gut.
- bleeding inside your head – symptoms of this may be difficulty with moving, speaking or understanding or seeing; sudden severe headache, seizure, numbness or weakness in any part of the body.
- difficulty breathing, swelling of the lips, itching or rash. This may be due to an allergic (hypersensitivity) reaction.

Tell your doctor or nurse immediately if you notice any of the side effects above.

Side effects of Dacogen include:

Very common (affects more than 1 in 10 people)

- lung infection (pneumonia)
- urine infection
- other infection in any part of the body, caused by bacteria, virus or fungi.
- a drop in the number of white blood cells (neutropenia, leukopenia) - you might get a fever and are more likely to get infections.
- bleeding or bruising more easily – these may be signs of a drop in the number of blood platelets (thrombocytopenia).
- feeling tired or looking pale – these may be signs of a drop in the number of red blood cells (anemia).
- headache
- nose bleeds
- diarrhea
- vomiting
- mouth or tongue ulcers
- nausea
- fever
- high levels of ‘bilirubin’ in the blood
- abnormal liver function
- high level of sugar in the blood

Common (affects less than 1 in 10 people)

- an infection of the blood caused by bacteria - this may be a sign of a low level of white blood cells
- sore or runny nose, sore sinuses
- a drop in the number of red blood cells, white blood cells and platelets (pancytopenia)
- allergic (hypersensitivity) reaction

Uncommon (affects less than 1 in 100 people)

- red, raised painful patches on the skin, fever, an increase in white blood cells – these may be signs of ‘Acute Febrile Neutrophilic Dermatositis’ or ‘Sweet’s Syndrome’
- heart muscle disease

Not known (cannot be estimated from the available data)

- serious immune reaction that may cause fever, cough, difficulty breathing, rash, decreased urine, dizziness, swelling of the arms or legs, and rapid weight increase (differentiation syndrome)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. HOW TO STORE DACOGEN

- Do not store above 25°C. Keep out of the reach and sight of children.
- Do not use Dacogen after the expiry date, which is stated on the label. The expiry date refers to the last day of that month.
- Dacogen is made into a solution from a powder before being given. Your doctor or nurse is responsible for storing and preparing Dacogen. They are also responsible for disposing of any unused Dacogen correctly.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Dacogen contains

- The active substance is decitabine. Each 20 ml single dose vial contains 50 mg decitabine. After preparation with 10 ml of Sterile Water for Injection, each ml of the solution for infusion contains 5 mg of decitabine.
- The other ingredients are potassium dihydrogen phosphate and sodium hydroxide.

What Dacogen looks like and contents of the pack

Dacogen is a white to almost white sterile powder for infusion. It is supplied in a glass vial containing 50 mg decitabine.

Marketing Authorization Holder:

Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

Manufacturer:

BSP Pharmaceuticals S.p.A., Via Appia Km 65, 561(loc. Latina Scalo) 04013, Latina, Italy.

Secondary packaged and released by:

Janssen Pharmaceutica NV, Turnhoutseweg 30, 2340 Beerse, Belgium.

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To contact us, go to www.janssen.com/contact-us

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists

The following information is intended for healthcare professionals only:

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. DACOGEN should not be infused through the same intravenous access/line with other medicinal products.

Instructions for Use and Handling and Disposal

This medicinal product is for single use only.

Skin contact with the solution should be avoided and protective gloves must be worn.

Standard procedures for dealing with anticancer agents should be adopted.

DACOGEN should be aseptically reconstituted with 10 mL of Sterile Water for Injection.

Upon reconstitution, each mL contains approximately 5.0 mg of decitabine at pH 6.7 to 7.3.

Immediately after reconstitution, the solution should be further diluted with 0.9% Sodium Chloride Injection or 5% Dextrose Injection to a final drug concentration of 0.15 to 1.0 mg/mL.

Unless used within 15 minutes of reconstitution, the diluted solution must be prepared using cold (2°C to 8°C) infusion fluids and stored at 2°C to 8°C for up to a maximum of 4 hours until administration.

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