

PATIENT INFORMATION

DOXORUBICIN (dakse-RU-besen) **(doxorubicin hydrochloride)** **for Injection**

Read this Patient information before you start receiving Doxorubicin and before each infusion. This information leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Doxorubicin?

Doxorubicin may cause serious side effects including:

- **Heart problems.** Doxorubicin may cause heart problems that may lead to death. These problems can happen during your treatment or months to years after stopping treatment. In some cases heart problems are irreversible. Your chance of heart problems is higher if you:
 - already have heart problems
 - have a history of radiation therapy or are currently receiving radiation therapy to your chest
 - have had treatment with certain other anti-cancer medicines
 - take other medicines that can affect your heart

Tell your doctor if you get any of these symptoms of heart problems:

- shortness of breath
- swelling of your feet and ankles
- cough
- fast heartbeat

Your doctor should do tests to check your heart before, during, and after your treatment with Doxorubicin.

- **Secondary cancers.** Some people who have received Doxorubicin have developed acute myelogenous leukemia (AML) or myelodysplastic syndrome (MDS). Your chance of developing a secondary cancer is higher if you receive Doxorubicin along with other anti-cancer medicines or with radiation therapy.
- **Decreased blood cell counts.** Doxorubicin can cause a severe decrease in neutrophils (a type of white blood cells important in fighting in bacterial infections), red blood cells (blood cells that carry oxygen to the tissues), and platelets (important for clotting and to control bleeding). Your doctor will check your blood cell count during your treatment with Doxorubicin and after you have stopped your treatment.

What is Doxorubicin?

Doxorubicin is a prescription anti-cancer medicine used to treat certain types of cancers. Doxorubicin may be used alone or along with other anti-cancer medicines.

Who should not receive Doxorubicin?

Do not receive Doxorubicin if:

- your blood cell counts are too low: platelets (which help your blood to clot), red blood cells (which help to carry iron and oxygen throughout your body), and white blood cells (which help to fight infection)
- you have a severe liver problem
- you have had a recent heart attack or have severe heart problems
- you have had previous treatment with Doxorubicin or certain other anti-cancer medicines and received the maximum dose allowed
- you are allergic to certain other anti-cancer medicines, doxorubicin hydrochloride, or any other ingredient in Doxorubicin. See the end of this leaflet for a complete list of ingredients in Doxorubicin.

Talk to your doctor before receiving Doxorubicin if you have any of the conditions listed above.

What should I tell my doctor before receiving Doxorubicin?

Before you receive Doxorubicin, tell your doctor if you:

- have heart problems
- have had radiation treatment or currently receiving radiation therapy
- are over the age of 50
- have liver problems
- plan to receive any vaccines. Talk to your doctor about which vaccines are safe for you to receive during your treatment with Doxorubicin. See "What should I avoid while receiving Doxorubicin?"
- have any other medical conditions
- are pregnant or plan to become pregnant. Doxorubicin can harm your unborn baby. Women who may become pregnant should use effective birth control (contraception). Talk to your doctor about the best way to prevent pregnancy while receiving Doxorubicin.
- are breastfeeding or plan to breast feed. Doxorubicin can pass into your breast milk and harm your baby. You and your doctor should decide if you will receive Doxorubicin or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Doxorubicin can interact with other medicines. Do not start any new medicine before you talk with the doctor that prescribed Doxorubicin.

Know the medicines you take. Keep a list to show your doctor and pharmacist each time you get a new medicine.

How will I receive Doxorubicin?

- Your doctor will prescribe Doxorubicin in an amount that is right for you.
- Doxorubicin will be given to you by intravenous (IV) infusion into your vein.
- Your doctor will do regular blood tests to check for side effects of Doxorubicin.
- Before receiving Doxorubicin you may receive other medicines to prevent or treat side effects.
- Caregivers of children receiving Doxorubicin should take precautions (such as wearing latex gloves) to prevent contact with the patient's urine and other body fluids for at least 5 days after each treatment.

What should I avoid while taking Doxorubicin?

- Avoid receiving live vaccines during treatment with Doxorubicin. Talk to your doctor to find out which vaccines are safe for you while receiving Doxorubicin. See "What should I tell my doctor before receiving Doxorubicin?"

What are the possible side effects of Doxorubicin?

Doxorubicin can cause serious side effects including:

- See "What is the most important information I should know about Doxorubicin?"

Infusion site reactions. Serious infusion site reactions can happen with Doxorubicin. Symptoms of infusion reaction may include:

- pain at injection site
- skin redness or swelling
- burning or stinging
- open skin sores at injection site

Your doctor will watch you closely while you are receiving Doxorubicin and after your infusion for signs of a reaction. You may experience these reactions immediately or within 2 hours of infusion.

Change in the color of your urine. You may have red colored urine for 1 to 2 days after your infusion of Doxorubicin. This is normal. Tell your doctor if it does not stop in a few days, or if you see what looks like blood or blood clots in your urine.

Infection. Call your doctor right away if you get any of the following signs of infection:

- fever (temperature of 100.4 F or greater) chills or shivering
- cough that brings up mucus
- burning or pain with urination

Doxorubicin may cause lower sperm counts and sperm problems in men.

This could affect your ability to father a child and cause birth defects. Men should use effective birth control (contraception) while receiving Doxorubicin. Do not have unprotected sexual contact with a female who could become pregnant. Tell your doctor if you do have unprotected sexual contact with a female who could become pregnant. Talk to your doctor if this is a concern for you.

Irreversible amenorrhea or early menopause. Your periods (menstrual cycle) may completely stop when you receive Doxorubicin. Your periods may or may not return after you complete your treatment of Doxorubicin.

The most common side effects of Doxorubicin include:

- hair loss (alopecia). Your hair may re-grow after your treatment.
- darkening of your nails or separation of your nails from your nailbed
- nausea
- vomiting
- lack of appetite or increased thirst
- bruise or bleed more easily
- abnormal heart beat
- a secondary cancer may occur when Doxorubicin is combined with other chemotherapy agents.
- mouth sores
- weight changes
- stomach (abdominal) pain
- diarrhea
- eye problems
- allergic reactions. Call your doctor right away if you have any of the following symptoms of an allergic reaction:
 - rash
 - flushed face
 - hives
 - itching
 - swelling of your lips or tongue
 - fever
 - dizziness or feel faint
 - shortness of breath or trouble breathing

Tell your doctor or nurse if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Doxorubicin. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Doxorubicin.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

This leaflet summarizes the most important information about Doxorubicin. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Doxorubicin that is written for healthcare professionals.

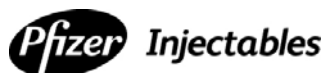
For more information, call 1-800-1-800-438-1985.

What are the ingredients of Doxorubicin?

Active ingredient: Doxorubicin hydrochloride

Inactive ingredient: lactose, methylparaben, sodium chloride 0.9%, water for injection, and hydrochloric acid.

This Patient Information has been approved by the U.S. Food and Drug Administration.



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