

DARZALEX™

TREATMENT INFORMATION



For distribution by healthcare professionals to patients prescribed with DARZALEX™.

Please consult your doctor or healthcare professional if you have any questions.

 **DARZALEX™**
daratumumab
concentrate for solution for infusion

What is in this leaflet

This leaflet answers some common questions about DARZALEX™ Concentrate for Solution for Infusion. 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 being given DARZALEX™ against the benefits this medicine is expected to have for you.

If you have any concerns about being given DARZALEX™ ask your doctor.



What DARZALEX™ is used for

DARZALEX™ is an anti-cancer medicine and contains the active substance daratumumab. This belongs to a group of medicines called “monoclonal antibodies”. One of the ways monoclonal antibodies work is by attaching themselves to specific cancer cells in your body, so your immune system can destroy them.²

DARZALEX™ is used to treat adults with multiple myeloma (cancer of the bone marrow).^{1,2}

Ask your doctor if you have any questions about why DARZALEX™ has been prescribed for you.

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

How much is given:

Your doctor will work out your dose and schedule of DARZALEX™. The dose of DARZALEX™ will depend on your body weight. The recommended dose is DARZALEX™ 16 mg per kg of body weight.^{1,2}

DARZALEX™ may be given alone or together with other medicines used to treat multiple myeloma.^{1,2}

Ask your doctor if you want to know more about the dose of DARZALEX™ you receive.

How it is given:

DARZALEX™ will be given to you by a doctor or nurse.²

DARZALEX™ will be diluted in 0.9% sodium chloride.^{1,2}

It is given over several hours as a drip into a vein (“intravenous infusion”).²

When it is given:

Your doctor will tell you when DARZALEX™ will be given. The frequency depends on whether it is given alone or together with other medicines used to treat multiple myeloma.²

Medicines given during treatment with DARZALEX™:

DARZALEX™ may be given alone or together with other medicines used to treat multiple myeloma (with bortezomib, thalidomide and dexamethasone, or with bortezomib, melphalan and prednisone, or with lenalidomide and dexamethasone or with bortezomib and dexamethasone).^{1,2}

You may be given medicines to lower the chance of getting shingles.²

Before each infusion of DARZALEX™ you will be given medicines which help to lower the chance of infusion-related reactions.^{1,2}

These may include:

medicines for an allergic reaction (anti histamines), medicines for inflammation (corticosteroids) and medicines for fever (such as paracetamol).^{1,2}

After each infusion of DARZALEX™ you will be given medicines by mouth (such as corticosteroids) to lower the chance of infusion-related reactions.^{1,2}

People with breathing problems:

If you have breathing problems, such as asthma or Chronic Obstructive Pulmonary Disease (COPD), you may be given medicines to inhale which help your breathing problems:²

medicines to help the airways in your lungs stay open (bronchodilators)²

medicines to lower swelling and irritation in your lungs (corticosteroids)²

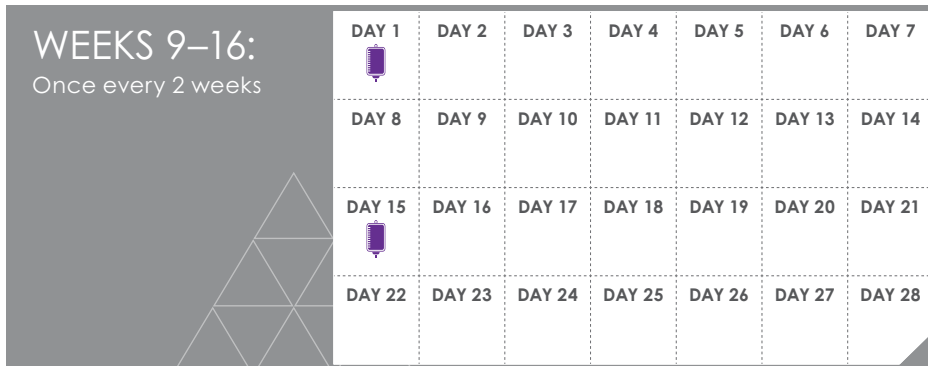
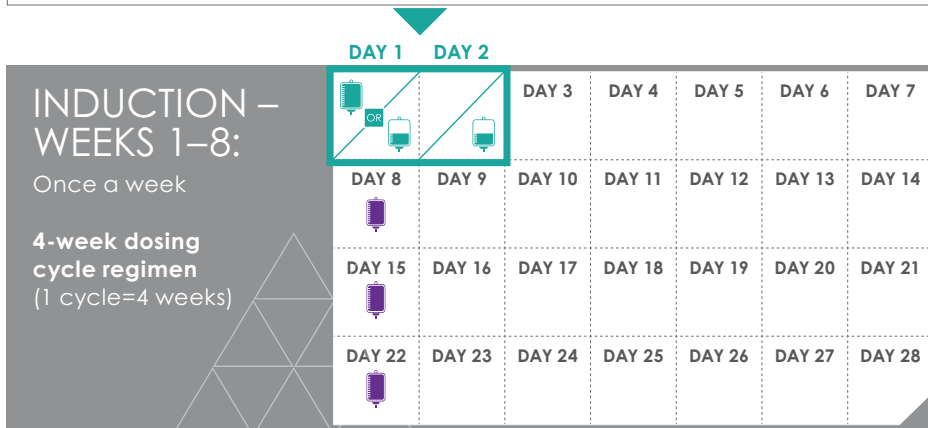
If you forget your appointment to have DARZALEX™: ²

It is very important to go to all your appointments to make sure your treatment works. If you miss an appointment, make another one as soon as possible.²

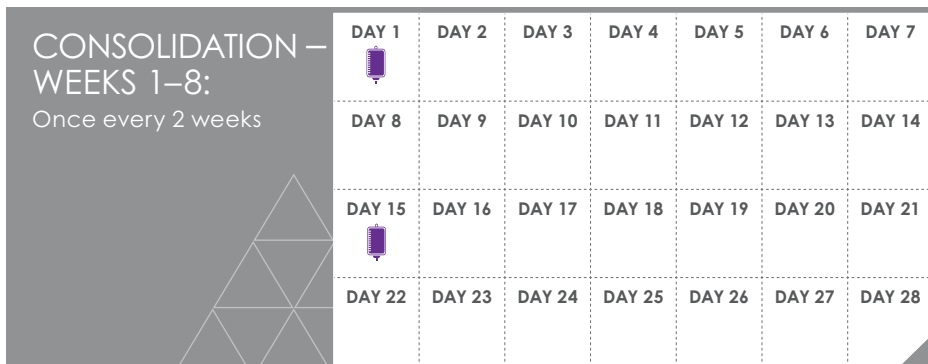
If you have any further questions on the use of this medicine, ask your doctor or nurse. ²

If you have been prescribed DARZALEX™ in combination with bortezomib, thalidomide, and dexamethasone (“D-VTd”), DARZALEX™ will be administered as follows:¹

During the first week of treatment, your doctor may choose to administer your **first dose** of DARZALEX™ over **two** consecutive days, rather than one, so that you receive half of the first dose on Day 1 and the other half on Day 2.¹



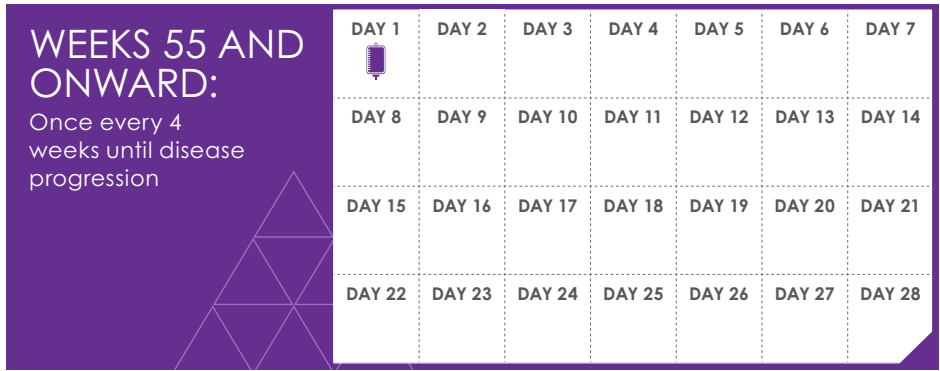
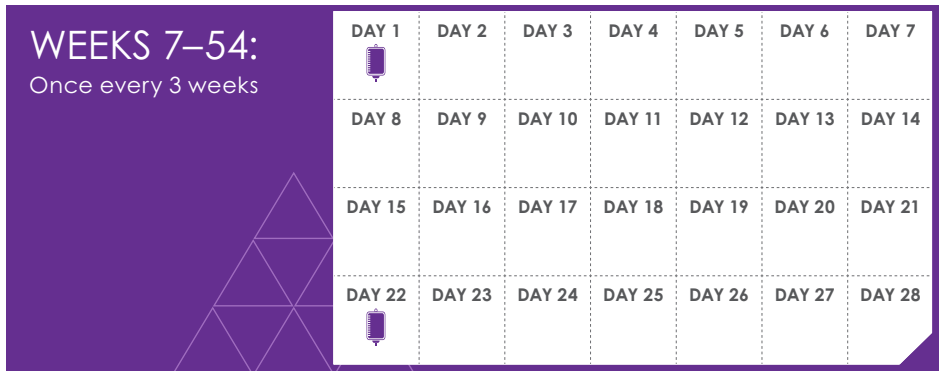
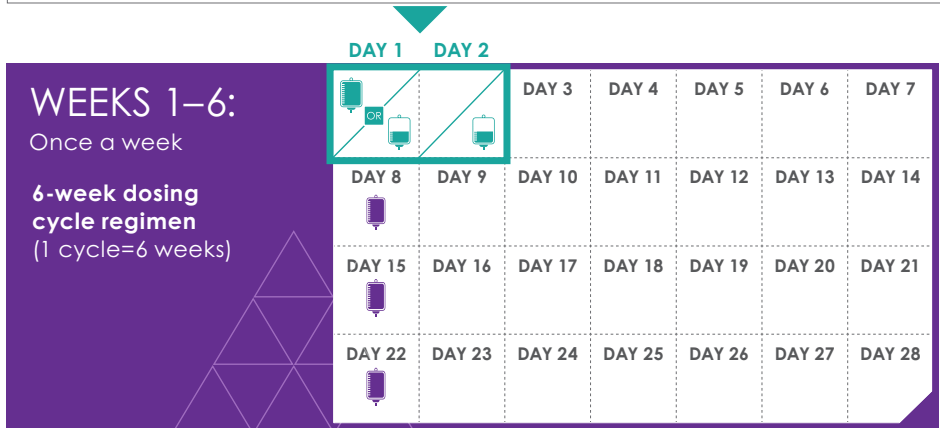
Stop for high dose chemotherapy and autologous stem cell transplant



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If you have been prescribed DARZALEX™ in combination with bortezomib, melphalan and prednisone (“D-VMP”), DARZALEX™ will be administered as follows:¹

During the first week of treatment, your doctor may choose to administer your **first dose** of DARZALEX™ over **two** consecutive days, rather than one, so that you receive half of the first dose on Day 1 and the other half on Day 2.¹

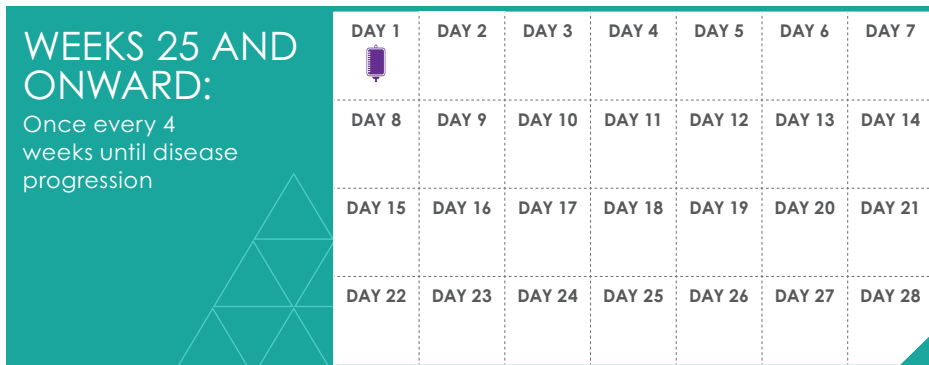
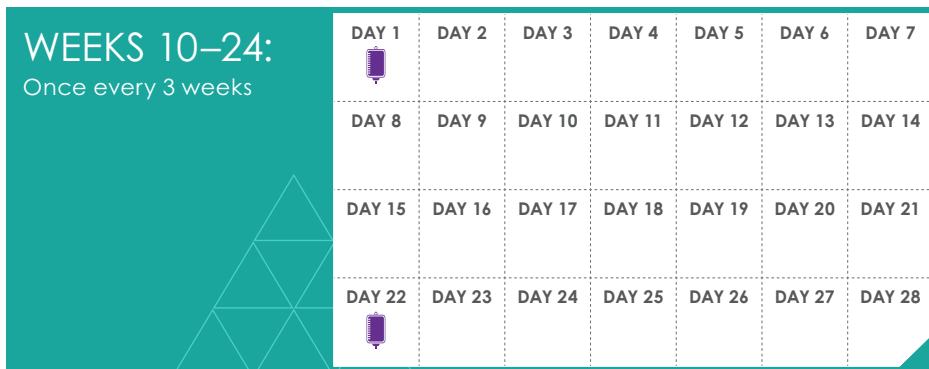
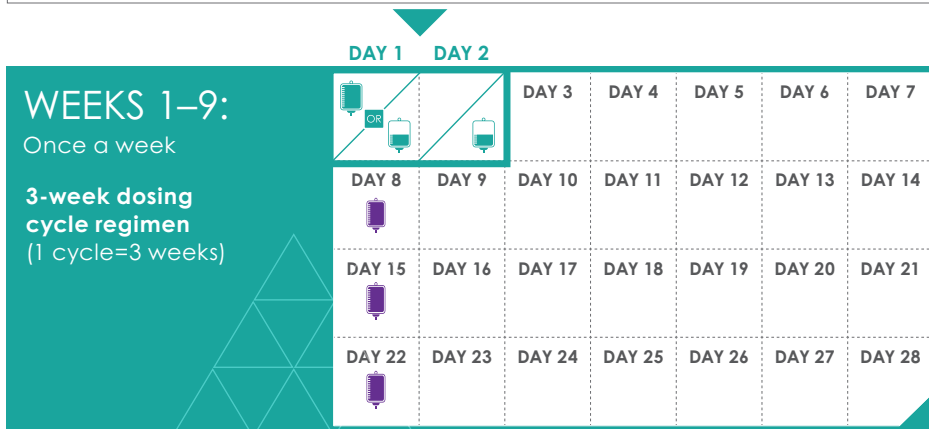


DARZALEX™ may be taken as long as your condition does not worsen.

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If you have been prescribed DARZALEX™ in combination with bortezomib and dexamethasone (“DVd”), DARZALEX™ will be administered as follows:¹

During the first week of treatment, your doctor may choose to administer your **first dose** of DARZALEX™ over **two** consecutive days, rather than one, so that you receive half of the first dose on Day 1 and the other half on Day 2.¹



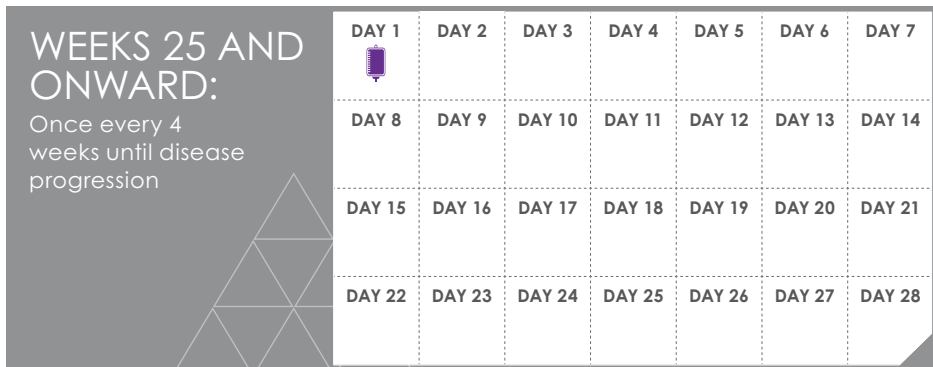
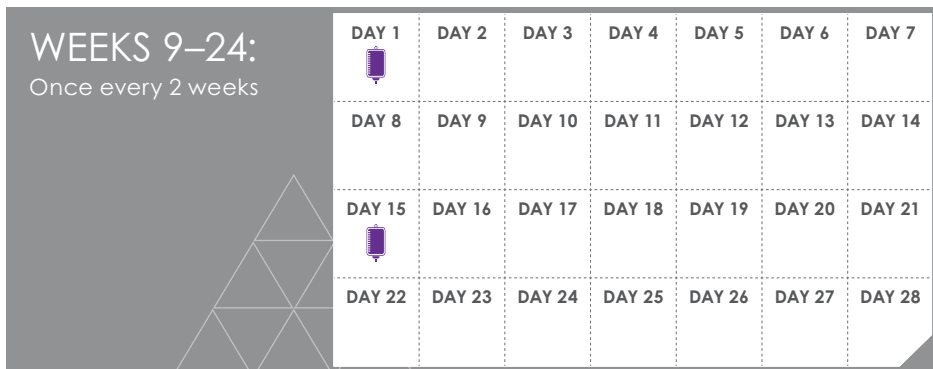
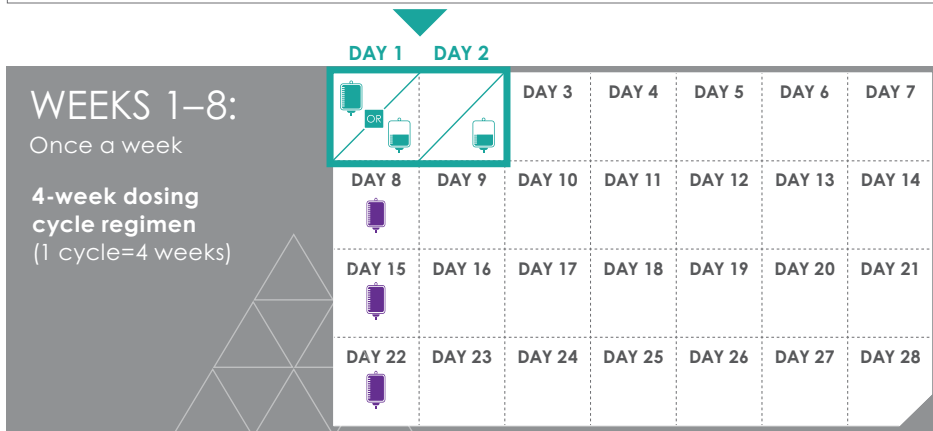
DARZALEX™ may be taken as long as your condition does not worsen.

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If you have been prescribed DARZALEX™ in combination with lenalidomide and low dose dexamethasone (“DRd”), and for monotherapy, DARZALEX™ will be administered as follows:¹

During the first week of treatment, your doctor may choose to administer your **first dose** of DARZALEX™ over **two** consecutive days, rather than one, so that you receive half of the first dose on Day 1 and the other half on Day 2. ¹



DARZALEX™ may be taken as long as your condition does not worsen.

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While you are using DARZALEX™

Things you must do:²

- 01** **Be sure to keep all your doctor's appointments so your progress can be checked.**
Your doctor will want to do some blood, urine and other tests from time to time to check on your progress and detect any unwanted side effects.²
- 02** **Keep follow up appointments with your doctor.**
It is important to have your follow-up doses of DARZALEX™ at the appropriate times to get the best effects from your treatment.²
- 03** **Be sure to follow your doctor's instructions about other medicines you should take, and other things you should do.²**
- 04** **Tell any other doctors, dentists and pharmacists who are treating you that you are having DARZALEX™.²**
- 05** **If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are having DARZALEX™.²**
- 06** **If you become pregnant or your partner becomes pregnant while being given DARZALEX™, tell your doctor immediately.²**
- 07** **If you need to have a blood test, tell the person doing the test that you are using DARZALEX™.²**

Decreased blood cell counts²

DARZALEX™ can decrease white blood cell counts which help fight infections, and blood cells called platelets which help to clot blood.²

Tell your doctor if you develop fever or if you have signs of bruising or bleeding.²

The following precautions should be taken to reduce your risk of infection or bleeding:²

Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it is painful or difficult to urinate.²

Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.²

Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.²

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Blood transfusions²

If you need a blood transfusion, you will have a blood test first to match your blood type. DARZALEX™ can affect the results of this blood test. Tell the person doing the test that you are using DARZALEX™.²

Hepatitis B^{1,2}

If you have ever had a hepatitis B infection, DARZALEX™ could cause hepatitis B virus to become active again. Your doctor will check you for signs of this infection before, during and for some time after treatment with DARZALEX™.^{1,2}

Tell your doctor right away if you get increasingly tired or get yellowing of your skin or white part of your eyes.²

Infusion-related reactions^{1,2}

Before and after each infusion of DARZALEX™, you will be given medicines which help to lower the chance of infusion-related reactions. Some serious allergic reactions and other severe infusion related reactions have resulted in death. These reactions can happen during the infusion or in the 3 days after the infusion.²

Tell your doctor or nurse right away if you get any of the infusion-related reactions.²

If you get infusion-related reactions, you may need other medicines, or the infusion may need to be slowed down or stopped. When these reactions go away, or get better the infusion can be started again.²

These reactions are most likely to happen with the first infusion. If you have had an infusion-related reaction once it is less likely to happen again. Your doctor may decide not to continue DARZALEX™ if you have a strong infusion-related reaction.²

Things to be careful of^{1,2}

Be careful driving or operating machinery until you know how DARZALEX™ affects you.^{1,2}

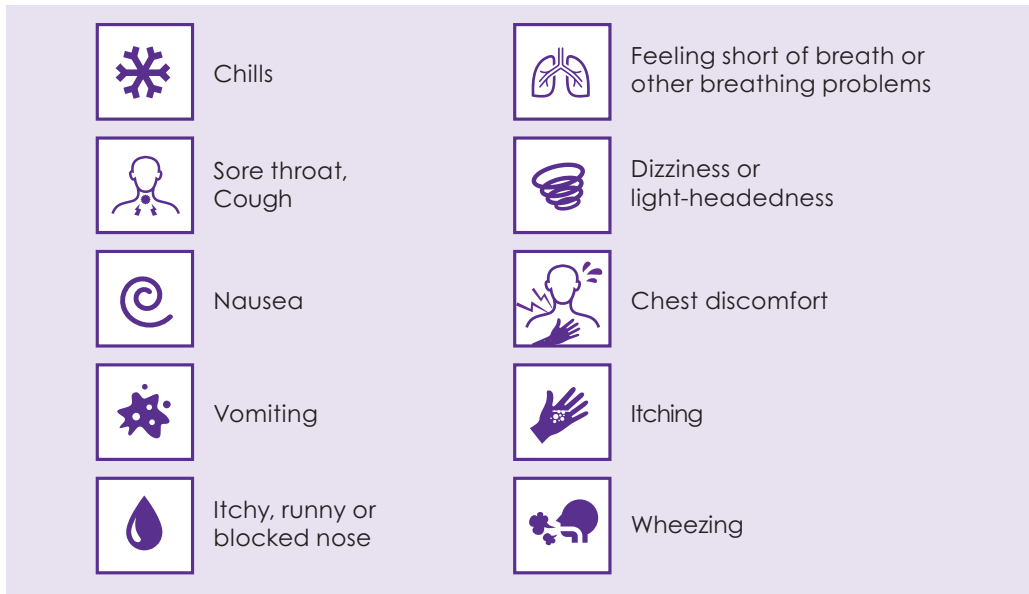
DARZALEX™ may cause tiredness and other effects in some people. Make sure you know how you react to DARZALEX™ before you drive a car, operate machinery, or do anything else that could be dangerous if you have side effects.²

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What are some other possible side effects with DARZALEX™?

DARZALEX™ may cause adverse reactions, including:

Infusion-related reactions^{1,2}



Other side effects²

- fever
- chills
- feeling very tired
- feeling weak
- flu
- headache
- diarrhoea
- constipation
- nerve damage that may cause tingling, numbness or pain
- high blood pressure
- muscle spasms
- swollen hands, ankles or feet
- lung infection (pneumonia)
- bronchitis
- build-up of fluid in the lungs making you short of breath
- infections of the airways – such as nose, sinuses or throat

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- low number of red blood cells which carry oxygen in the blood (anaemia)
- low number of white blood cells which help fight infections (neutropenia, lymphopenia, leukopenia)
- low number of a type of blood cell called platelets which help to clot blood (thrombocytopenia)
- high level of sugar in the blood
- low level of calcium in the blood
- inflamed pancreas
- irregular heart beat (atrial fibrillation)
- urinary tract infection
- dehydration
- fainting
- chest pain
- other pain (eg back, joints)
- inflamed liver (hepatitis)
- small blisters in clusters on the skin (herpes)
- a type of herpes virus infection (cytomegalovirus infection)
- rash, itching
- unusual feeling in the skin (such as tingling or crawling feeling)
- redness of the skin or redness and pain at injection site
- decreased appetite
- severe infection throughout the body (sepsis).

Allergic reaction²

Symptoms usually include some or all of the following:

- rash, itching or hives on the skin
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

If you think you are having an allergic reaction to DARZALEX, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.²

Other side effects not listed above may also occur in some people.²

Tell your doctor, nurse or pharmacist if you notice any other effect that is making you feel unwell.²

References:

1. DARZALEX™ Approved Prescribing Information Malaysia [CCDS v01 Jun2021].
2. DARZALEX™ Australia Consumer Medicine Information. https://media.healthdirect.org.au/medicines/GuildLink_Information/281842/CMI/jccdarza10821.pdf. Accessed 07 January 2022.18:00

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