

ADALIMUMAB : DRUG FACTS, INDICATIONS, SIDE EFFECTS AND DOSING
WHAT IS ADALIMUMAB?
ADALIMUMAB DOSAGE AND APPLICATION
WHAT ARE THE POSSIBLE SIDE EFFECTS OF ADALIMUMAB?
WHAT ARE THE RISKS OF TAKING ADALIMUMAB?

Exemptia(adalimumab) has been researched, developed and produced by scientists at the Zydus Research Centre. The biosimilar is the first to be launched by any company in the world and is a 'fingerprint match' with the originator in terms of safety, purity and potency of the product. The biosimilar of Adalimumab is a part of Zydus' robust biologics programme which has the largest number of monoclonal antibodies under development in India. The group's R&D pipeline which comprises 15 biologics includes biosimilars and two novel biologics. These biologics are being developed to treat auto immune disorders like arthritis, cancer, infertility and stroke.
Adalimumab prescribed varies from region to region and affects the immune system and other health conditions promoted by Zydus Cadila in India.

Adalimumab : Drug Facts, Indications, Side Effects and Dosing

Rheumatoid Arthritis is a chronic inflammatory disorder of the joints that may cause painful swelling and result into joint deformity or bone erosion. It is one of the most common auto-immune disorders today and occurs when the immune system attacks its own body's tissues mistakenly. Rheumatoid Arthritis is more common in women in the age group of 30 to 50 years. Adalimumab may help alleviate the symptoms of Rheumatoid Arthritis and other inflammatory diseases.

What is Adalimumab?

Adalimumab, trade name Exemptia, is a potent TNF-inhibitor and anti-inflammatory drug manufactured and promoted by Zydus Cadila in India. When people have Rheumatoid Arthritis or other inflammatory diseases, it causes over-secretion of TNF, a protein naturally produced in the body, causing inflammation and damage to the joints. Adalimumab works as anti-TNF, blocking over production of TNF and its harmful effects on the body. It helps to reduce inflammation and alleviate the symptoms of arthritis and other joint disorders.

When is Adalimumab Prescribed?

Adalimumab is prescribed to people who have Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, and to children having Juvenile Idiopathic Arthritis (JIA).

The guidelines for when is Adalimumab prescribed varies from region to region and based on the kind of disorder. If a person has Rheumatoid Arthritis, Exemptia will only be prescribed by the doctors if:

- the condition is active and
- if the patient has already used Methotrexate or other Disease-Modifying Anti Rheumatic Drug (DMARD) like Hydroxychloroquine or Sulfasalazine or
- the person cannot use these medicines from some reason

Before Using Adalimumab

A patient will not be prescribed Adalimumab if his/her Rheumatoid Arthritis condition is not active; he/she has not been under standard treatments and medications first; he/she has an active infection. The doctor may also not prescribe it if:

- You have a history of Tuberculosis
- You are breastfeeding
- You are pregnant or planning to become pregnant
- You have had cancer
- You have had heart failure or suffering from critical heart diseases
- You have Multiple Sclerosis
- You have lung fibrosis, a condition where the lung tissues thicken abnormally
- You have other infections that keep coming back
- You are taking prescription or non-prescription medicine, dietary supplement or herbal preparation
- You had Hepatitis B or other liver problems, high blood pressure, high cholesterol, bone marrow problems, an auto-immune disorders or other immune system and nervous system problems
- You have received treatment with Rituximab or other TNF blocker recently

Adalimumab Dosage and Application

Adalimumab is available only on prescription from a Rheumatologist. The usual dosage for Rheumatoid Arthritis is 40mg once in every 2 weeks.

- The drug comes with a Medication Guide regarding dosage and application. Read it carefully every time you use **Adalimumab**
- Do not use the medicine if is cloudy or discolored, contains particle, or if the syringe or pen is damaged or cracked
- It is applied by subcutaneous injection or an injection under the skin. Your healthcare provider or a Rheumatology nurse will teach you how to use the injection. Follow the steps carefully when you use a dose. Make sure that the drug is injected under the skin and not into muscles
- Change the areas of injection application for every new dosage

How Long Does the Drug Take to Work?

If your body responds to the medicine positively, the results may start showing in 2-12 weeks.

What are the Possible Side Effects of Adalimumab?

The most common side effects of Adalimumab are reactions at the site of injection like swelling, redness and pain; back pain; headache; nausea;

mild stomach pain; runny or stuffy nose. The side effects are not serious and generally go away in few hours after taking the injection.

Here, it is important to know how Adalimumab works. The TNF-inhibitor affects the body's defense system, i.e. the immune system. Therefore, you may develop certain infections. On the other hand, it may only show the symptoms of an infection, while you might not actually be affected. However, you should inform your doctor if you develop fever, sore throat, any symptoms of infection or any new symptoms that concern you.

When to See a Doctor?

Typically, usage of Adalimumab does not cause any serious side effects. However, you should stop taking the drug and consult your doctor immediately if you experience:

- Severe allergic reactions like difficulty breathing, rashes, itching, swelling of the mouth, unusual hoarseness or tightness in the chest
- Blood in urine or stool
- Open sore that does not heal
- Chest pain; irregular or fast heartbeat
- Mood swings and depression
- Butterfly-shaped rashes on the cheeks and nose
- Persistent pain, redness or swelling at the injection site
- Flu-like symptoms
- Blood in the phlegm
- Persistent or severe headache, nausea and dizziness
- Unusual bleeding or bruising
- Vision changes
- Unusual weakness and tiredness

These are only few possible side effects that may occur when you use Adalimumab. If you see or feel something unusual or persistent, contact your doctor immediately.

If you develop Chickenpox or Shingles while you are on Adalimumab, consult your doctor immediately. You may be put under anti-viral treatment and your dosage of Adalimumab will be stopped.

The long-term side effects of Adalimumab are still unknown since it is relatively a new drug.

What are the Risks of Taking Adalimumab?

Since Adalimumab affects the immune system, you might be at a risk of certain infections and other health conditions.

There might be a little increased risk of developing cancers in patients using the drug that affects the body's immune system. However, this hasn't been proven yet and is under research. Often, TNF-inhibitor drugs have been associated with certain kinds of skin cancer, which can be treated if diagnosed early.

In very rare cases, Adalimumab may cause a condition called Drug-induced Lupus. The symptoms include fever, rash, increased joint pain. The health condition is mild and can be easily diagnosed by a blood test.

How to Reduce the Risk of Infection?

Since the drug affects your immune system, with Adalimumab you may be at a higher risk of developing infections. When you are using the medicine, avoid close contact with people having severe and active infections. Thoroughly clean your hands before taking food as this may help prevent spreading of germs.

Is There Any Interaction Between Adalimumab and Alcohol?

Though no known interactions have been found between Adalimumab and alcohol, it is recommended that you keep well within limits if you are also taking Methotrexate. The latter and alcohol can interact and cause liver damages. The recommended amount of alcohol is 2-3 units per day for women and 3-4 units per day for men. In certain cases, the doctor may recommend even lower limits like 4 units per week if you are suffering from Psoriatic Arthritis.

Will Taking Adalimumab Affect Vaccinations?

If you are on Adalimumab, it is advised to avoid live vaccinations like Yellow Fever. In certain cases where live vaccine may be necessary as for Rubella immunization in female of childbearing age, your doctor may discuss the possible benefits or risks of the vaccination and its interaction with the drug.

Pneumovax and annual flu vaccines have been proved to have no interaction with Adalimumab and are recommended.

If you are aged 70 or more and prescribed Shingles vaccination, your doctor may recommend you to have it before you start the drug. Typically, Shingles vaccine is not advised for people who are on Adalimumab already.

Adalimumab and Pregnancy

Though there are no scientific findings regarding Adalimumab and pregnancy, it is often recommended that women of childbearing age use contraception while using the drug. If you are pregnant or planning to get pregnant, discuss with your doctor or gynecologist whether you should or not stop using the drug. Your doctor will weigh the benefits of using the drug to control your arthritis as against its possible risk on your pregnancy or fertility. It is important to remember here that uncontrolled arthritis may also affect the unborn baby. If your doctor recommends not using Adalimumab any further when you are trying to get pregnant, then you should continue using contraception for at least 5 months after stopping the medicine and give your body the time to completely flush it out of your system.

Does Adalimumab Affects Breastfeeding?

Usually, breastfeeding is not recommended if you are on Adalimumab, or you should not use the drug if you are breastfeeding. The medicine may pass into your breast milk and could be harmful to the baby.

Other Information About Adalimumab

- Safety: Make sure that your family or anyone treating you is aware that you are on Adalimumab and therefore, you are at a risk of its possible side effects, like infections. The drug should only be used by the person to whom it is prescribed. Do not ever share it with any other people, not even under similar health conditions or symptoms. Keep it away from children and pets.
- Storage: Store the drug in the refrigerator between 36 and 46 degrees F. Do not freeze. If you have to carry the medicine when traveling, it may be stored at room temperature for up to 14 days and in up to 77 degrees F. Protect from extreme heat or cold. Do not take the medicine after its expiration date. Do not use it if it has been frozen ever. If you do not use the medicine within 14 days of taking it out of the refrigerator, throw it away.
- Alternatives: There are a number of other medicines used in the treatment of Rheumatoid Arthritis and other inflammatory disorders. Your doctor will discuss the other options with you.

- Other Medications: Adalimumab may often be prescribed along with other medicines, including Methotrexate. However, you should always inform any other doctor treating you that you are using the drug.
- Screening and Diagnosis: Before Adalimumab is prescribed to you, you might have to do certain blood tests, chest X-ray and screening to diagnose whether you have had Tuberculosis or Hepatitis. Certain patients may undergo a serious of treatment for Latent Tuberculosis before you start Adalimumab. The drug may increase the risk of reactivating a previous hepatitis infection. Therefore, further blood tests may be done while you are on the medicine.
- General Information: Adalimumab is not a painkiller and may not provide relief from arthritis pain. However, if you respond to the medicine well, your doctor may reduce your painkillers or non-steroidal anti-inflammatory drug after a time.

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