

Please note that this summary only contains information from the full scientific article:

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How do product features of reference adalimumab medicine and biosimilar adalimumab medicines in the United States affect people's experiences of treatment?



Adalimumab

<ada-LIM-yoo-mab>

Biosimilar

<BY-oh-SIH-mih-ler>

Citrate

<SIT-trayt>

Cytokine

<SY-toh-kine>

Interchangeability

<in-ter-CHAYNG-eh-bil-ih-tee>

Subcutaneous

<SUB-kyoo-TAY-nee-us>

Tumor necrosis factor alpha

<TOO-mer neh-KROH-sis FAK-ter AL-fuh>

Date of summary: December 2023

The full title of this article: Relevance of adalimumab product attributes to patient experience in the biosimilar era: a narrative review

Key takeaway

- Biological medicines are medicines that are made by living organisms such as bacteria, animal or plant cells. Many biological medicines are proteins.
- A biosimilar medicine is an approved biological medicine that is very similar to an approved biological medicine that is already available (called the reference medicine). Approved biosimilar medicines must:
 - Show in studies that they are as safe and work as well as the reference biological medicine.
 - Be taken in the same way and at the same dose as the reference biological medicine.
- Adalimumab is a biological medicine approved by the United States Food and Drug Administration for people with conditions that cause long-term inflammation (swelling) of the joints, intestines, or skin (inflammatory conditions for short).
- Reference adalimumab and biosimilar adalimumab medicines approved in the United States have different product features.
- These features can affect people's experiences of treatment, including how much pain they feel at the site of injection.
- People taking adalimumab may want to discuss the product features with their doctor when deciding which adalimumab (reference or biosimilar) medicine to use.

The purpose of this plain language summary is to help you to understand the findings from a recent review article.

- Reference and biosimilar adalimumab medicines are approved in the United States to treat the conditions that are discussed in this summary. Approval varies by country; please check with your local provider for more details if you live outside the United States.
- Healthcare professionals must look at the results of many types of studies to understand whether a study drug works, how it works, and whether it is safe to prescribe to people. This summary reports information from a review article. The findings may differ from those of other review articles.

More information can be found in the scientific article of this review, which you can access here: [View Scientific Article](#)

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What is adalimumab?

- Adalimumab is biological medicine.
- People with inflammatory conditions of the joints, intestines, or skin may be prescribed adalimumab to reduce inflammation.
 - In people with inflammatory conditions, the immune system (the body's own defense system) attacks healthy cells. This causes inflammation which, depending on the condition, can cause a range of symptoms.
- Adalimumab works by blocking the activity of a cytokine called tumor necrosis factor alpha (TNF- α).
 - Cytokines are proteins that attract immune cells to areas of damage, inflammation, and infection.
 - TNF- α is released by immune cells and causes inflammation.
- In people with inflammatory conditions, immune cells continue to release TNF- α , which causes long-lasting inflammation and painful symptoms.
 - Adalimumab binds to TNF- α and stops it from attracting other immune cells. This reduces inflammation and painful symptoms.
- Doctors have been prescribing adalimumab to people with inflammatory conditions in the United States since 2003.
 - The brand name of the reference adalimumab medicine is Humira®.

What are biosimilar medicines?

- Biosimilar medicines (or biosimilars) are approved biological medicines that are very similar to reference biological medicines that are already available.

Biosimilars are:



Tested to check that they work as well and are as safe as reference biological medicines.



Taken at the same dose and in the same way as reference biological medicines.



Cost less to develop than reference biological medicines and provide people with more options for treatment.

- Biosimilars may decrease healthcare costs and allow more people to get treatment with biological medicines.
- Adalimumab biosimilars are approved in the United States.
- The United States Food and Drug Administration (FDA), the regulatory agency that approves medicines, has recommended that the product labels for all biosimilars approved in the United States say that they are very similar to reference biological medicines.
 - A product label is a set of instructions that give doctors information about prescribing a medicine.
 - Product labels for all approved biological medicines can be found in an online database called the Purple Book. This resource is available to everyone, not just healthcare providers.

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How do people take adalimumab?

- People take the reference or biosimilar adalimumab by injecting it under the skin into the stomach area or upper thigh. To inject adalimumab people can use:



A pre-filled syringe, similar to syringes that people with diabetes use to inject insulin.



A pre-filled pen, which can only be used once and is disposable.

- After injecting adalimumab (reference or biosimilar), people may feel pain at the site of injection (called injection site pain).

What causes injection site pain after taking adalimumab?

- Certain product features of medicines like adalimumab that are injected under the skin may affect how much injection site pain people feel.
- These include:
 - Ingredients that are added to the medicine.
 - The amount of liquid people need to inject (called injection volume), if it is more than 1.5 milliliters.
 - The type of injection device.
 - The size of the needle used for injection.
- These product features differ among the reference and biosimilar adalimumab medicines that doctors can prescribe for people with inflammatory conditions.

What is this review about?

- In this review article, researchers looked at:
 - The different product features of reference and biosimilar adalimumab medicines that are approved for use in the United States.
 - How product features of reference and biosimilar adalimumab medicines affect people's experiences of treatment, such as injection site pain.
- Researchers also looked at other factors that may help people and their doctors decide which type of adalimumab medicine to take.

How was this review performed?

- Researchers reviewed research studies that looked at injecting reference or biosimilar adalimumab medicines under the skin into the stomach area or upper thigh.
- To find out more information about the product features of reference and biosimilar adalimumab medicines researchers also looked at:
 - Documents created by the United States FDA.
 - Product labels of reference or biosimilar adalimumab medicines.

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What did researchers find?

How many adalimumab biosimilars are approved in the United States?



In the United States 9 adalimumab biosimilars are approved for inflammatory conditions.

What are the biosimilars' brand names?

Abrilada™

Hadlima™

Idacio®

Amjevita™

Hulio®

Yuflyma®

Cyltezo®

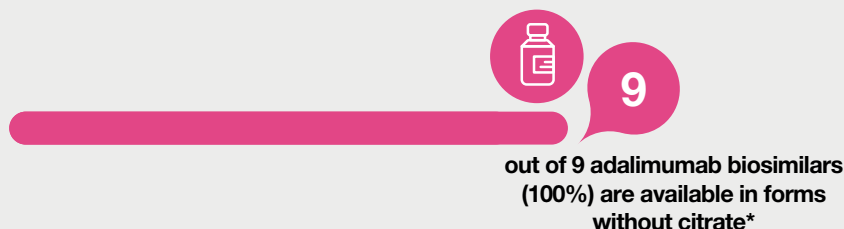
Hyrimoz®

Yusimry™

How do the ingredients of adalimumab medicines affect people's experiences of treatment?

- Adalimumab medicines (reference and biosimilar) contain an active ingredient and inactive ingredients.
 - Adalimumab is the active ingredient in reference and biosimilar adalimumab medicines. It reduces inflammation and painful symptoms.
 - Inactive ingredients in medicines are not intended to have an effect on people.
 - Inactive ingredients are added to stop adalimumab from breaking down and to make sure it stays dissolved in liquid for injection.
- Citrate is an inactive ingredient that is often used to make medicines stable, and has been used with adalimumab, but there are other options.
- Reference adalimumab is available in forms with and without citrate in the United States.
- Adalimumab biosimilars can contain different inactive ingredients than those in the reference adalimumab medicine.

How many adalimumab biosimilars in the United States are available in forms without citrate?



*Some adalimumab biosimilars are also available in forms with citrate

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- People report feeling more pain at the injection site after injecting adalimumab medicine (reference or biosimilar) with citrate than after injecting adalimumab medicine (reference or biosimilar) without citrate.
 - People who feel less pain after injecting adalimumab medicine without citrate are more likely to:
 - Continue using adalimumab.
 - Take adalimumab as advised by their doctor.



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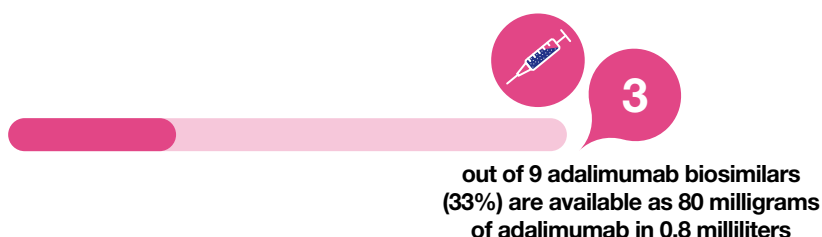
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How does the injection volume of adalimumab medicine affect people's experiences of treatment?

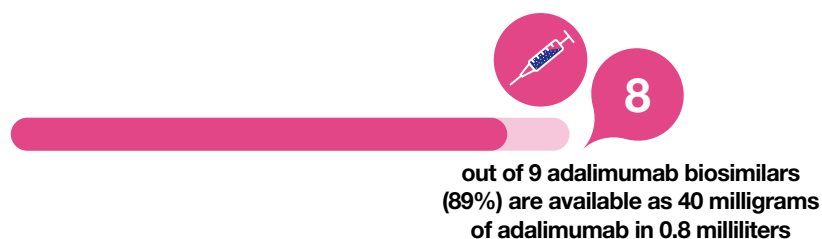
- People may have more injection site pain after injecting a medicine if the injection volume is more than 1.5 milliliters.
 - All adalimumab medicines (reference or biosimilar) come in injection volumes of less than 1.5 milliliters, so the volume of injection should not cause injection site pain.
 - Depending on the disease condition, at the beginning of treatment, doctors may prescribe 80 milligrams of adalimumab.
 - Reference adalimumab and some adalimumab biosimilars are available as 80 milligrams of adalimumab in an injection volume of 0.8 milliliters.

How many adalimumab biosimilars are available as 80 milligrams of adalimumab in an injection volume of 0.8 milliliters?

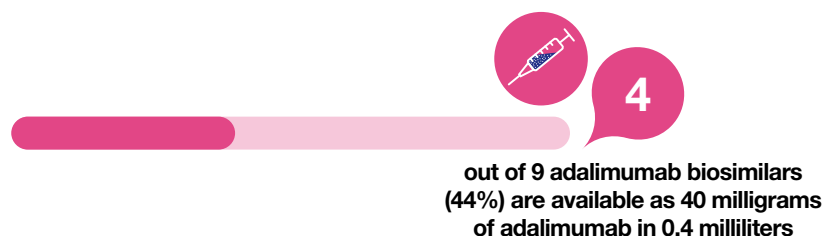


- After a person starts adalimumab and their disease is under control (called remission), they may continue taking adalimumab for a long time to keep their disease in remission. This is called maintenance therapy.
 - Usually, the dose of adalimumab for maintenance therapy for adults is 40 milligrams. This amount of adalimumab may come in an injection volume of 0.4 milliliters or 0.8 milliliters, depending on the adalimumab medicine.
 - Reference adalimumab and most adalimumab biosimilars are available as 40 milligrams of adalimumab in an injection volume of 0.8 milliliters.
 - Reference adalimumab and some adalimumab biosimilars are available as 40 milligrams of adalimumab in an injection volume of 0.4 milliliters.

How many adalimumab biosimilars are available as 40 milligrams of adalimumab in an injection volume of 0.8 milliliters?



How many adalimumab biosimilars are available as 40 milligrams of adalimumab in an injection volume of 0.4 milliliters?



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Does the type of device used for injecting adalimumab affect people's experiences of treatment?

- People can inject adalimumab using a pre-filled pen or pre-filled syringe.
- All adalimumab medicines (reference and biosimilar) approved in the United States are available as a pre-filled pen and pre-filled syringe.
- All devices for injecting adalimumab have slightly different features. This is the case even when comparing one pre-filled syringe with another pre-filled syringe, or one pre-filled pen with another pre-filled pen.
- Most people in the United States taking adalimumab prefer to inject themselves with a pre-filled pen as they are convenient and easy to use.
 - In a clinical trial that compared injecting adalimumab with a pre-filled pen versus a pre-filled syringe, around 9 in 10 people (90%) preferred using a pre-filled pen. Of those who preferred the pre-filled pen, around 8 in 10 people (80%) said it was less painful.
- Reference adalimumab and all biosimilar adalimumab pre-filled pens have:



Either a button people press once, or

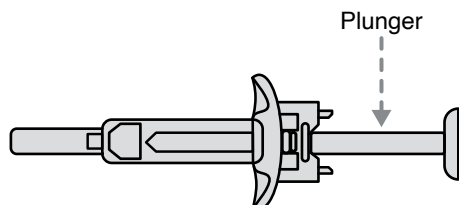


A device that people press down against their skin to inject themselves with adalimumab, and



A click at the start and/or end of injection.

- Reference adalimumab and 4 out of 9 adalimumab biosimilars (44%) are available in pre-filled pens that have been independently tested and proven as being easier to use for people living with arthritis, chronic pain, and limited functionality.
- Some people taking adalimumab may prefer to use a pre-filled syringe so that they can control the speed of their injection. Pre-filled syringes have:



A plunger people press down to inject themselves with adalimumab.

The speed of the injection will depend on how fast people press the plunger down.

- People report less injection site pain with slower injections.

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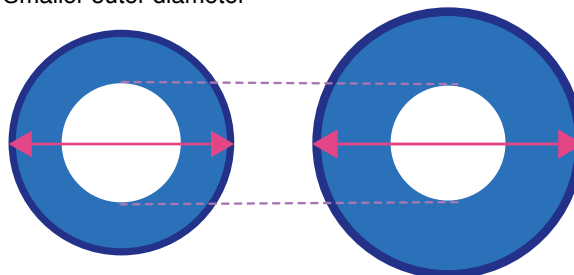
Does the size of the needle used to inject adalimumab affect people's experiences of treatment?

- People can inject adalimumab using a 27-gauge or 29-gauge needle.
 - Needle gauge describes how wide the outside of the needle is (called outer diameter).
 - The outer diameter of a 27-gauge needle is larger than the outer diameter of a 29-gauge needle.
 - The size of the outer diameter of the needle is important because it can affect how much pain people experience when injecting medicine.

29-gauge needle

27-gauge needle

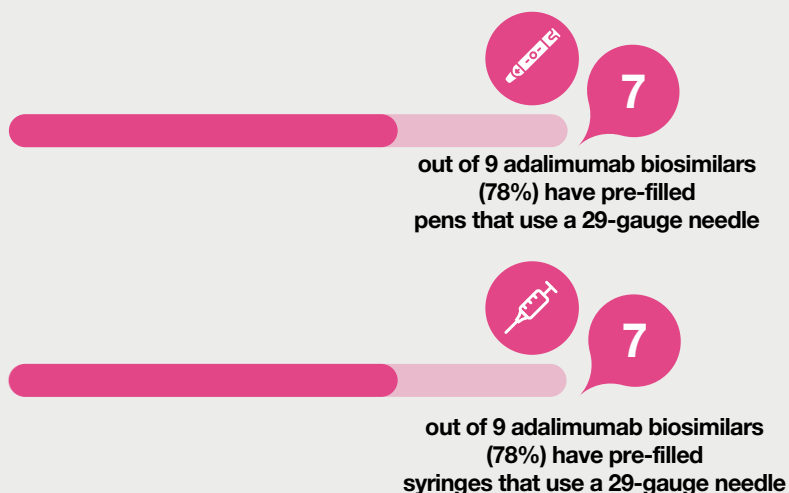
Smaller outer diameter



People can inject medicine at the same speed because it passes through the same size area

- People report less injection site pain when injecting medication using a 29-gauge needle than when using a 27-gauge needle.
- Most adalimumab biosimilars and reference adalimumab are available in pre-filled pen and pre-filled syringe devices that use a 29-gauge needle.

How many adalimumab biosimilars in the United States use a 29-gauge needle?



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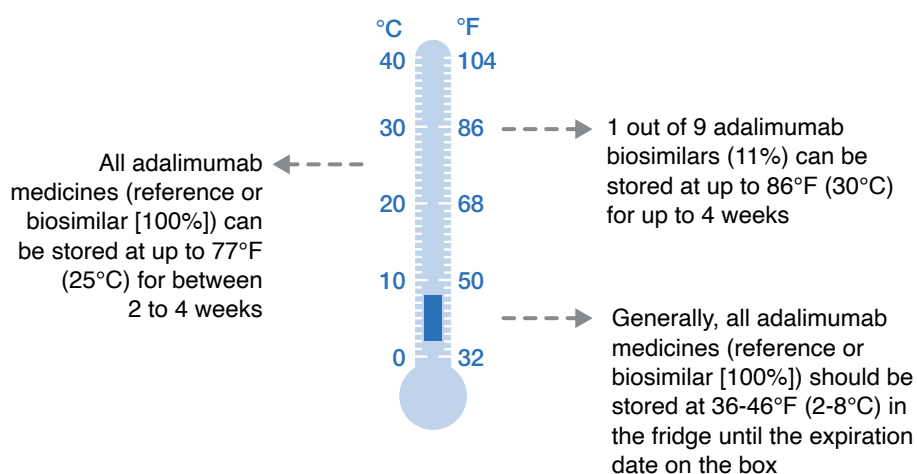
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How do adalimumab storage conditions affect people's experiences of treatment?

- Generally, people should store all adalimumab medicines (reference and biosimilar) in the fridge.
- Sometimes, it might be difficult for people to store adalimumab in the fridge, such as when they are travelling.
- All adalimumab medicines (reference and biosimilar) approved in the United States can be stored at room temperature of 77°F (25°C) for between 2 to 4 weeks. One adalimumab biosimilar can be stored at an even higher temperature of up to 86°F (30°C) for up to 4 weeks.

What temperature can adalimumab medicines in the United States be stored at?



- Being able to store adalimumab (reference and biosimilar) at room temperature gives people more flexibility with their treatment.

How can interchangeability designation affect people's choice of adalimumab medicines?

- A biosimilar can receive an additional designation called interchangeability from the United States FDA.
 - This means that a pharmacist can dispense a biosimilar instead of the reference biological without first checking with the doctor who prescribed the medicine if state law allows this.
- To receive the interchangeability designation a biosimilar must show in a clinical study that:
 - It has the same treatment benefits as the reference biological medicine in anyone taking the medicine; and
 - Switching from the reference biological medicine to the biosimilar does not make treatment less effective and does not cause people to have more side effects compared with not switching medicines.
 - A side effect is something (expected or unexpected) that people feel was caused by a medicine or treatment they take.
- New FDA guidelines recommend that information about whether a biosimilar is interchangeable should be in the Purple Book.

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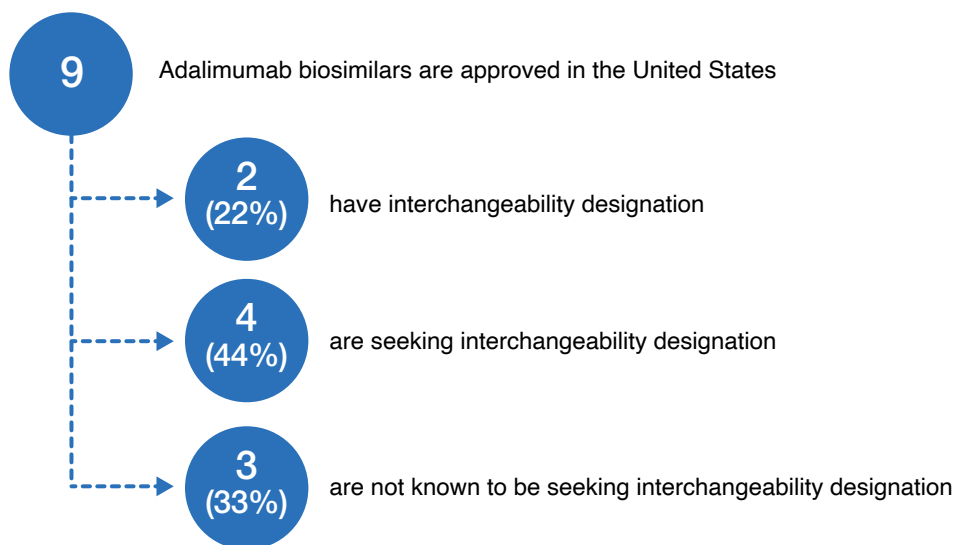
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How many adalimumab biosimilars have interchangeability designation in the United States?



- As all devices for injecting adalimumab differ slightly, people will need training to use a new device when they switch from the reference biological to an interchangeable biosimilar.
 - People switching to an interchangeable biosimilar may wish to consider how easy it will be for them to learn to use a new device.

How can patient support programs affect people's choice of adalimumab medicines?

- All companies that make adalimumab (reference and biosimilar) in the United States support patients through patient assistance programs. The amount of support varies between companies.
- Some patient assistance programs have learning tools. People taking adalimumab can use these to find out about:
 - The cost of their medication
 - Their insurance plans
 - Their inflammatory condition
 - Medication options
 - Adalimumab
- Patient assistance programs can improve people's access to adalimumab products.

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What were the main conclusions reported by the researchers?

- Reference adalimumab and adalimumab biosimilars approved in the United States have different product features.
- These product features can affect people's experiences of treatment, including how much injection site pain they feel. Product features that can influence people's injection site pain include:
 - Medicine ingredients.
 - Injection volume (if more than 1.5 milliliters).
 - Injection device.
 - Needle size.
- People taking adalimumab may want to discuss the product features with their doctors when deciding which adalimumab product to use.
- Other factors for people taking adalimumab and their doctors to consider when choosing an adalimumab product are:
 - Biosimilar interchangeability designation.
 - Patient assistance programs.

Where can readers find more information about biosimilars?

- Biosimilar basics (https://fda.report/media/130918/Biosimilar_Basics_infographic_508.pdf)
- Biosimilars: An introduction for patients (<https://www.pfizerbiosimilars.com/downloadable-resources>)
- Biosimilars (<https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars>)
- The Purple Book (<https://purplebooksearch.fda.gov/>)

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This review was sponsored by Pfizer.

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