

MEDICATION GUIDE

EXEMPTIA™

(adalimumab)

injection

Please go through this medication guide carefully that is given with EXEMPTIA™, before you start taking it. There may be new information available. This medication guide does not substitute talking to your doctor regarding your medical disorder and its treatment.

What is most important information that I need to know about EXEMPTIA™?

EXEMPTIA™ is a medicine that will affect your immune system. EXEMPTIA™ can lower your immunity to fight against infections. Serious infections have occurred in people taking adalimumab. These serious infections may include but are not limited to tuberculosis (TB), certain bacterial, fungal or viral infections. Some people have died from these infections.

1. Your doctor should test you for tuberculosis before starting EXEMPTIA™.
2. Your doctor should examine you closely for signs and symptoms of TB during treatment with EXEMPTIA™.

You should not start taking EXEMPTIA™ if you are having any kind of infection unless and until your doctor says that it is okay.

Before starting EXEMPTIA™, inform your doctor if you:

- Suspect you have an infection or have symptoms of infection such as:
 - Fever, chills or sweats
 - Muscle aches
 - Weight loss
 - Blood in phlegm
 - Diarrhoea or pain in stomach
 - Cough
 - Burning sensation while passing urine or increased frequency of urination
 - Red, warm and painful skin or sores on your body

- are being treated for an infection
- any history of recurrent infections
- have diabetes
- have TB, or have been in close contact with someone with TB. These infections may occur or become more severe if you use EXEMPTIA™
- have or have had history of hepatitis B
- use similar kind of medicines such as abatacept, anakinra, rituximab, azathioprine, or 6-mercaptopurine (6-MP)
- are scheduled to have major surgery

After starting EXEMPTIA™, call your doctor right away if you have an infection, or any signs of an infection.

Cancer

- For children and adults taking TNF-blockers, including adalimumab, the chances of getting cancer may increase.
- There have been cases of unusual cancers in children, teenagers, and young adults using TNF-blockers.
- People with rheumatoid arthritis (RA), especially more serious RA, may have a higher chance for getting a kind of cancer called lymphoma.
- If you use TNF blockers including adalimumab your chance of getting two types of skin cancer may increase (basal cell cancer and squamous cell cancer of the skin). These types of cancer are generally not life-threatening if treated. Tell your doctor if you have a bump or open sore that doesn't heal.
- Some people receiving TNF blockers including adalimumab developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. Most of these people were male teenagers or young men. Also, most people were being treated for Crohn's disease or ulcerative colitis with another medicine called azathioprine or 6-mercaptopurine (6-MP).

For details see “What are the possible side effects of EXEMPTIA™?” section.

What is EXEMPTIA™?

EXEMPTIA™ is a Tumour Necrosis Factor (TNF) inhibitor.

EXEMPTIA™ can be used alone or in combination with certain other medicines to reduce the signs and symptoms of moderate to severe rheumatoid arthritis (RA) in adults.

What should I tell my doctor before taking EXEMPTIA™?

Before starting EXEMPTIA™, tell your doctor about all of your health conditions, including but not limited to the following:

- if you have an infection. See “What is the most important information I should know about EXEMPTIA™?”
- if you have or had any history of cancer.
- if you have numbness or tingling or have a disease that affects your nervous system such as multiple sclerosis or Guillain-Barré syndrome.
- if you have or had heart failure.
- if you have recently received or are scheduled to receive a vaccine. You may receive vaccines, except for live vaccines while using EXEMPTIA™.
- if you are allergic to EXEMPTIA™ or to any of its ingredients. See the end of this Medication Guide for a list of ingredients in EXEMPTIA™.
- if you are pregnant or planning to become pregnant. It is not known whether EXEMPTIA™ will harm your unborn baby. EXEMPTIA™ should only be used during pregnancy if needed.
- if you are breastfeeding or plan to breastfeed. You and your doctor should decide if you will breastfeed or use EXEMPTIA™. Both the things should not be done at the same time.

Inform your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your doctor if you are using:

- Abatacept, anakinra, infliximab, etanercept, certolizumab pegol or golimumab, because you should not use EXEMPTIA™ while you are taking any one of these medicines.
- Rituximab. Your doctor may not want to give you EXEMPTIA™ if you have received rituximab recently.
- Azathioprine or 6–mercaptopurine (6-MP).

Keep a list of your medicines with you to show your doctor each time you get a new medicine.

How should I take EXEMPTIA™?

- EXEMPTIA™ is given by an injection under the skin. Your doctor will tell you how often to take an injection of EXEMPTIA™. This is based on your condition to be treated. Do not inject EXEMPTIA™ more often than you are prescribed.
- See the Instructions for Use inside the carton for complete instructions for the right way to prepare and inject EXEMPTIA™.
- Make sure you have been shown how to inject EXEMPTIA™ before you do it yourself. You can call your doctor if you have any questions about giving yourself an injection. Someone you know can also help you with your injection after he/she has been shown how to prepare and inject EXEMPTIA™.
- Do not try to inject EXEMPTIA™ yourself until you have been shown the right way to give the injections. If your doctor decides that you or a caregiver may be able to give your injections of EXEMPTIA™ at home, you should receive training on the right way to prepare and inject EXEMPTIA™.
- Do not miss any doses of EXEMPTIA™ unless your doctor says it is okay. If you forget to take EXEMPTIA™, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. This will put you back on schedule. In case you are not sure when to inject EXEMPTIA™, call your doctor.
- If you take more EXEMPTIA™ than you were told to take, call your doctor.

What are the possible side effects of EXEMPTIA™?

EXEMPTIA™ can cause serious side effects, including but not limited to:

See “What is the most important information I should know about EXEMPTIA™?”

- Serious Infections: Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with EXEMPTIA™ and during treatment with EXEMPTIA™. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you

are taking EXEMPTIA™. People who had a negative TB skin test before receiving adalimumab have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking EXEMPTIA™:

- cough that does not go away
- low grade fever
- weight loss
- loss of body fat and muscle (wasting)

• Hepatitis B infection in people who carry the virus in their blood: if you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use EXEMPTIA™. Your doctor should do blood tests before you start treatment, while you are using EXEMPTIA™, and for several months after you stop treatment with EXEMPTIA™. Tell your doctor if you have any of the following symptoms of a possible hepatitis B infection:

- muscle aches
- clay-colored stools
- feel very tired
- fever
- dark urine
- skin or eyes look yellow
- stomach discomfort
- little or no appetite
- skin rash
- vomiting

• Allergic reactions: Allergic reactions can happen in people who use EXEMPTIA™. Call your doctor or get medical help right away if you have any of these symptoms of a serious allergic reaction:

- urticarial (allergic skin reaction causing localized redness, swelling, and itching)
- swelling of your face, eyes, lips or mouth

- difficulty in breathing

- Nervous system problems: Signs and symptoms of a nervous system problem include: numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.

- Blood problems: Your body may not make enough of the blood cells that help fight infections or help to stop bleeding. Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.

- New heart failure or worsening of heart failure you already have: Call your doctor right away if you get new worsening symptoms of heart failure while taking EXEMPTIA™, including:

- shortness of breath

- swelling of your ankles or feet

- sudden weight gain.

- Immune reactions including a lupus like syndrome: Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on your cheeks or arms that gets worse in the sun. Symptoms may improve when you stop EXEMPTIA™.

- Liver Problems: Liver problems can occur in people taking TNF-blockers. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms:

- feel very tired

- skin or eyes look yellow

- poor appetite or vomiting

- pain on the right side of your stomach (abdomen)

- Psoriasis: Some people using adalimumab had new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus. Your doctor may decide to stop your treatment with EXEMPTIA™.

Call your doctor or get medical care right away if you develop any of the above symptoms.

Your treatment with EXEMPTIA™ may be stopped.

Common side effects with EXEMPTIA™ include:

- Injection site reactions: redness, rash, swelling, itching, or bruising. These symptoms usually will go away within a few days. Call your doctor right away if you have pain, redness or swelling around the injection site that does not go away within a few days or gets worse.
- Upper respiratory infections (including sinus infections), headaches, rash, nausea.

The above mentioned list does not cover all the possible side effects with EXEMPTIA™. Tell your doctor if you have any side effect that bothers you or that does not go away. Ask your doctor for more information. Call your doctor for medical advice about side effects.

General information about EXEMPTIA™

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use EXEMPTIA™ for a condition for which it was not prescribed. Do not give EXEMPTIA™ to other people, even if they have the same condition. It may harm them. This Medication Guide summarizes the most important information about EXEMPTIA™. If you would like more information, talk with your doctor. You can ask your doctor for information about EXEMPTIA™ that was written for health professionals.

What are the ingredients in EXEMPTIA™?

Active ingredient: adalimumab

Inactive ingredients: Succinic acid NF, Sodium hydroxide NF, Sodium chloride USP, L Arginine monohydrochloride USP, Sorbitol NF, Polysorbate 80 NF and Water for Injection –q.s.