

INFORMATION FOR THE USER

Altebrel™ 25 Prefilled Syringe injection (Etanercept)

This leaflet contains important information for patient so, it is recommended to read it carefully before using the medicine.

- *Altebrel™* contains 25 mg etanercept as active ingredient, in form of solution for injection in prefilled syringe.
- Inform your doctor or pharmacist if you got any side effects.
- This medicine has been prescribed for you or a child in your care. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or those of the child you are caring for.
- Your doctor will give you some important information about safety of *Altebrel™*, please pay attention to them.
- Ask your doctor, pharmacist or nurse If you had any further questions

Altebrel™ Leaflet Overview

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1. Description

Altebrel™ is a medicine that is made from two human proteins. It blocks the activity of another protein in the body which is defined as tumor necrosis factor (TNF) that causes inflammation. By blocking TNF, *Altebrel™* reduces the inflammation associated with certain diseases.

2. Indication

In adults (aged 18 and over), *Altebrel™* can be used for moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and moderate or severe psoriasis - in each case usually when other widely used treatments have not worked well enough or are not suitable for you. For rheumatoid arthritis, *Altebrel™* is usually used in combination with methotrexate, although it may also be used alone if treatment with methotrexate is unsuitable for you. Whether used alone or in combination with methotrexate, *Altebrel™* may be effective in reducing signs and symptoms of inflammatory arthritis (such as pain, morning stiffness and fatigue), may help improve your ability to do simple daily activities (such as dressing, walking and climbing stairs), and may help prevent damage to your bones and joints. For psoriatic arthritis patients with multiple joint involvement, *Altebrel™* can improve your ability to do normal daily

activities. For patients with multiple symmetrical painful or swollen joints (e.g., hands, wrists and feet), *Altebrel™* can slow down the structural damage to those joints caused by the disease. In patients with psoriatic skin conditions, *Altebrel™* may be effective in clearing skin and improving quality of life (such as personal relationships, work and daily activities, and treatment satisfaction)

Altebrel™ is also prescribed for the treatment of the following diseases in children and adolescents:

- juvenile idiopathic arthritis (JIA) in patients older than 4 years who have had inadequate response to MTX or it is not suitable for them;
- Severe psoriasis in patients older than 8 years who have had inadequate response to phototherapy or other systemic therapies or who are unable to take these treatments.

3. Using Instruction

Using other medicines

Inform the doctor or pharmacist if you or the child are taking or have recently taken any other medicines (including anakinra, abatacept or sulfasalazine), even those not prescribed by the doctor. You or the child should not use *Altebrel™* with medicines that contain the active substance anakinra or abatacept.

Taking with food and drink

Altebrel™ can be taken with or without food or drink.

Method and route of administration

Altebrel™ is administered by an injection under the skin (subcutaneous injection). Do not mix the *Altebrel™* solution with any other medicine.

Dosing

Always use *Altebrel™* exactly as the doctor has told you. You should check with the doctor or pharmacist if you are not sure.

If you feel that the effect of *Altebrel™* is too strong or too weak, talk to your doctor or pharmacist.

Dosing for adult patients (aged 18 years or over)

Rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis

The usual dose is 25 mg given twice weekly or 50 mg once weekly as an injection under the skin. However, your doctor may consider an alternative frequency for injection of *Altebrel™*.

Plaque psoriasis

The recommended starting dose of *Altebrel™* for adult patients is a 50 mg dose given twice weekly (administered 3 or 4 days apart) for 3 months followed by a reduction to a maintenance dose of 50 mg per week or 25 mg twice weekly. A maintenance dose of 50 mg given twice weekly has also been shown to be efficacious.

Your doctor will decide how long you should take *Altebrel™* and whether retreatment is needed based on your response. If *Altebrel™* has no effect on your condition after 3 months, your doctor may tell you to stop taking this medicine.

Dosing for children and adolescents

The appropriate dose and frequency of dosing for the child or adolescent will depend on body weight and disease. This is a single-use syringe for patients weighing 62.5 kg or more. The doctor will provide you with detailed directions for measuring the appropriate dose.

The recommended dose of *Altebrel™* for pediatric patients ages 4 to 17 years with active polyarticular JIA is 0.8 mg/kg per week (up to a maximum of 50 mg per week) or 0.4 mg/kg twice weekly (up to a maximum of 25 mg twice weekly).

For psoriasis in patients from the age of 8 years, the usual dose is 0.8 mg/kg of *Altebrel™* (up to a maximum of 50 mg), and should be given once weekly. If *Altebrel™* has no effect on the child's condition after 3 months, your doctor may tell you to stop using this medicine.

What should I do if I take too much *Altebrel™*

If you have used more *Altebrel™* than you should (either by injecting too much on a single occasion or by using it too frequently), inform your doctor or pharmacist immediately. Always have the outer carton of the medicine with you, even if it is empty.

What should I do if I miss a dose of *Altebrel™*

If you forget a dose, you should inject it as soon as you remember, unless the next scheduled dose is the next day; in which case you should skip the missed dose. Then continue to inject the medicine on the usual day(s). If you do not remember until the day that the next injection is due, do not take a double dose (two doses on the same day) to make up for a forgotten dose.

If you stop using *Altebrel™*

Your symptoms may return upon discontinuation.

4. Contraindications & Precautions

Contraindications:

- **Allergic:** if you, or the child you are caring for, are allergic to etanercept or any of the other ingredients of *Altebrel™*. If you or the child experience allergic reactions such as chest tightness, wheezing, dizziness or rash, do not inject more, and contact your doctor immediately.
- **Serious Blood infection:** if you or the child have, or are at risk of developing a serious blood infection called sepsis. If you are not sure, please contact your doctor.
- **Infections:** if you or the children have an infection of any kind. If you are not sure, please talk to your doctor.

Precautions:

- **Allergic reactions:** If you or the child experience allergic reactions such as chest tightness, wheezing, dizziness or rash, do not inject more *Altebrel™*, and contact your doctor immediately.
- **Tuberculosis:** As cases of tuberculosis have been reported in patients treated with

Altebrel™, your doctor will check for signs and symptoms of tuberculosis before starting *Altebrel™*. This may include a thorough medical history, a chest X-ray and a tuberculin test. It is very important that you tell your doctor if you or the child have ever had tuberculosis, or have been in close contact with someone who has had tuberculosis. If symptoms of tuberculosis (such as persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy, tell your doctor immediately.

- **Infections/surgery:** If you or the child develop a new infection, or are about to have any major surgery, your doctor may wish to monitor the treatment with *Altebrel™*
- **Infections/diabetes:** Tell your doctor if you or the child have a history of recurrent infections or suffer from diabetes or other conditions that increase the risk of infection.
- **Infections/monitoring:** Tell your doctor of any recent travel to endemic region. If you or the child develop symptoms of an infection such as fever, chills or cough, notify your doctor immediately. Your doctor may decide to continue to monitor you or the child for the presence of infections after you or the child stop using *Altebrel™*.
- **Hepatitis B:** Tell your doctor if you or the child have or have ever had hepatitis B. Your doctor should test for the presence of hepatitis B infection before you or the child begin treatment with *Altebrel™*. Treatment with *Altebrel™* may result in the reactivation of hepatitis B in patients who have been previously infected with the hepatitis B virus. If this occurs, you should using *Altebrel™*.
- **Hepatitis C:** Tell your doctor if you or the child have hepatitis C. Your doctor may wish to monitor the treatment with *Altebrel™* in case the infection worsens.
- **Blood disorders:** Seek medical advice immediately if you or the child have any signs or symptoms such as persistent fever, sore throat, bruising, bleeding or paleness. Such symptoms may point to the existence of potentially life-threatening blood disorders, which may require discontinuation of *Altebrel™*.
- **Nervous system and eye disorders:** Tell your doctor if you or the child have multiple sclerosis, optic neuritis (inflammation of the nerves of the eyes) or transverse myelitis'. (Inflammation of the spinal cord). Your doctor will determine if *Altebrel™* is an appropriate treatment.
- **Congestive heart failure:** Tell your doctor if you or the child have a history of congestive heart failure, because *Altebrel™* needs to be used with caution under these circumstances. Cancer: There have been cases of certain kinds of cancer in patients taking *Altebrel™*. Some patients receiving *Altebrel™* have developed skin cancers called non-melanoma skin cancer. Tell your doctor if you or the child develop any change in the appearance of the skin or growths on the skin.
- **Anti-diabetic medicines:** Tell your doctor if you or the child have diabetes or are taking medicines to treat diabetes. Your doctor may decide if you or the child need less anti-diabetic medicine while taking *Altebrel™*
- **Vaccinations:** If possible, children should be up to date with all vaccinations before using *Altebrel™*. Some vaccines, such as oral polio vaccine, should not be given while using *Altebrel™*. Please consult your doctor before you or the child receive any vaccines.
- **Chickenpox:** Tell your doctor if you or the child are exposed to chickenpox when using *Altebrel™*. Your doctor will determine if preventive treatment for chickenpox is appropriate.

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- **Alcohol abuse:** *Altebrel™* should not be used for the treatment of hepatitis related to alcohol abuse. Please tell your doctor if you or the child in your care have a history of alcohol abuse.
- **Wegener's granulomatosis:** *Altebrel™* is not recommended for the treatment of Wegener's granulomatosis, a rare inflammatory disease. If you or the child in your care have Wegener's granulomatosis, talk to your doctor.
- **Latex:** The needle cover is made from latex (dry natural rubber). Contact your doctor before using *Altebrel™* if the needle cover will be handled by, or *Altebrel™* will be given to, someone with a known or possible hypersensitivity (allergy) to latex.

Pregnancy and breast-feeding

There have been no studies in pregnant women. *Altebrel™* should not be used during pregnancy unless benefits outweigh the risks. *Altebrel™* has no established use in labor or delivery. Women using *Altebrel™* should not become pregnant. If the patient becomes pregnant, you should consult the patient's doctor.

Altebrel™ is excreted in human milk following subcutaneous administration. Because of the potential of serious adverse reactions in nursing infants from *Altebrel™*, a decision should be made whether to discontinue nursing or to discontinue the drug.

Driving and using machines

The use of *Altebrel™* is not expected to affect the ability to drive or use machines.

5. Side Effects

Like all medicines, *Altebrel™* can cause side effects, although not everybody gets them.

Other side effects that are not listed in this leaflet may occur. If you are concerned about any side effect, or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

• **Allergic reactions**

If any of the following happen, do not inject more *Altebrel™*. Tell your doctor immediately, or go to the casualty department at your nearest hospital.

- Trouble swallowing or breathing
- Swelling of the face, throat, hands, or feet
- Feeling nervous or anxious, throbbing sensations, sudden reddening of the skin and/or a warm feeling
- Severe rash, itching, or hives (elevated patches of red or pale skin that often itch)

Serious allergic reactions are rare. However, any of the above symptoms may indicate an allergic reaction to *Altebrel™*, so you should seek immediate medical attention.

• **Serious side effects**

If you notice any of the following, you or the child may need urgent medical attention.

- Signs of serious infections, such as high fever that may be accompanied by cough, shortness of breath, chills, weakness, or a hot, red, tender, sore area on the skin or joints
- Signs of blood disorders, such as bleeding, bruising, or paleness
- Signs of nerve disorders, such as numbness or tingling, changes in vision, eye pain, or onset of weakness in an arm or leg
- Signs of worsening heart failure, such as fatigue or shortness of breath with activity, swelling in the ankles, a feeling of fullness in the neck or abdomen, night-time shortness of breath or coughing, bluish color of the nails or the lips

These are rare or uncommon side effects, but are serious conditions (some of which may rarely be fatal). If these signs occur, tell your doctor immediately, or visit the casualty department at your nearest hospital.

The frequency of possible side effects listed below is defined using the following convention:

Very common (> 1/ 10)

Common (1 to 10 / 100)

Uncommon (1 to 10 / 1,000)

Rare (1 to 10 / 10,000)

Very rare (< 1/ 10,000)

Not known (frequency cannot be estimated from the available data)

The side effects listed below are those that have been seen in adult patients. The side effects seen in children and adolescents are similar to those seen in adults.

- Very common: Infections (including colds, sinusitis, bronchitis, urinary tract infections and skin infections); injection site reactions (including bleeding, bruising, redness, itching, pain, and swelling). Reactions at the injection site are very common, but do not occur as often after the first month of treatment. Some patients have developed a reaction at an injection site that was used before.
- Common: Allergic reaction; fever; itching; antibodies directed against normal tissue (autoantibody formation).
- Uncommon: Serious infection (including pneumonia, deep skin infections, joint infections, blood infection, and infections at various sites); low blood platelet count; skin cancer (excluding melanoma); localized swelling of the skin (angioedema); hives (elevated patches of red or pale skin that often itch); eye inflammation; psoriasis; rash; inflammation or scarring of the lungs.
- Rare: Serious allergic reaction (including severe localized swelling of the skin and wheezing); combined low platelet, red, and white blood cell count; nervous system disorders (with signs and symptoms similar to those of multiple sclerosis or inflammation of the nerves of the eyes or spinal cord); tuberculosis; worsening congestive heart failure; seizures; lupus or lupus-like syndrome (symptoms may include

persistent rash, fever, joint pain, and tiredness); inflammation of the blood vessels; low white blood cell count, low neutrophil (a type of the white blood cell) count; elevated liver blood tests; skin rash, which may lead to severe blistering and peeling of the skin.

- Very rare: failure of the bone marrow to produce crucial blood cells.
- Not known: excessive activation of white blood cells associated with inflammation (macrophage activation syndrome).

6. Storage Condition

Keep out of the reach and sight of children.

Do not use *Altebrel™* after the expiry date which is stated on the carton and pre-filled syringe after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2° - 8°C). Do not freeze.

Keep the pre-filled syringes in the outer carton in order to protect from light.

After taking a syringe from the refrigerator, wait approximately 15-30 minutes to allow the *Altebrel™* solution in the syringe to reach room temperature. Do not warm in any other way. Immediate use is then recommended.

Inspect the solution in the syringe. Only inject the solution in the syringe if it is clear, colorless or pale yellow, and free from easily visible particles. If it is not, use a different syringe, then contact your pharmacist for assistance.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. Packing Details

Altebre™ is supplied as pre-filled syringe containing a clear, pale yellow solution for injection. Each pack contains 4 pre-filled syringes and with alcohol swabs.

MANUFACTURING BY:

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