เอกสารกำกับยาสำหรับผู้ป่วยฉบับภาษาอังกฤษ

REMICADE®

(INN: Infliximab)

Powder for concentrate for solution for infusion

WHAT IS REMICADE USED FOR?

REMICADE is a medicine used to treat adult and pediatric patients with Crohn's disease, adult patients with ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and psoriasis. In these diseases, the body produces too much of a substance called tumor necrosis factor alpha (TNF-alpha). Too much of this substance causes your body's immune system to attack healthy tissue and result in inflammation. Blocking TNF-alpha with REMICADE can reduce inflammation, but can also reduce your immune system's ability to fight off infections. Your doctor has decided to treat you with REMICADE because your disease is still active even though you have tried other treatments.

Crohn's disease:

Crohn's disease is an inflammatory disease of the bowels. If you have moderate to severe Crohn's disease that is active and has not responded to other medications and you are an adult, you will be given REMICADE to:

- reduce the signs and symptoms of your disease
- induce and maintain remission of your disease
- induce healing of your bowel tissue
- reduce or eliminate your use of corticosteroids
- improve your quality of life by helping you feel better
- reduce the number of draining fistulas.

If you are a child or teenager with Crohn's disease, you will be given REMICADE to:

- reduce the signs and symptoms of your disease
- induce and maintain remission of your disease

- improve your quality of life by helping you feel better.

Ulcerative colitis:

Ulcerative colitis is an inflammatory disease of the bowels. If you have moderate to severe ulcerative colitis that is active and has not responded to other medications, you will be given REMICADE to:

- reduce the signs and symptoms of your disease
- induce and maintain remission of your disease
- induce and maintain healing of your bowel tissue
- reduce or eliminate your use of corticosteroids
- improve your quality of life by helping you feel better
- reduce the need for you to have your large intestine removed.

If you are a child or teenager with ulcerative colitis, you will be given REMICADE to:

- reduce the signs and symptoms of your disease
- induce and maintain remission of your disease
- induce and maintain healing of your bowel tissue
- reduce or eliminate your use of corticosteroids.

Rheumatoid arthritis:

Rheumatoid arthritis is an inflammatory disease of the joints. If you have moderately to severely active rheumatoid arthritis, you will be given REMICADE in combination with methotrexate to:

- reduce the signs and symptoms of your disease
- prevent damage to your joints
- improve your physical function.

Ankylosing spondylitis:

Ankylosing spondylitis is an inflammatory disease of the spine. If you have ankylosing spondylitis and you have not responded to or tolerated other medications, you will be given REMICADE to:

- improve the signs and symptoms of your disease, including range of motion
- improve your physical function
- improve your quality of life.

Psoriatic arthritis:

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis that has not responded to other medications, you will be given REMICADE to:

- reduce the signs and symptoms of your arthritis, including reduction of pain and swelling in and around your joints
- induce major clinical response in active arthritis
- inhibit progression of structural damage of active arthritis
- improve dactylitis and enthesopathy
- improve your psoriasis
- improve your physical function
- improve your quality of life.

Psoriasis:

Psoriasis is an inflammatory disease of the skin. If you have moderate to severe plaque psoriasis and phototherapy or conventional systemic treatments have been inadequate or are inappropriate, you will be given REMICADE to:

- reduce the signs and symptoms of your psoriasis
- improve your quality of life.

Entero-Behçet's disease

Entero-Behçet's disease is an inflammatory disease of gastrointestinal tract. REMICADE will be given when you have inadequate response to conventional therapy.

WHEN NOT TO RECEIVE REMICADE

You should not receive REMICADE if you have:

- an infection that you are being treated for. If you have or think you may have an infection, ask your doctor if it is the kind of infection that could put you at risk for serious side effects from REMICADE.
- heart failure because you may not be a candidate for treatment with REMICADE. Your doctor will decide if you should receive REMICADE.
- an allergy to REMICADE or any of the ingredients in REMICADE (sucrose, sodium phosphate, and polysorbate 80).
- an allergy to murine (mouse) proteins.

WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?

Before receiving treatment with REMICADE, you should tell your doctor if you:

- have an infection that won't go away or a history of infection that keeps coming back.
- have had tuberculosis (TB), or if you have recently been with anyone who might have TB. Your doctor will evaluate you for TB and perform a skin test. If your doctor feels that you are at risk for TB, he or she may start treating you for TB before you begin REMICADE therapy.
- have lived in or traveled to an area where infections called histoplasmosis, coccidioidomycosis, or blastomycosis are common. These infections are caused by fungus that can affect the lungs or other parts of your body. Ask your doctor if you don't know if these infections are common in the area in which you have lived or traveled.
- have heart failure, or if you previously had or currently have any heart condition. If you develop new or worsening symptoms of heart failure, such as shortness of breath or swelling of your feet, you must notify your doctor.
- have or have had a condition that affects your nervous system, like multiple sclerosis, Guillain-Barré syndrome, or seizures, or if you have been diagnosed with optic neuritis. You should tell your doctor if you experience numbness, tingling, visual disturbances or seizures.
- have recently received or are scheduled to receive a vaccine.

- if you have a baby while you are using REMICADE, tell your baby's doctor about your REMICADE use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines. For more information see section on Pregnancy and Breast-feeding.

- if you are breast-feeding, it is important that you tell your baby's doctors and other healthcare professionals about your REMICADE use before your baby is given any vaccine

- have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).

Pregnancy and Breast-feeding

Tell your doctor if you are pregnant, plan to become pregnant or are breast-feeding. If you have a baby while you are using REMICADE, it is important to tell your baby's doctor and other healthcare professionals about your REMICADE use so they can decide when your baby should receive their vaccinations.

If you received REMICADE while you were pregnant, your baby may be at higher risk for getting an infection. It is important that you tell your baby's doctors and other health care professionals about your REMICADE use before the baby receives any vaccine, including live vaccines such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines. Administration of BCG vaccine within 12 months after birth to the baby whose mother received REMICADE while pregnant may result in infection in the newborn with severe complications, including death. For other types of vaccines, discuss with your doctor.

If you are breast-feeding, it is important that you tell your baby's doctors and other healthcare professionals about your REMICADE use before your baby is given any vaccine. Live vaccines should not be given to your baby while you are breast-feeding unless your baby's doctor recommends otherwise.

Severely decreased numbers of white blood cells have also been reported in infants born to women treated with REMICADE during pregnancy. If your baby has continual fevers or infections, contact your baby's doctor immediately.

Other medicines

In studies of REMICADE, patients were taking other medications along with REMICADE for the treatment of their disease. Tell your doctor if you are taking or have recently taken other medications before and during treatment with REMICADE. These include any other medicines to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis or psoriasis. Also tell your doctor if you plan to take other medications.

Especially, tell your doctor if you take anakinra or abatacept. REMICADE should not be taken together with anakinra or abatacept.

While using REMICADE you should not receive live vaccines. If you have a baby or if you are breast-feeding while you are using REMICADE, tell your baby's doctor about your REMICADE use before the baby receives any live vaccines. If possible, you should have all of your vaccines brought up to date before starting treatment with REMICADE.

HOW TO USE REMICADE AND HOW MUCH

REMICADE will be prepared and given to you by a healthcare professional. REMICADE is administered as an intravenous infusion, which means that the medicine will be administered to you through a needle placed in a vein in your arm. If you have Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, or psoriasis, the infusion will be given to you over a period of about 2 hours. If you have rheumatoid arthritis, the first 2-3 infusions (depends on your body weight) will be given to you over a period of about 2 hours, after the third infusion your doctor may decide to give you REMICADE over a 1 hour period. During the infusion and for a period of time after you receive REMICADE, you will be monitored for side effects. Your doctor may ask you to take other medications along with REMICADE.

Crohn's disease or Fistulizing Crohn's disease

If you are an adult, child or teenager and have Crohn's disease or fistulizing Crohn's disease, you will receive a dose of REMICADE followed by additional doses at 2 and 6 weeks after the first dose. You will then receive a dose every 8 weeks. Your doctor will monitor your response to REMICADE and may adjust your dose.

Ulcerative colitis

If you are an adult, child or teenager and have ulcerative colitis, you will receive a dose of REMICADE followed by additional doses at 2 and 6 weeks after the first dose. You will then receive a dose every 8 weeks. Your doctor will monitor your response to REMICADE and if you are an adult, may adjust your dose.

Rheumatoid arthritis

If you have rheumatoid arthritis, you will initially receive 2-3 infusions of REMICADE (depends on your body weight). The first dose will be followed by doses at 2 and 6 weeks after the first dose. You will then receive a dose every 8 weeks. Your doctor will monitor your response to REMICADE and may adjust your dose or dose you more frequently (as often as every 4 weeks). Your doctor will also give you methotrexate or you will need to continue taking it.

Ankylosing Spondylitis

If you have ankylosing spondylitis you will initially receive three doses of REMICADE. The first dose will be followed by doses at 2 and 6 weeks after the first dose. You will then receive a dose every 6 weeks.

Psoriatic arthritis

If you have psoriatic arthritis you will initially receive three doses of REMICADE. The first dose will be followed by doses at 2 and 6 weeks after the first dose. You will then receive a dose every 8 weeks.

Psoriasis

If you have psoriasis you will initially receive three doses of REMICADE. The first dose will be followed by doses at 2 and 6 weeks after the first dose. You will then receive a dose every 8 weeks.

Entero-Behçet's disease

If you have Entero-Behçet's disease you will initially receive a dose of REMICADE. The first dose will be followed by 2 and 6 weeks after the first dose. You will then receive a dose every 8 weeks. Your doctor will monitor your response to REMICADE and may adjust dose.

UNDESIRED EFFECTS

The most common side effects of REMICADE are respiratory infections (such as bronchitis, sinus infections, cold), pain, fever, headache, nausea, vomiting, diarrhea, dizziness, coughing, rash and tiredness.

The most common reason patients stop REMICADE treatment is because they experience a reaction during their infusion (such as shortness of breath, rash, and headache).

Serious side effects that may require treatment can occur during REMICADE therapy. Possible serious side effects of REMICADE include:

Serious infections

Some patients, especially those 65 or older, have had serious infections while receiving REMICADE, including tuberculosis, and systemic bacterial, fungal, and viral infections. A few patients have died from these infections. The use of a 'live' vaccine may result in an infection

caused by the 'live' viruses or bacteria contained in the vaccine (when you have a weakened immune system).

If you develop a fever, feel tired, have a cough, develop flu-like symptoms, or develop an abscess, while or after receiving REMICADE, you should tell your doctor right away because these could be signs that you are getting an infection.

Congestive heart failure

If you have heart failure and you are being treated with REMICADE, your heart failure status must be closely monitored by your doctor. If you develop new or worsening symptoms of heart failure (such as shortness of breath or swelling of your feet), you must contact your doctor right away.

Other heart problems

Some patients have experienced a heart attack (some of which led to death), low blood flow to the heart, or abnormal heart rhythm within 24 hours of beginning their infusion of REMICADE. Symptoms may include chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea, vomiting, fluttering or pounding in your chest, and/or a fast or a slow heartbeat. Tell your doctor right away if you have any of these symptoms.

Lung problems

Some patients have developed inflammation in the lungs (such as interstitial lung disease) that could lead to permanent damage. You should inform your doctor if you develop new or worsening shortness of breath.

Allergic reactions

Some patients get severe allergic reactions to REMICADE. This reaction can occur while you are getting your infusion or shortly afterwards. Symptoms of an allergic reaction may include hives, difficulty breathing, chest pain, and high or low blood pressure. Your doctor may decide to slow down or stop your REMICADE infusion and give you medication to treat the allergic reaction.

Some allergic reactions are delayed and were seen 3 to 12 days after REMICADE treatment. Symptoms of this type of delayed reaction include muscle or joint pain with fever or rash. Tell your doctor if you develop any of these symptoms after REMICADE treatment.

Lupus-like symptoms

Some patients treated with REMICADE have developed symptoms that can resemble lupus. These symptoms may include prolonged chest discomfort or pain, shortness of breath, joint pain, or a rash on the cheeks or arms that is sensitive to the sun. Notify your physician if you develop any of these symptoms. Your doctor will evaluate you and may decide to stop your treatment with REMICADE.

Nervous System Problems

There have been cases where people taking REMICADE have developed serious nervous system problems that have resulted in inflammation of the nerve of the eye, that may cause changes in vision (including blindness); problems with the nerves behind the eye, which may lead to painful and limited eye movements, loss of feeling in the forehead and vision loss (orbital apex syndrome); numbness or tingling; seizures; weakness in the arms or legs. If you experience any of these symptoms, contact your doctor right away.

Skin Problems

Some patients treated with REMICADE have developed lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes) or other skin rashes, including redness, itching, skin peeling and blistering, that could be serious. Small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis), have been reported in some patients. Notify your physician if you develop any new or worsening skin changes.

Cancer

Reports of a type of blood cancer called lymphoma in patients on REMICADE or other TNF-blockers are rare but occur more often than expected for people in general. People who have been treated for rheumatoid arthritis, Crohn's disease, ankylosing spondylitis or psoriatic arthritis for a long time, particularly those with highly active disease may be more prone to develop lymphoma. Cancers, other than lymphoma, have also been reported. There have been cases of cancers, including unusual types, in children and teenage patients taking TNF-blocking agents, which sometimes resulted in death. Some patients who have received TNF-blockers, including REMICADE have developed a rare type of cancer called Hepatosplenic T-cell Lymphoma. Of these patients, most were teenage or young adult males and most had either Crohn's disease or ulcerative colitis. This type of cancer usually results in death. Almost all patients had also received drugs known as azathioprine or 6-mercaptopurine in addition to TNF-blockers. Patients with a specific type of lung disease called COPD (Chronic Obstructive Pulmonary Disease) may be at increased risk for cancer with REMICADE treatment. If you have COPD you should discuss with your doctor whether REMICADE is appropriate for you.

For children and adults taking TNF-blocker medicines, the chances of getting lymphoma or other cancers may increase. You should tell your doctor if you have had or develop lymphoma or other cancers while you are taking REMICADE.

Some patients treated with REMICADE have developed certain kinds of skin cancer. If any changes in the appearance of the skin or growths on the skin occur during or after therapy, tell your doctor.

Some women being treated for rheumatoid arthritis with REMICADE have developed cervical cancer. For women taking REMICADE, including those over 60 years of age, your doctor may recommend that you continue to be regularly screened for cervical cancer.

Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin.

Liver Injury

There have been cases where people taking REMICADE have developed serious liver problems, some fatal. Signs that you could be having a problem include: jaundice (skin and eyes turning yellow), dark brown-colored urine, right-sided abdominal pain, fever, and severe fatigue (tiredness). You should contact your doctor immediately if you develop any of these symptoms.

Hepatitis B

Treatment with TNF-blocking agents such as REMICADE may result in a reactivation of the hepatitis B virus in people who carry this virus. If you have or have had Hepatitis B infection or know or suspect you may be a carrier of hepatitis B virus, be sure to tell your doctor about this as this may impact the decision to start or continue treatment with REMICADE. Your doctor should do a blood test for hepatitis B virus before you start treatment with REMICADE.

Blood Problems

In some instances, patients treated with TNF-blocking agents may develop low blood counts, including a severely decreased number of white blood cells. If you develop symptoms such as persistent fever or infections, bleeding, or bruising, you should contact your doctor right away.

Stroke

Some patients have experienced a stroke within approximately 24 hours of their infusion with REMICADE. Tell your doctor right away if you have symptoms of a stroke which may include:

numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes, sudden trouble walking, dizziness, loss of balance or coordination or a sudden, severe headache.

Metabolism and nutrition disorders

Changes in cholesterol and fat levels in the blood.

Other

Weight gain (for most patients, the weight gain was small).

Any medicine may have side effects. This is not a complete list of side effects. Please talk with your doctor if you experience any unusual symptoms.

OVERDOSE

In the unlikely event that you are given an overdose, your doctor will take the necessary action.

Information for the doctor in case of overdose

Single doses up to 20 mg/kg have been administered without toxic effects.

HOW TO STORE REMICADE

REMICADE is stored in the refrigerator (2°C to 8°C).

It can also be stored in the original carton outside of refrigerated storage up to a maximum of 30°C for a single period of up to 6 months. In this situation, do not return to refrigerated storage again. Write the new expiration date on the carton, including day/month/year. Discard the medicine if not used by the new expiration date or the expiration date printed on the carton, whichever is earlier.

It must be kept out of the reach and sight of children.

Once the infusion is prepared, it should be given to you within 3 hours.

WHAT IS IN REMICADE?

The active ingredient in REMICADE, infliximab, is a monoclonal antibody (proteins that recognize and bind to other proteins). Infliximab is made from mouse and human proteins.

The other ingredients in REMICADE are dibasic sodium phosphate, monobasic sodium phosphate, polysorbate 80, and sucrose.

REMICADE is white lyophilized powder.

REMICADE is supplied in a vial as a powder for concentrate for solution for infusion. Each vial contains 100 mg of infliximab. Before REMICADE is given to you, it will be dissolved with Sterile Water for Injection and further diluted with 0.9% sodium chloride solution.

Manufactured by

Cilag AG, Schaffhausen, Swiss Confederation

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To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at https://ndi.fda.moph.go.th