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Ocrelizumab Injection

pronounced as (ok" re liz' ue mab)

Why is this medication prescribed?

Ocrelizumab injection is used to treat adults with various forms of multiple sclerosis (MS; a disease in which the nerves do not function properly and people may experience weakness, numbness, loss of muscle coordination, and problems with vision, speech, and bladder control) including:

- primary-progressive forms (symptoms gradually become worse over time) of MS,
- clinically isolated syndrome (CIS; nerve symptom episodes that last at least 24 hours),
- relapsing-remitting forms (course of disease where symptoms flare up from time to time), or
- secondary progressive forms (course of disease where relapses occur more often).

Ocrelizumab is in a class of medications called monoclonal antibodies. It works by stopping certain cells of the immune system from causing damage.

How should this medicine be used?

Ocrelizumab injection comes as a solution (liquid) to be injected intravenously (into a vein) by a doctor or nurse. It is usually given once every 2 weeks for the first two doses (at week 0 and week 2), and then infusions are given once every 6 months.

Ocrelizumab injection may cause serious reactions during an infusion and up to a day after receiving the infusion. You may be given other medications to treat or help prevent reactions to ocrelizumab. A doctor or nurse will watch you closely while receiving the infusion and for at least 1 hour afterwards to provide treatment in case of certain side effects to the medication. Your doctor may temporarily or permanently stop your treatment or decrease the dose, if you experience certain side effects. Tell your doctor or nurse if you experience any of the following during or within 24 hours after your infusion: rash; itching; hives; redness at the injection site; difficulty breathing or swallowing; cough; wheezing; rash; feeling faint; throat irritation; mouth or throat pain; shortness of breath; swelling of the face, eyes, mouth, throat, tongue, or lips; flushing; fever; fatigue; tiredness; headache; dizziness; nausea; or a racing heartbeat. Call your doctor immediately or get immediate emergency medical attention if you experience any of these symptoms after you leave your doctor's office or medical facility.

Ocrelizumab may help to control multiple sclerosis symptoms but does not cure them. Your doctor will watch you carefully to see how well ocrelizumab works for you. It is important to tell your doctor how you are feeling during your treatment.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with ocrelizumab injection and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>) or the manufacturer's website to obtain the Medication Guide.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving ocrelizumab injection,

- tell your doctor and pharmacist if you are allergic to ocrelizumab, any other medications, or any of the ingredients in ocrelizumab injection. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention medications that suppress your immune system such as the following: corticosteroids including dexamethasone, methylprednisolone (Medrol), and prednisone (Rayos); cyclosporine (Gengraf, Neoral, Sandimmune); daclizumab (Zinbryta); fingolimod (Gilenya); mitoxantrone; natalizumab (Tysabri); tacrolimus (Astagraf, Prograf); or teriflunomide (Aubagio). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had hepatitis B (HBV; a virus that infects the liver and may cause severe liver damage or liver cancer). Your doctor will probably tell you not to receive ocrelizumab.
- tell your doctor if you have any type of infection before you begin your treatment with ocrelizumab injection.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. Use effective birth control during your treatment with ocrelizumab and for 6 months after the final dose. If you become pregnant while receiving ocrelizumab, call your doctor. If you receive ocrelizumab injection during your pregnancy, be sure to talk to your baby's doctor about this after your baby is born. Your baby may need to delay receiving certain vaccines.
- tell your doctor if you have had a recent vaccination or are scheduled to receive any vaccinations. You may need to receive certain types of vaccines at least 4 weeks before and others at least 2 weeks before you start treatment with ocrelizumab injection. Do not have any vaccinations without talking to your doctor during your treatment.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss an appointment to receive a ocrelizumab, call your doctor as soon as possible to reschedule your appointment.

What side effects can this medication cause?

Ocrelizumab may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- swelling or pain in hands, arms, legs, or feet
- diarrhea

Some side effects can be serious. If you experience any of these symptoms or those listed in the HOW section, call your doctor immediately or get emergency medical treatment:

- fever, chills, persistent cough, or other signs of infection
- mouth sores
- shingles (a rash that can occur in people who have had chickenpox in the past)
- sores around the genitals or rectum
- skin infection
- weakness on one side of the body; clumsiness of arms and legs; vision changes; changes in thinking, memory, and orientation; confusion; or personality changes

Ocrelizumab may increase your risk of certain cancers, including breast cancer. Talk to your doctor about the risks of receiving this medication.

Ocrelizumab may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during your treatment to check your body's response to ocrelizumab injection.

Ask your pharmacist any questions you have about ocrelizumab injection.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Ocrevus[®]

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