



Important Information

Can I take other medications while being treated with KESIMPTA®?²

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor or pharmacist:

- If you are taking, have recently taken or may take any other medicines that affect the immune system. This is because these may have an added effect on the immune system.
- If you plan to have any vaccinations.



Can I take KESIMPTA® if I have recently had a vaccination?²

If you need a type of vaccine called a live or live-attenuated vaccine, this should be given at least 4 weeks before you start treatment. It is not recommended you receive 'live' or 'live-attenuated' vaccines while you are being treated or until your doctor tells you that you can. Whenever possible, you should receive other types of vaccines at least 2 weeks before you start treatment.



Can I take KESIMPTA® while pregnant/breast-feeding?²

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

You should avoid becoming pregnant while on treatment and for 6 months after you stop using it, unless otherwise advised by your doctor.

If there is a possibility that you could become pregnant you should use an effective birth control method during treatment and for 6 months after stopping treatment. Ask your doctor about the options available to you.



If you do become pregnant or think you may be pregnant during treatment or within 6 months after the last dose, tell your doctor straight away.

KESIMPTA® can pass into breast milk. Talk to your doctor about benefits and risks before breast-feeding your baby while using this medication.

Vaccination of newborn babies²

Ask your doctor or pharmacist for advice before vaccinating your newborn baby if you have used KESIMPTA® during your pregnancy.

While using KESIMPTA®, tell your doctor:²

- If you have a general injection related reaction or a local injection site reaction after you have injected, such as fever, headache, muscle pain, chills and tiredness. These are the most common side effects of treatment. They usually occur in the 24 hours after injection, in particular after the first injection. The first injection should take place under the guidance of a healthcare professional.
- If you have an infection. You may get infections more easily or an infection you already have may get worse. This is because the immune cells that the treatment targets also help to fight infection. Infections could be serious and sometimes even life-threatening.
- If you plan to have any vaccinations. Your doctor will tell you whether the vaccination you need is a live vaccine, a live-attenuated vaccine, or another type of vaccine. You should not be given live or live-attenuated vaccines during your treatment as this may result in infection. Other types of vaccines may work less well if they are given during treatment.
- If you get any of the following during your treatment because they could be signs of a serious condition: if you have rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue or throat, chest tightness, or feel faint. These could be signs or symptoms of an allergic reaction.
- If you think your MS is getting worse (e.g. weakness or visual changes) or if you notice any new or unusual symptoms, **tell your doctor straight away**. These effects may indicate a rare brain disorder called progressive multifocal leukoencephalopathy (PML), which is caused by a virus infection.

Side effects that some people may experience

Like all medicines, KESIMPTA® can potentially cause side effects in some people.

It is important to be aware of these before you start your medicine. Your doctor, nurse or pharmacist will be able to provide more information if you would like to discuss these.

Very common side effects that may affect more than 1 in 10 people:²

- Upper respiratory tract infections with symptoms such as sore throat and runny nose.
- Injection-related symptoms such as fever, headache, muscle pain, chills and tiredness. These usually occur in the 24 hours after an injection, in particular after the first injection.
- Injection-site reactions. Symptoms include redness, pain, itching and swelling at the injection site.
- Urinary tract infections.

Common side effects that may affect up to 1 in 10 people include:²

- A decrease in the blood level of a protein called immunoglobulin M, which helps protect against infection.
- Oral herpes.
- Nausea and vomiting have been reported in association with systemic injection-related reactions.

Not known (frequency cannot be estimated from the available data):²

- allergic reactions, with symptoms such as rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue or throat, chest tightness, or feeling faint



Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

