

1582  
1583  
1584  
1585  
1586  
1587  
1588  
1589  
1590  
1591  
1592  
1593  
1594  
1595  
1596  
1597  
1598  
1599  
1600  
1601  
1602  
1603  
1604  
1605  
1606  
1607  
1608  
1609  
1610  
1611  
1612  
1613  
1614  
1615  
1616  
1617  
1618  
1619  
1620  
1621  
1622  
1623  
1624  
1625  
1626

---

**Rx Only**

**MEDICATION GUIDE**  
**REMICADE® (Rem-eh-kaid)**  
**(infliximab)**

Read the Medication Guide that comes with REMICADE before you receive the first treatment, and before each time you get a treatment of REMICADE. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment.

**What is the most important information I should know about REMICADE?**

REMICADE is a medicine that affects your immune system. It can cause serious side effects including:

Serious Infections

- Patients treated with REMICADE and other medicines that block TNF have an increased risk for infections. Some patients have had serious infections while receiving REMICADE. In some cases, the infections got worse (progressed) and became serious enough that patients needed to be in the hospital for treatment. These serious infections include TB (tuberculosis), and infections caused by viruses, fungi or bacteria that have spread throughout the body. Some patients have died from these infections.
- Tell your doctor right away if you have any of the following symptoms, which may be early signs of a serious infection, while taking or after taking REMICADE:
  - a fever
  - feel very tired
  - have a cough
  - have flu-like symptoms
  - warm, red, or painful skinThese may be early signs of a serious infection.

Cancer

- Some children and young adults with Crohn’s disease who have received REMICADE have developed a rare type of cancer called Hepatosplenic T-cell Lymphoma. This type of cancer often results in death. These patients were also receiving drugs known as azathioprine or 6-mercaptopurine.
- Tell your doctor if you have ever had any type of cancer.

See also, “**What are the possible side effects of REMICADE?**” below.

**What is REMICADE?**

REMICADE is a prescription medicine that is approved for patients with:

- Rheumatoid Arthritis - adults with moderately to severely active rheumatoid arthritis, along with the medicine methotrexate

- 
- 1627
- Crohn's Disease - children over the age of 6 and adults with Crohn's disease who have not responded well enough to other medicines
- 1628
- Ankylosing Spondylitis
- 1629
- Psoriatic Arthritis
- 1630
- Plaque Psoriasis- adult patients with plaque psoriasis that is chronic (doesn't go away) severe, extensive, and/or disabling.
- 1631
- Ulcerative Colitis - patients with moderately to severely active ulcerative colitis who have not responded well enough to other medicines.
- 1632
- 1633
- 1634
- 1635

1636 REMICADE blocks the action of a protein in your body called tumor necrosis factor-alpha (TNF-alpha). TNF-alpha is made by your body's immune system. People with certain diseases have too much TNF-alpha that can cause the immune system to attack normal healthy parts of the body. REMICADE can block the damage caused by too much TNF-alpha.

1637

1638

1639

1640

1641 **Who should not receive REMICADE?**

1642

1643 You should not receive REMICADE if you have:

- heart failure, unless your doctor has examined you and decided that you are able to take REMICADE. Talk to your doctor about your heart failure.
  - had an allergic reaction to REMICADE, or any of the other ingredients in REMICADE. See the end of this Medication Guide for a complete list of ingredients in REMICADE.
- 1644
- 1645
- 1646
- 1647
- 1648

1649 **What should I tell my doctor before starting treatment with REMICADE?**

1650

1651 Your doctor will assess your health before each treatment.

1652

1653 Tell your doctor about all of your medical conditions, including if you:

- have any kind of infection even if it is very minor (such as an open cut or sore). REMICADE affects the body's immune system and makes you less able to fight infections.
  - have an infection that won't go away or a history of infection that keeps coming back.
  - have had TB (tuberculosis), or if you have recently been near anyone who might have TB. If you have been near someone with TB and have the TB germ in your body, even if you don't have symptoms of an infection, you can get a serious TB infection while taking REMICADE. Sometimes these serious TB infections can cause death.
  - were born in, lived in or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure.
  - live or have lived in certain parts of the country where there is more risk for certain kinds of fungal infections (histoplasmosis or coccidioidomycosis). These infections may develop or become more severe if you take REMICADE. If you don't know if you have lived in an area where histoplasmosis or coccidioidomycosis is common, ask your doctor.
  - have or had hepatitis B. If you are a chronic carrier of the virus that causes hepatitis B, taking REMICADE could cause the hepatitis B virus to become an active infection again.
  - have other liver problems including liver failure.
- 1654
- 1655
- 1656
- 1657
- 1658
- 1659
- 1660
- 1661
- 1662
- 1663
- 1664
- 1665
- 1666
- 1667
- 1668
- 1669
- 1670

- 
- 1671 • have heart failure or other heart conditions. If you have heart failure, it may get worse  
1672 while you take REMICADE.
- 1673 • have or have had any type of cancer.
- 1674 • have had phototherapy (treatment with ultraviolet light or sunlight along with a medicine  
1675 to make your skin sensitive to light) for psoriasis. You may have a higher chance of  
1676 getting skin cancer while receiving REMICADE.
- 1677 • have COPD (Chronic Obstructive Pulmonary Disease), a specific type of lung disease.  
1678 Patients with COPD may have an increased risk of getting cancer while taking  
1679 REMICADE.
- 1680 • have or have had a condition that affects your nervous system such as
- 1681 • multiple sclerosis, or Guillain-Barré syndrome, or
  - 1682 • if you experience any numbness or tingling, or
  - 1683 • if you have had a seizure.
- 1684 • have recently received or are scheduled to receive a vaccine. **Adults and children**  
1685 **should not receive a live vaccine while taking REMICADE.** Children with Crohn's  
1686 disease should have all of their vaccines brought up to date before starting treatment with  
1687 REMICADE.
- 1688 • are pregnant or planning to become pregnant. It is not known if REMICADE harms your  
1689 unborn baby. REMICADE should be given to a pregnant woman only if clearly needed.  
1690 Talk to your doctor about stopping REMICADE if you are pregnant or planning to  
1691 become pregnant.
- 1692 • are breast-feeding or planning to breast-feed. It is not known whether REMICADE  
1693 passes into your breast milk. Talk to your doctor about the best way to feed your baby  
1694 while taking REMICADE. You should not breast-feed while taking REMICADE.
- 1695

### 1696 **How should I receive REMICADE?**

- 1697
- 1698 • You will be given REMICADE through a needle placed in a vein (IV or intravenous  
1699 infusion) in your arm.
  - 1700 • Your doctor may decide to give you medicine before starting the REMICADE infusion to  
1701 prevent or lessen side effects.
  - 1702 • Only a healthcare professional should prepare the medicine and administer it to you.
  - 1703 • REMICADE will be given to you over a period of about 2 hours.
  - 1704 • If you have side effects from REMICADE, the infusion may need to be adjusted or  
1705 stopped. In addition, your healthcare professional may decide to treat your symptoms.
  - 1706 • A healthcare professional will monitor you during the REMICADE infusion and for a  
1707 period of time afterward for side effects.
  - 1708 • Your doctor may do certain tests while you are taking REMICADE to monitor you for  
1709 side effects and to see how well you respond to the treatment.
  - 1710 • Your doctor will determine the right dose of REMICADE for you and how often you  
1711 should receive it. Make sure to discuss with your doctor when you will receive infusions  
1712 and to come in for all your infusions and follow-up appointments.
- 1713

### 1714 **What should I avoid while receiving REMICADE?**

1715  
1716  
1717  
1718  
1719  
1720  
1721  
1722  
1723  
1724  
1725  
1726  
1727  
1728  
1729  
1730  
1731  
1732  
1733  
1734  
1735  
1736  
1737  
1738  
1739  
1740  
1741  
1742  
1743  
1744  
1745  
1746  
1747  
1748  
1749  
1750  
1751  
1752  
1753  
1754  
1755  
1756  
1757  
1758

---

Do not take REMICADE and the medication KINERET (Anakinra) together.

**Tell your doctor about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

**What are the possible side effects of REMICADE?**

Serious and sometimes fatal side effects have been reported in patients taking REMICADE (see also “**What is the most important information I should know about REMICADE?**”). These include:

Serious Infections

- Some patients have had serious infections while receiving REMICADE. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients die from these infections. If you get an infection while receiving treatment with REMICADE your doctor will treat your infection and may need to stop your REMICADE treatment.
- Tell your doctor right away if you have any of the following signs of an infection while taking or after taking REMICADE:
  - a fever
  - feel very tired
  - have a cough
  - have flu-like symptoms
  - warm, red, or painful skin
- 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 REMICADE and during treatment with REMICADE.
- Even if your TB test is negative your doctor should carefully monitor you for TB infections while you are taking REMICADE. Patients who had a **negative** TB skin test before receiving REMICADE have developed active TB.
- If you are a chronic carrier of the hepatitis B virus, the virus can become active while you are being treated with REMICADE. Your doctor may do a blood test before you start treatment with REMICADE and occasionally while you are being treated. Tell your doctor if you have any of the following symptoms:
  - feel unwell
  - poor appetite
  - tiredness (fatigue)
  - fever, skin rash and/or joint pain

Cancer

- 
- 1759
- 1760
- 1761
- 1762
- 1763
- 1764
- 1765
- 1766
- 1767
- 1768
- 1769
- 1770
- 1771
- 1772
- In clinical studies, more cancers were seen in patients who took REMICADE and other medicines that block TNF than patients who did not receive these treatments.
  - Some children and young adults with Crohn's disease who have received REMICADE have developed a rare type of cancer called Hepatosplenic T-cell Lymphoma. This type of cancer often results in death. These patients were also receiving drugs known as azathioprine or 6-mercaptopurine.
  - People who have been treated for rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis for a long time may be more likely to develop lymphoma. This is especially true for people with very active disease.
  - Patients with COPD (a specific type of lung disease) may have an increased risk for getting cancer while being treated with REMICADE.
  - If you take REMICADE, your chances of getting lymphoma or other cancers may increase.

### 1773 Heart Failure

1774 If you have a heart problem called congestive heart failure, your doctor should check you closely  
1775 while you are taking REMICADE. Your congestive heart failure may get worse while you are  
1776 taking REMICADE. Be sure to tell your doctor of any new or worse symptoms including:

- 1777
- 1778
- 1779
- Shortness of breath
  - Swelling of ankles or feet
  - Sudden weight gain

1780 Treatment with REMICADE may need to be stopped if you get new or worse congestive heart  
1781 failure.

### 1782 Liver Injury

1784 In rare cases, some patients taking REMICADE have developed serious liver problems. Tell  
1785 your doctor if you have

- 1786
- 1787
- 1788
- 1789
- 1790
- Jaundice (skin and eyes turning yellow)
  - Dark brown-colored urine
  - Pain on the right side of your stomach area (right-sided abdominal pain)
  - Fever
  - Extreme tiredness (severe fatigue)

### 1791 Blood Problems

1792 In some patients taking REMICADE, the body may not make enough of the blood cells that help  
1793 fight infections or help stop bleeding. Tell your doctor if you

- 1794
- 1795
- 1796
- 1797
- Have a fever that does not go away
  - Bruise or bleed very easily
  - Look very pale

### 1798 Nervous System Disorders

1799 In rare cases, patients taking REMICADE have developed problems with their nervous system.  
1800 Tell your doctor if you have

- 1801
- 1802
- Changes in your vision

- 
- 1803       • Weakness in your arms and/or legs  
1804       • Numbness or tingling in any part of your body  
1805       • Seizures

1806

1807   Allergic Reactions

1808   Some patients have had allergic reactions to REMICADE. Some of these reactions were severe.  
1809   These reactions can happen while you are getting your REMICADE treatment or shortly  
1810   afterwards. Your doctor may need to stop or pause your treatment with REMICADE and may  
1811   give you medicines to treat the allergic reaction. Signs of an allergic reaction can include:

- 1812       • Hives (red, raised, itchy patches of skin)  
1813       • Difficulty breathing  
1814       • Chest pain  
1815       • High or low blood pressure  
1816       • Fever  
1817       • Chills

1818   Some patients treated with REMICADE have had delayed allergic reactions. The delayed  
1819   reactions occurred 3 to 12 days after receiving treatment with REMICADE. Tell your doctor  
1820   right away if you have any of these signs of delayed allergic reaction to REMICADE:

- 1821       • Fever  
1822       • Rash  
1823       • Headache  
1824       • Sore throat  
1825       • Muscle or joint pain  
1826       • Swelling of the face and hands  
1827       • Difficulty swallowing

1828

1829   Lupus-like Syndrome

1830   Some patients have developed symptoms that are like the symptoms of Lupus. If you develop any  
1831   of the following symptoms your doctor may decide to stop your treatment with REMICADE.

- 1832       • Chest discomfort or pain that does not go away  
1833       • Shortness of breath  
1834       • Joint pain  
1835       • Rash on the cheeks or arms that gets worse in sun

1836

1837   **The most common side effects of REMICADE are**

1838

- 1839       • Respiratory infections, such as sinus infections and sore throat)  
1840       • Headache  
1841       • Rash  
1842       • Coughing  
1843       • Stomach pain

1844   Children who took REMICADE in studies for Crohn's disease, showed some differences in side  
1845   effects compared with adults who took REMICADE for Crohn's disease. The side effects that

---

1846 happened more in children were: anemia (low red blood cells), blood in stool, leukopenia (low  
1847 white blood cells), flushing (redness or blushing), viral infections, neutropenia (low neutrophils,  
1848 the white blood cells that fight infection), bone fracture, bacterial infection and allergic reactions  
1849 of the breathing tract.

1850 Tell your doctor about any side effect that bothers you or does not go away.

1851 These are not all of the side effects with REMICADE. Ask your doctor or pharmacist for more  
1852 information.

1853

### 1854 **General information about REMICADE**

1855

1856 Medicines are sometimes prescribed for purposes that are not mentioned in Medication Guides or  
1857 patient information sheets. Do not use REMICADE for a condition for which it was not  
1858 prescribed.

1859

1860 This information sheet summarizes the most important information about REMICADE. You can  
1861 ask your doctor or pharmacist for information about REMICADE that is written for health  
1862 professionals.

1863

1864 For more information go to [www.remicade.com](http://www.remicade.com) or call 1-800-457-6399.

1865

### 1866 **What are the ingredients in REMICADE?**

1867

1868 The active ingredient is Infliximab.

1869 The inactive ingredients in REMICADE include: sucrose, polysorbate 80, monobasic sodium  
1870 phosphate monohydrate, and dibasic sodium phosphate dihydrate. No Preservatives are present.

1871

1872 Product developed and manufactured by:

1873 Centocor, Inc.

1874 200 Great Valley Parkway

1875 Malvern, PA 19355

1876

1877 Rx only

1878 Revised September 2006

1879

1880 This Medication Guide has been approved by the U.S. Food and Drug Administration.