

PACKAGE LEAFLET: INFORMATION FOR THE USER

MabThera 100 mg concentrate for solution for infusion rituximab

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. What MabThera is and what it is used for
2. Before you use MabThera
3. How to use MabThera
4. Possible side effects
5. How to store MabThera
6. Further information

1. WHAT MABTHERA IS AND WHAT IT IS USED FOR

MabThera contains an antibody (rituximab) which is a type of protein. Rituximab binds to the surface of a type of white blood cell, the B lymphocyte. When rituximab binds to the surface of this cell it causes the cell to die.

MabThera may be used for the treatment of three different conditions. Your doctor may prescribe MabThera for the treatment of:

a) Non-Hodgkin's Lymphoma

Non-Hodgkin's lymphoma is a disease of the lymphatic system. B lymphocytes are involved in the cause of some of the symptoms you may have. MabThera can be used alone or with other medicines your doctor may prescribe to induce remission of your disease. MabThera may be used as a continuous (maintenance) treatment for 2 years in patients who have responded to induction treatment.

b) Chronic lymphocytic leukaemia

Chronic lymphocytic leukaemia (CLL) is the most common form of adult leukaemia. CLL affects a particular lymphocyte, the B cell, which originates from the bone marrow and develops in the lymph nodes. Patients with CLL have too many abnormal lymphocytes, which accumulate mainly in the bone marrow and blood. The proliferation of these abnormal B-lymphocytes is the cause of symptoms you may have. MabThera in combination with chemotherapy destroys these cells which are gradually removed from the body by biological processes.

c) Rheumatoid arthritis

MabThera is used for the treatment of rheumatoid arthritis. Rheumatoid arthritis is a disease of the joints. B lymphocytes are involved in the cause of some of the symptoms you have. MabThera is used to treat rheumatoid arthritis in people who have already tried some other medicines which have either stopped working, have not worked well enough or have caused side effects. MabThera is usually taken together with another medicine called methotrexate.

MabThera slows down the damage to your joints caused by rheumatoid arthritis and improves your ability to do normal daily activities.

The best responses to MabThera are seen in those who have a positive blood test to rheumatoid factor (RF) and/or anti-Cyclic Citrullinated Peptide (anti-CCP). Both tests are commonly positive in rheumatoid arthritis and aid in confirming the diagnosis.

2. BEFORE YOU USE MABTHERA

Do not take MabThera

- if you are allergic to rituximab, to other similar proteins, or to any of the other ingredients in the solution
- if you have an active, severe infection or have a severely decreased immune system function.

If you are not sure about this, you should ask your doctor who will inform you accordingly.

Tell your doctor before your MabThera treatment

- if you think you have hepatitis infection now or have had it in the past. In a few cases, patients who have had hepatitis B might have a repeated attack of hepatitis, which can be fatal in very rare cases. Patients with a history of hepatitis B infection will be carefully checked by their doctor for signs of active hepatitis B.
- if you are taking treatment for high blood pressure. You may be asked not to take your medicines 12 hours before your infusion of MabThera. Some people have a fall in their blood pressure during the infusion.
- if you have ever had heart disease (i.e. angina, palpitations, or heart failure) or a history of breathing problems.
Your doctor may need to take special care of you during your treatment with MabThera (in any of the above cases).

Take special care with MabThera

- tell your doctor if you are taking or have previously taken medicines which may affect your immune system, such as chemotherapy or immunosuppressive agents.

If you have rheumatoid arthritis also tell your doctor

- if you think you may have an infection, even a mild one like a cold. The cells that are affected by MabThera help to fight infection and you should wait until the infection has passed before you are given MabThera. Also please tell your doctor if you had a lot of infections in the past or suffer from severe infections.
- if you think you may need any vaccinations in the near future, including vaccinations needed to travel to other countries. Some vaccines should not be given at the same time as MabThera or in the months after you receive MabThera. Your doctor will check if you should have any vaccines before you receive MabThera.

At present, there is not very much information about MabThera treatment in children and adolescents; if you are under 18 years of age, you or your parent/carer should ask your doctor if MabThera is right for you.

Taking other medicines

Before starting treatment, make sure your doctor knows if you are taking or have recently taken any other medicines (including those you have bought for yourself from a pharmacy, supermarket or health store). This is extremely important, as using more than one medicine at the same time can strengthen or weaken their effect. MabThera should not be used with other drugs unless your doctor has told you it is safe to do so.

Pregnancy and breast-feeding

You must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. This is because MabThera is an antibody and can cross the placenta and affect your baby.

If you can get pregnant, you must use an effective method of birth control during therapy with MabThera and for 12 months after the last time you were treated with MabThera.

MabThera might also get into breast milk and so you should not breast-feed your baby during therapy with MabThera and for 12 months after the last time you were treated with MabThera

Driving and using machines

It is not known whether MabThera has an effect on your ability to drive a car or use machines.

3. HOW TO USE MABTHERA

MabThera is an infusion (“drip”) which is given directly into your veins. You will be observed by a health care professional while you are being given MabThera in case you have any side effects during the infusion.

Before the infusion is given you will be given medicines to prevent or reduce possible reactions to MabThera.

a) If you are being treated for non-Hodgkin’s Lymphoma

If you are treated with MabThera alone you will receive infusions at weekly intervals for a total of four infusions (days 1, 8, 15 and 22), so that the a course of treatment usually lasts for 22 days. Repeated treatment courses with MabThera are possible. If you are treated with MabThera in combination with other medicines, you will receive an infusion of MabThera on the same day as the other medicines, which are usually given 8 times at 3-week intervals. If you have responded to treatment and are further treated with MabThera as continuous (maintenance) treatment, you will receive one infusion of MabThera every 2 or 3 months (as directed by your doctor) for two years. Your doctor may change the number of infusions depending on your disease.

b) If you are being treated for chronic lymphocytic leukemia

When you are treated with MabThera in combination with chemotherapy, you will receive MabThera infusions on day 0 cycle 1 then day 1 of each cycle for 6 cycles in total. Each cycle has a duration of 28 days. The chemotherapy should be given after the MabThera infusion. Your doctor will decide if you should receive concomitant supportive therapy.

c) If you are being treated for rheumatoid arthritis

Each course of treatment is made up of two separate infusions which are given 2 weeks apart. Repeated courses of treatment with MabThera are possible. Depending on the signs and symptoms of your disease, your doctor will decide when you should receive more MabThera. This may be months from now.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MabThera can cause side effects, although not everybody gets them. Most side effects are mild to moderate but some may be serious and require treatment. Rarely, some of these reactions have been fatal.

Infusion reactions

During or within the first 2 hours of the first infusion you may develop fever, chills and shivering. Less frequently, some patients may experience blisters, itching, sickness, tiredness, headache, breathing difficulties, tongue or throat swelling, itchy or runny nose, vomiting, flushing or palpitations, heart attack or low number of platelets. If you have heart disease or angina, these reactions might get worse. **Tell the person giving you the infusion immediately** if you develop any of these symptoms, as the infusion may need to be slowed down or stopped for a while. You may

require additional treatment such as an antihistamine or paracetamol. When these symptoms go away, or improve, the infusion can be continued. These reactions are less likely to happen after the second infusion.

Infections

Tell your doctor after your MabThera treatment if you get any symptoms of an infection, for example fever, cough, sore throat, burning pain when passing urine, or you start to feel weak or generally unwell. You might get infections more easily following MabThera therapy. Often these are colds, but there have been cases of pneumonia or urinary infections.

Very rarely, some patients taking MabThera have had a serious brain infection, which has been fatal. **Tell your doctor immediately** if you have memory loss, trouble thinking, difficulty with walking or loss of vision.

If you are being treated for rheumatoid arthritis, you will also find this information in the Patient Alert Card you have been given by your doctor. It is important that you keep this Alert Card and show it to your partner or caregiver.

Other reactions

a) If you are being treated for non-Hodgkin's Lymphoma or chronic lymphocytic leukaemia
The most commonly reported side effects due to MabThera (reported in more than 1 out of 10 patients) are:

- infections such as pneumonia (bacterial) and herpes (viral) or bronchial tube inflammation (bronchitis)
- low number of white blood cells, with or without fever, low number of platelets in the blood
- allergic reactions after infusion
- nausea
- skin rashes, itching, bald spots on the scalp, fever, chills, physical weakness, headache
- decreased immunity (decreased IgG levels)

Common side effects due to MabThera (reported in more than 1 out of 100 patients) include:

- infections such as sepsis and pneumonia (bacterial), herpes and hepatitis B (viral) or candidal (fungal) bronchial tube and sinuses inflammation, or other general infections of unknown origin
- low number of red blood cells, low number of red and white blood cells and platelets
- allergic reactions (hypersensitivity)
- high sugar level in the blood, weight loss, excess fluid in the face and the body, increased blood levels of the enzyme (LDH), low blood level of calcium
- abnormal sensations of the skin, such as numbness, tingling, pricking, burning, a creeping skin sensation, decreased sense of touch. Feeling restless, difficulty falling asleep, becoming red in the face and bruising of the skin as a consequence of dilation of the blood vessels, dizziness, anxiety
- an increased production of tears, secretion and shedding disorders, inflammation of the eye (conjunctivitis)
- ringing sound in the ears, ear pain
- heart disorders (heart attack, irregular heart rate, abnormally fast heart rate)
- high or low blood pressure, a decrease in blood pressure upon assuming an upright posture
- inflammation, irritation and / or tightness of the lungs, throat and / or sinuses, shortness of breath, too little oxygen reaching the body organs, coughing
- vomiting, diarrhoea, pain in the abdomen, irritation and /or ulceration of the throat and the mouth, difficulties in swallowing, constipation, indigestion. Eating disorders: decrease in the amount of food eaten with a consequential dangerous loss in weight
- skin disorders, burning sensation of the skin, itching, increased perspiration, night sweats
- musculoskeletal disorders, abnormal increase in tightness of muscle tone, pain, joint pain, muscle pain, back and neck pain

- general disorders, tumour pain, becoming markedly red in the face and other areas of the skin, general discomfort or uneasiness, flu syndrome, fatigue, shaking, multi-organ dysfunction

Uncommon side effects due to MabThera (reported in more than 1 out of 1000 patients) include:

- abnormal clotting, decrease of blood cells production, autoimmune decrease of red blood cells, swollen/enlarged lymph nodes
- low mood and loss of interest or pleasure in usual activities, nervousness
- taste changes
- heart disorder (heart attack, abnormally fast heart rate, reduced heart rate, irregular heart rate, chest pain) inflammation, irritation and/or tightness of the lungs, asthma, shortness of breath
- enlargement of the abdomen
- pain at the infusion site

b) If you are being treated for rheumatoid arthritis

The most commonly reported side effects due to MabThera (reported in more than 1 out of 10 patients) are:

- Infections such as pneumonia (bacterial)
- Pain on passing water (urinary tract infection)
- Allergic reactions after infusion
- Changes in blood pressure, nausea, rash, fever, feeling itchy, runny or block nose and sneezing, shaking, rapid heart beat, and tiredness
- Headache

Commonly side effects due to MabThera (reported in more than 1 out of 100 patients) include:

- Infections such as bronchial tube inflammation (bronchitis)
- A feeling of fullness or a throbbing pain behind the nose, cheeks and eyes (sinusitis), pain in the abdomen, vomiting and diarrhoea, breathing problems
- Fungal foot infection (athlete's foot)
- High cholesterol levels in the blood
- Abnormal sensations of the skin, such as numbness, tingling, pricking or burning, sciatica, migraine, dizziness
- Loss of hair
- Anxiety, depression
- Indigestion, diarrhoea, acid reflux, irritation and /or ulceration of the throat and the mouth
- Pain in the tummy, back, muscles and/or joints

Uncommon side effects due to MabThera (reported in more than 1 out of 1000 patients) include:

- Excess fluid retention in the face and body
- Inflammation, irritation and / or tightness of the lungs, and throat, coughing
- Skin reactions including hives, itching and rash
- Allergic reactions including wheezing or shortness of breath, swelling of the face and tongue, collapse

Very rare side effects due to MabThera (reported in less than 1 in 10,000 patients) include:

- A complex of symptoms occurring within a few weeks of an infusion of MabThera including allergic like reactions such as rash, itching, joint pain, swollen lymph glands and fever

If you are receiving MabThera in combination with other medicines, some of the side effects you may experience may be due to the other medicine.

If any of the side effects gets serious, or, if you notice any side effects not listed in this leaflet, please inform your doctor, nurse or pharmacist (chemist) immediately.

5. HOW TO STORE MABTHERA

Keep out of the reach and sight of children.

Do not use MabThera after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Keep the container in the outer carton in order to protect from light.

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

6. FURTHER INFORMATION

What MabThera contains

- The active ingredient in MabThera is called rituximab. The vial contains 100 mg of Rituximab (10 mg/ml).
- The other ingredients are sodium citrate, polysorbate 80, sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

What MabThera looks like and contents of the pack

MabThera is a clear, colourless solution, supplied as a concentrate for solution for infusion. Vials of 10 ml are available as a pack of 2 vials.

Marketing Authorisation Holder

Roche Registration Limited
6 Falcon Way
Shire Park
Welwyn Garden City
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Manufacturer

Roche Pharma AG
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This leaflet was last approved in October 2010

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1. WHAT MABTHERA IS AND WHAT IT IS USED FOR

MabThera contains an antibody (rituximab) which is a type of protein. Rituximab binds to the surface of a type of white blood cell, the B lymphocyte. When rituximab binds to the surface of this cell it causes the cell to die.

MabThera may be used for the treatment of three different conditions. Your doctor may prescribe MabThera for the treatment of:

a) Non-Hodgkin's Lymphoma

Non-Hodgkin's lymphoma is a disease of the lymphatic system. B lymphocytes are involved in the cause of some of the symptoms you may have. MabThera can be used alone or with other medicines your doctor may prescribe to induce remission of your disease. MabThera may be used as a continuous (maintenance) treatment for 2 years in patients who have responded to induction treatment.

b) Chronic lymphocytic leukaemia

Chronic lymphocytic leukaemia (CLL) is the most common form of adult leukaemia. CLL affects a particular lymphocyte, the B cell, which originates from the bone marrow and develops in the lymph nodes. Patients with CLL have too many abnormal lymphocytes, which accumulate mainly in the bone marrow and blood. The proliferation of these abnormal B-lymphocytes is the cause of symptoms you may have. MabThera in combination with chemotherapy destroys these cells which are gradually removed from the body by biological processes.

c) Rheumatoid arthritis

MabThera is used for the treatment of rheumatoid arthritis. Rheumatoid arthritis is a disease of the joints. B lymphocytes are involved in the cause of some of the symptoms you have. MabThera is used to treat rheumatoid arthritis in people who have already tried some other medicines which have either stopped working, have not worked well enough or have caused side effects. MabThera is usually taken together with another medicine called methotrexate.

MabThera slows down the damage to your joints caused by rheumatoid arthritis and improves your ability to do normal daily activities.

The best responses to MabThera are seen in those who have a positive blood test to rheumatoid factor (RF) and/or anti- Cyclic Citrullinated Peptide (anti-CCP). Both tests are commonly positive in rheumatoid arthritis and aid in confirming the diagnosis.

2. BEFORE YOU USE MABTHERA

Do not take MabThera

- if you are allergic to rituximab, to other similar proteins, or to any of the other ingredients in the solution
- if you have an active, severe infection or have a severely decreased immune system function.

If you are not sure about this, you should ask your doctor who will inform you accordingly.

Tell your doctor before your MabThera treatment

- if you think you have hepatitis infection now or have had it in the past. In a few cases, patients who have had hepatitis B might have a repeated attack of hepatitis, which can be fatal in very rare cases. Patients with a history of hepatitis B infection will be carefully checked by their doctor for signs of active hepatitis B.
- if you are taking treatment for high blood pressure. You may be asked not to take your medicines 12 hours before your infusion of MabThera. Some people have a fall in their blood pressure during the infusion.
- if you have ever had heart disease (i.e. angina, palpitations, or heart failure) or a history of breathing problems.
Your doctor may need to take special care of you during your treatment with MabThera (in any of the above cases).

Take special care with MabThera

- tell your doctor if you are taking or have previously taken medicines which may affect your immune system, such as chemotherapy or immunosuppressive agents.

If you have rheumatoid arthritis also tell your doctor

- if you think you may have an infection, even a mild one like a cold. The cells that are affected by MabThera help to fight infection and you should wait until the infection has passed before you are given MabThera. Also please tell your doctor if you had a lot of infections in the past or suffer from severe infections.
- if you think you may need any vaccinations in the near future, including vaccinations needed to travel to other countries. Some vaccines should not be given at the same time as MabThera or in the months after you receive MabThera. Your doctor will check if you should have any vaccines before you receive MabThera.

At present, there is not very much information about MabThera treatment in children and adolescents; if you are under 18 years of age, you or your parent/carer should ask your doctor if MabThera is right for you.

Taking other medicines

Before starting treatment, make sure your doctor knows if you are taking or have recently taken any other medicines (including those you have bought for yourself from a pharmacy, supermarket or health store). This is extremely important, as using more than one medicine at the same time can strengthen or weaken their effect. MabThera should not be used with other drugs unless your doctor has told you it is safe to do so.

Pregnancy and breast-feeding

You must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. This is because MabThera is an antibody and can cross the placenta and affect your baby.

If you can get pregnant, you must use an effective method of birth control during therapy with MabThera and for 12 months after the last time you were treated with MabThera.

MabThera might also get into breast milk and so you should not breast-feed your baby during therapy with MabThera and for 12 months after the last time you were treated with MabThera

Driving and using machines

It is not known whether MabThera has an effect on your ability to drive a car or use machines.

3. HOW TO USE MABTHERA

MabThera is an infusion (“drip”) which is given directly into your veins. You will be observed by a health care professional while you are being given MabThera in case you have any side effects during the infusion.

Before the infusion is given you will be given medicines to prevent or reduce possible reactions to MabThera.

a) If you are being treated for non-Hodgkin’s Lymphoma

If you are treated with MabThera alone you will receive infusions at weekly intervals for a total of four infusions (days 1, 8, 15 and 22), so that the a course of treatment usually lasts for 22 days. Repeated treatment courses with MabThera are possible. If you are treated with MabThera in combination with other medicines, you will receive an infusion of MabThera on the same day as the other medicines, which are usually given 8 times at 3-week intervals. If you have responded to treatment and are further treated with MabThera as continuous (maintenance) treatment, you will receive one infusion of MabThera every 2 or 3 months (as directed by your doctor) for two years. Your doctor may change the number of infusions depending on your disease.

b) If you are being treated for chronic lymphocytic leukemia

When you are treated with MabThera in combination with chemotherapy, you will receive MabThera infusions on day 0 cycle 1 then day 1 of each cycle for 6 cycles in total. Each cycle has a duration of 28 days. The chemotherapy should be given after the MabThera infusion. Your doctor will decide if you should receive concomitant supportive therapy.

c) If you are being treated for rheumatoid arthritis

Each course of treatment is made up of two separate infusions which are given 2 weeks apart. Repeated courses of treatment with MabThera are possible. Depending on the signs and symptoms of your disease, your doctor will decide when you should receive more MabThera. This may be months from now.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MabThera can cause side effects, although not everybody gets them. Most side effects are mild to moderate but some may be serious and require treatment. Rarely, some of these reactions have been fatal.

Infusion reactions

During or within the first 2 hours of the first infusion you may develop fever, chills and shivering. Less frequently, some patients may experience blisters, itching, sickness, tiredness, headache, breathing difficulties, tongue or throat swelling, itchy or runny nose, vomiting, flushing or palpitations, heart attack or low number of platelets. If you have heart disease or angina, these reactions might get worse. **Tell the person giving you the infusion immediately** if you develop any of these symptoms, as the infusion may need to be slowed down or stopped for a while. You may require additional treatment such as an antihistamine or paracetamol. When these symptoms go away, or improve, the infusion can be continued. These reactions are less likely to happen after the second infusion.

Infections

Tell your doctor after your MabThera treatment if you get any symptoms of an infection, for example fever, cough, sore throat, burning pain when passing urine, or you start to feel weak or generally unwell. You might get infections more easily following MabThera therapy. Often these are colds, but there have been cases of pneumonia or urinary infections.

Very rarely, some patients taking MabThera have had a serious brain infection, which has been fatal. **Tell your doctor immediately** if you have memory loss, trouble thinking, difficulty with walking or loss of vision.

If you are being treated for rheumatoid arthritis, you will also find this information in the Patient Alert Card you have been given by your doctor. It is important that you keep this Alert Card and show it to your partner or caregiver.

Other reactions

a) If you are being treated for non-Hodgkin's Lymphoma or chronic lymphocytic leukaemia
The most commonly reported side effects due to MabThera (reported in more than 1 out of 10 patients) are:

- infections such as pneumonia (bacterial) and herpes (viral) or bronchial tube inflammation (bronchitis)
- low number of white blood cells, with or without fever, low number of platelets in the blood
- allergic reactions after infusion
- nausea
- skin rashes, itching, bald spots on the scalp, fever, chills, physical weakness, headache
- decreased immunity (decreased IgG levels)

Common side effects due to MabThera (reported in more than 1 out of 100 patients) include:

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- low number of red blood cells, low number of red and white blood cells and platelets
- allergic reactions (hypersensitivity)
- high sugar level in the blood, weight loss, excess fluid in the face and the body, increased blood levels of the enzyme (LDH), low blood level of calcium
- abnormal sensations of the skin, such as numbness, tingling, pricking, burning, a creeping skin sensation, decreased sense of touch. Feeling restless, difficulty falling asleep, becoming red in the face and bruising of the skin as a consequence of dilation of the blood vessels, dizziness, anxiety
- an increased production of tears, secretion and shedding disorders, inflammation of the eye (conjunctivitis)
- ringing sound in the ears, ear pain
- heart disorders (heart attack, irregular heart rate, abnormally fast heart rate)
- high or low blood pressure, a decrease in blood pressure upon assuming an upright posture
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Uncommon side effects due to MabThera (reported in more than 1 out of 1000 patients) include:

- abnormal clotting, decrease of blood cells production, autoimmune decrease of red blood cells, swollen/enlarged lymph nodes
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- taste changes
- heart disorder (heart attack, abnormally fast heart rate, reduced heart rate, irregular heart rate, chest pain) inflammation, irritation and/or tightness of the lungs, asthma, shortness of breath
- enlargement of the abdomen
- pain at the infusion site

b) If you are being treated for rheumatoid arthritis

The most commonly reported side effects due to MabThera (reported in more than 1 out of 10 patients) are:

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- Allergic reactions after infusion
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Commonly side effects due to MabThera (reported in more than 1 out of 100 patients) include:

- Infections such as bronchial tube inflammation (bronchitis)
- A feeling of fullness or a throbbing pain behind the nose, cheeks and eyes (sinusitis), pain in the abdomen, vomiting and diarrhoea, breathing problems
- Fungal foot infection (athlete's foot)
- High cholesterol levels in the blood
- Abnormal sensations of the skin, such as numbness, tingling, pricking or burning, sciatica, migraine, dizziness
- Loss of hair
- Anxiety, depression
- Indigestion, diarrhoea, acid reflux, irritation and /or ulceration of the throat and the mouth
- Pain in the tummy, back, muscles and/or joints

Uncommon side effects due to MabThera (reported in more than 1 out of 1000 patients) include:

- Excess fluid retention in the face and body
- Inflammation, irritation and / or tightness of the lungs, and throat, coughing
- Skin reactions including hives, itching and rash
- Allergic reactions including wheezing or shortness of breath, swelling of the face and tongue, collapse

Very rare side effects due to MabThera (reported in less than 1 in 10,000 patients) include:

- A complex of symptoms occurring within a few weeks of an infusion of MabThera including allergic like reactions such as rash, itching, joint pain, swollen lymph glands and fever

If you are receiving MabThera in combination with other medicines, some of the side effects you may experience may be due to the other medicine.

If any of the side effects gets serious, or, if you notice any side effects not listed in this leaflet, please inform your doctor, nurse or pharmacist (chemist) immediately.

5. HOW TO STORE MABTHERA

Keep out of the reach and sight of children.

Do not use MabThera after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Keep the container in the outer carton in order to protect from light.

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

6. FURTHER INFORMATION

What MabThera contains

- The active ingredient in MabThera is called rituximab. The vial contains 500 mg of Rituximab (10 mg/ml).
- The other ingredients are sodium citrate, polysorbate 80, sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

What MabThera looks like and contents of the pack

MabThera is a clear, colourless solution, supplied as a concentrate for solution for infusion. Pack of 1 vial.

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Manufacturer

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