

## Use of abatacept in rheumatoid arthritis - patient information

### Key points

1. Abatacept is a medication that is effective in rheumatoid arthritis (RA), even in patients who have already received other medications (such as methotrexate or other biological agents).
2. Contact your doctor if you have a fever above 38°C or any other sign of infection (cold, urinary tract infection, infected wound, rash). Abatacept can weaken your immune defenses and therefore any infection must be treated promptly to prevent complications.
3. Tell your doctor if you need surgery or dental care, to ensure that steps are taken to prevent infectious complications.
4. Tell your doctor or pharmacist that you are taking abatacept before starting a new medication, to check that receiving both medications concomitantly is safe.
5. Do not decrease the doses of your long-term concomitant medications for RA (such as methotrexate) by yourself.

**To give you a good understanding of the benefits and specificities of abatacept treatment, important questions were addressed in the following sections.**

### What is abatacept?

Abatacept is a medication that treats rheumatoid arthritis (RA). It is one of the disease-modifying drugs, or anti-rheumatic drugs, because it targets the mechanisms involved in RA. The objective of abatacept treatment is to halt the progression of your disease by diminishing your risk of experiencing further joint damage (joint space narrowing and bone erosions). To achieve greater benefits, abatacept is often prescribed together with another anti-RA medication, such as methotrexate. Abatacept can be combined with symptomatic drugs (and/or “comfort” drugs) such as antiinflammatory drugs or analgesics.

### How does abatacept work?

Abatacept is a member of the family of anti-RA drugs known as biologics or biotherapies. These drugs specifically target substances or cells involved in the immune system dysregulation and chronic joint inflammation that characterize RA. Abatacept targets a category of white blood cells (the T lymphocytes) that are markedly overactivated in RA.

### Why did your rheumatologist suggest abatacept treatment?

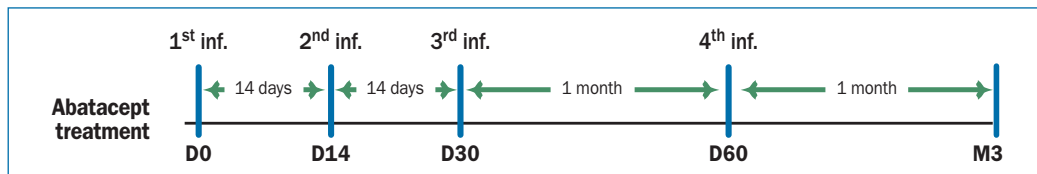
Your rheumatologist suggested abatacept because this medication has been proved effective in patients with RA when one or more anti-RA drugs such as methotrexate or TNF antagonists are inadequately effective or poorly tolerated. For this reason, French healthcare authorities granted abatacept a marketing authorization, in 2007, with a broadening of the indications in 2010. You and your rheumatologist have decided together to use abatacept based on the features of your disease and on your own characteristics (past medical history, infections, allergies ...).

### How is abatacept used in practice?

Abatacept can only be given in hospitals. Your doctor will refer you to a hospital department where the specialists have acquired experience with abatacept and are accredited to use it. Abatacept must be given as an intravenous infusion once a month (with an additional infusion 2 weeks after the first infusion). The infusion, which contains only abatacept, is given over 30 minutes, on a day-hospitalization basis.

You will continue your other treatments for rheumatoid arthritis. In particular, methotrexate is useful, as it increases the effectiveness of abatacept. Do not change your treatment without first talking to your doctor.

You will have blood drawn at regular intervals to monitor any effects of the methotrexate on your liver and white blood cells.



### What are the risks of abatacept therapy?

Abatacept was licensed for use in Europe in 2007. The experience acquired over the years has provided valuable knowledge on abatacept. At present, several thousand patients with rheumatoid arthritis are receiving abatacept, providing a substantial level of experience.

The main risk is the development of infections, since abatacept blunts the immune responses related to T lymphocytes. The most common infections involve the lungs, lower airways, and urinary tract. Most of them are non-serious infections and can be treated easily.

Other abatacept-related complications may occur. For this reason, your doctor will monitor you closely during and after the treatment. You must inform your doctor of any symptom you may experience.

### What will happen before the first abatacept infusion?

Your doctor will ask questions about several important points.

- Your doctor will need detailed information on the medications you are receiving.
- Your doctor will need to obtain details on your medical history. In particular, your doctor will need to know whether you have had any of the following:
  - Infections
  - Viral hepatitis (B or C)
  - Lung disease or another chronic disease
  - Allergies to medications or foods
- You must check that you are properly immunized against tetanus and polio, and your doctor may recommend that you receive vaccines against flu and pneumococcal disease. If your immunizations are not up to date, you will have to receive new shots.
- If you are a woman, you must make sure that you are not pregnant, and if you have just had a baby you will not be able to breast-feed, since the effects of abatacept during pregnancy and

breast-feeding are unknown. You must use an effective method of birth control throughout abatacept treatment and for the first 14 weeks after stopping abatacept.

- If you have any questions before the first abatacept infusion, feel free to discuss them with your doctor.

### What will happen during your abatacept infusion?

You will be expected at the hospital early in the morning. The infusion will last about 30 minutes. You may eat breakfast before leaving home. Remember to bring the things you might need (such as books, drinks, your phone ...).

You will be comfortable during the infusion. You will be able to read, listen to music, or watch television.

During the infusion, pay attention to any abnormal symptoms that might indicate a reaction to the medication. Reactions to abatacept are rare. The symptoms may consist of:

- Trouble breathing
- Swelling of your tongue and lips
- A headache
- A feeling of warmth and/or shivering
- Redness or itching (pruritus) of the skin
- Nausea and/or vomiting
- Itchiness inside your nose and/or sneezing
- Itchiness in your throat
- Pain in your chest, and/or an abnormally fast heartbeat

You must report all your symptoms to the nurse in charge of monitoring you. If you experience symptoms of any kind, the nurse will stop or slow the infusion and call the doctor working in the hospital department. If your symptoms resolve rapidly, the doctor may decide to continue the infusion. Severe reactions that require permanent discontinuation of the infusion are extremely rare.

If you experience any symptoms during the infusion, you will be monitored at the hospital for at least 2 hours before returning home.

### What will happen after the infusion?

If the infusion went well, you will return home. You may leave with a family member or friend or ask us to help you find an appropriate means of transportation. Pay attention to any possible symptoms during the first few hours and days following the infusion.

- **During the first few hours:** delayed allergic reactions are exceedingly rare.
- **During the first few days:** pay attention to any symptoms you may experience and that may indicate an infection. These symptoms may consist of a fever, chills, a sore throat or bad cold, an unusual cough and/or trouble breathing, a burning sensation during urination, or back pain.

Feel free to contact your rheumatologist if you notice anything unusual, or talk to your primary-care doctor if needed. It is better to ask questions right away rather than wait. Do not take any medications without first talking to your doctor

### When will you notice the effects of the treatment?

Abatacept has been proven effective in rheumatoid arthritis. Abatacept alleviates the pain and fatigue and also decreases the joint swelling. However, the full treatment effect often requires several weeks to develop (often 2 to 4 months after treatment initiation). Until the benefits begin to be felt, keep in touch with your doctor, who may give you an appropriate analgesic treatment to take until the abatacept effect reaches its peak.

### How long should you stay on abatacept therapy?

Although abatacept therapy may induce a remission, your disease will return if abatacept is stopped. Therefore, if the drug is well tolerated and effective, it should be continued. The maximal treatment duration is not known, but some patients have been taking abatacept for several years.

Your rheumatologist will see you regularly, at least once every 6 months, to ask questions, perform a physical examination, and order blood tests to measure the level of inflammation. You will discuss the appropriateness of continued therapy with your rheumatologist. In the intervals between rheumatologist visits, you will see your primary doctor if needed, according to the course of your joint disease and other health problems that may require attention, particularly infections, which may be promoted by abatacept therapy.

### Frequently asked questions

#### **What arrangements should I make if I need surgery?**

Tell your doctor if you need surgery, because abatacept weakens the immune defenses and increases the risk of infection. Therefore, your surgical procedure may have to be postponed. In general, a 2-month wait is recommended between the last abatacept infusion and surgery. A shorter or longer wait may be appropriate depending on the risk of infection associated with the type of surgery you need and on the other medications you are receiving. If surgery is mandatory or urgent, your doctor can take the necessary steps to ensure that the procedure is performed under optimal conditions.

#### **Can I have dental care?**

Standard care for a cavity does not require any special precautions and can be performed during abatacept treatment. For scaling, a tooth extraction, or placement of an implant, your dentist may prescribe prophylactic antibiotic therapy. For more complicated dental procedures (surgery), it is best to wait at least 2 months after the last abatacept infusion.

#### **Can I have the flu vaccine?**

Yes, the flu vaccine (once a year), pneumococcal vaccine (usually every 3-5 years), and most of the other vaccines are possible and even recommended when the immune defenses are weakened. However, live attenuated vaccines are contraindicated. Live attenuated vaccines include the yellow fever vaccine required to enter a number of countries and the BCG vaccine against tuberculosis.

#### **Will I feel ill during the treatment?**

Abatacept therapy carries a potential risk of infection. Follow standard hygiene precautions and promptly inform your doctor of any symptoms of infection (fever above 38°C, cough, or abdominal pain). Your doctor will determine whether you need investigations and/or antibiotics.

**What should I do if I have a cold? Abdominal pain or a headache?**

Don't panic. Anyone may experience indigestion or a headache at some periods of the year. However, inform your doctor of any abnormal signs that last longer than 1 day, particularly if you have a fever. Your doctor will be able to prescribe an appropriate treatment, for instance an antibiotic.

**Can I visit friends who have a sick child?**

One of the treatment goals is to allow a life as normal as possible, without exclusion from social activities, even with people who are ill. You may prefer not to kiss someone who is ill, which is simply reasonable regardless of whether drugs such as abatacept are being used.

**Pregnancy and breast-feeding**

As with many medications, as a precaution, initiating a pregnancy during abatacept treatment is not recommended (whether you are a man or a woman). Use an effective birth control method throughout your abatacept treatment. If you want a child, talk to your doctor. Before stopping birth control, you must wait 14 weeks after the last abatacept infusion. In addition, some of the other medications used to treat rheumatoid arthritis are not compatible with a pregnancy. As a precaution, you should not breast-feed your baby if you are on abatacept therapy.

**Will there be a change in my physical appearance?**

The treatment will have no effect on your physical appearance or body weight and will not cause your hair to fall out.

**Can I drive while on abatacept treatment?**

Except if your doctor tells you otherwise, you may drive during your abatacept treatment. Abatacept has no adverse effects on concentration or the ability to drive motor vehicles.

**Can I drink alcohol?**

Yes, you can drink alcoholic beverages, provided you follow the usual advice about moderation.

**Can I expose myself to sunlight?**

Exposure to sunlight is not contraindicated. You simply need to follow the skin protection rules that apply to everyone. An annual visit to a dermatologist is recommended.

**We hope this information has been helpful.  
If you have questions, feel free to discuss them with your doctor.**

## PATIENT SHEET

Name of your rheumatologist: .....

Telephone: .....

• **Date of the 1<sup>st</sup> abatacept infusion (D):** .....

Dose: .....

How did your infusion go? .....

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What did you notice during the first 48 hours after the first infusion?

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What did you notice during the first 2 weeks after the first infusion?

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• **Date of the 2<sup>nd</sup> abatacept infusion (D+14):** .....

Dose: .....

How did your infusion go? .....

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What did you notice during the first 2 weeks after the second infusion?

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• **Date of the 3<sup>rd</sup> abatacept infusion (D+30):** .....

Dose: .....

How did your infusion go? .....

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What did you notice during the month following the third infusion

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• **Date of the 4<sup>th</sup> abatacept infusion (D+60):** .....

Dose: .....

How did your infusion go? .....

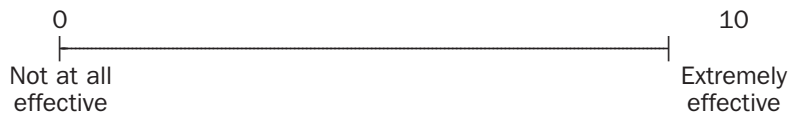
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What did you notice during the month following the fourth infusion?

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What is your assessment of the effectiveness of abatacept?

● 16 weeks after the first infusion



● 24 weeks after the first infusion

