

# Pregnancy, DMARDs and Biologic Therapies

Information for rheumatology patients who are pregnant or planning a pregnancy



## Rheumatology, NHS Lothian



### Websites

<https://services.nhslothian.scot/Rheumatology>

[www.edrheum.org](http://www.edrheum.org)

### Advice Line

Telephone: 0131 537 1405

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## The aim of this leaflet

This leaflet has been written for patients who are currently pregnant or planning to become pregnant, or who have had a recent delivery, who are prescribed disease modifying anti-rheumatic drugs (DMARDs) or biologic drugs and men whose partners are planning to conceive. The information provided is based on data from pregnancy registries, small studies, and current expert advice and opinion. Therefore, the advice given may differ from the guidance in the information leaflet contained within the medicine packaging.

This booklet is to guide you however, it is very important that you discuss your pregnancy plans with your medical team to achieve a shared decision about your arthritis, pregnancy, and treatment.

## Introduction

The management of your arthritis is very important before, during and after pregnancy. Your arthritis should be under control so you are feeling well and healthy. Research shows if mother is well, she is likely also to have a well baby, i.e. "well mother, well baby".

Many DMARDs or biologic drugs can be continued throughout pregnancy but certain drugs should be stopped as they can be harmful to baby or there is limited data about their safety.

You may find that the information in this booklet differs from other sources. The recommendations written here are based on evidence and clinical experience. In this booklet, we have included links to helpful resources which we hope you will find helpful.

## What should I do if I'm planning a pregnancy?

It is important to discuss your pregnancy plans with your rheumatologist and other healthcare team early. Research suggests that only 1 in 5 patients ask for guidance from their rheumatologist before becoming pregnant. To develop a personalised treatment plan, you are advised to discuss with your specialist as soon as you are planning pregnancy.

Achieving the best health possible before your pregnancy is important to reduce the chance of pregnancy-related health problems such as preeclampsia (when you develop high blood pressure with protein in your urine during and after pregnancy), an early delivery, baby having a lower birth weight, or miscarriage.

Some medicines are compatible with pregnancy although not all. Your healthcare team are here to guide you so talk to them about any questions or concerns you may have. You may find it helpful to wait until your symptoms are controlled before deciding to get pregnant. Having a healthier lifestyle can also make it easier to fall pregnant.

Delaying plans for pregnancy may make it more difficult to conceive as older women can take longer to become pregnant.

## What if I have a fertility problem?

If you have an ongoing fertility concern, it is best to discuss this with your healthcare professional team.

## Is breastfeeding safe?

There are numerous benefits to breastfeeding. The World Health Organization (WHO) recommends breastfeeding exclusively for the first 6 months with continued intermittent breastfeeding for up to 2 years and beyond. As women with Rheumatic and Musculoskeletal Diseases (RMD) may experience disease flare post partum (after birth) and may need treatment, it is therefore important to balance the benefits of disease control with the risk of infant exposure to medicines through breast milk.

There are several rheumatic drugs that are safe to use during breastfeeding but some are not recommended either due to a lack of research or because they might harm the baby.

For information on individual medicines please see medicine lists below.

## **Which vaccinations should I have?**

- Covid-19 vaccination is safe and recommended.
- Pneumonia and yearly flu vaccines are safe and recommended.
- Live vaccines should be avoided during pregnancy.

## **What are the benefits of disease modifying anti-rheumatic drugs (DMARDs)?**

These are groups of medicines that are used to help relieve the symptoms of arthritis and reduce the damaging effect of the disease on the joints. DMARDs are also used for Connective Tissue Disease. They work by blocking the way inflammation develops in the joints.

Research shows that DMARDs are more beneficial when used at an early stage of your disease, and when two or more DMARDs are used together.

## **Will taking DMARDs affect my unborn baby? Which DMARDs are harmful to my unborn baby?**

There are DMARDs that can be taken throughout pregnancy and some need to be discontinued because of harmful effects to the unborn baby.

For information on individual medicines please see under DMARDs lists.

## **What are the benefits and risks of Non-Steroidal Anti-inflammatory Drugs (NSAIDs)?**

NSAIDs are given to relieve pain and inflammation. If you are at risk of developing stomach problems (such as ulcers or bleeding) you may be prescribed another drug, such as a proton-pump inhibitor (PPI) to help protect your stomach. Examples of PPI are esomeprazole, lansoprazole, omeprazole, and pantoprazole. NSAID gels or creams are also available which can be applied directly to the affected area for localised pain and may help avoid some side effects.

You should speak to your doctor if you need regular pain relief. NSAIDs should not be used long-term without an occasional break, except on medical advice. The most common NSAIDs that are used in Rheumatology are:

- Ibuprofen
- Naproxen
- Diclofenac

There are newer types of NSAIDs also known as COX-2 inhibitors:

- Celecoxib
- Etoricoxib

## **Will NSAIDs affect fertility, pregnancy or breastfeeding?**

NSAIDs (particularly the COX-2 inhibitors mentioned above) can stop you from ovulating (releasing egg from your ovary) if used regularly around the time of ovulation; this affects up to one third of women using regular NSAIDs. They should therefore be avoided to improve your chances of conceiving. There may be a small increased risk of miscarriage if NSAIDs are taken around time of conception. Ibuprofen is the second-line recommended pain killer (after paracetamol) in pregnancy and could be used intermittently throughout first and second trimesters if needed. Regular use of NSAIDs should be avoided in the third trimester (after 28-30 weeks) because this can affect the blood vessels in the baby's heart.

COX-2 inhibitors are not recommended when trying to conceive or during pregnancy due to limited data (meaning not enough research) in the use of these drugs during pregnancy.

## **DMARDs Lists**

### **Steroids (Prednisolone and Methylprednisolone)**

Steroids are often used to treat disease flares. You should carry a steroid warning card if you are taking high doses of steroids or on them for more than 3 weeks because it can be unsafe to stop treatment with steroids abruptly. The British Society for Rheumatology guidelines state that steroids may be continued during pregnancy and breastfeeding. Steroids should only be taken at the lowest dose possible for as short a time as possible because there is a link to low birth weight and premature birth (baby being delivered earlier than the due date) with bigger doses.

Men who are trying to conceive with their partner can continue to take steroid medication.

### **Azathioprine**

Azathioprine can be continued (at less than 2mg/kg per day) in pregnancy and throughout breastfeeding. Men who are trying to conceive with their partner can continue to take azathioprine.

### **Ciclosporin**

Ciclosporin may be continued throughout pregnancy at its lowest dose.

It can also be used throughout breastfeeding and men who are trying to conceive with their partner can continue to take ciclosporin.

### **Cyclophosphamide**

Cyclophosphamide is not recommended during pregnancy and breast feeding.

Women and men should continue using contraceptives for at least 3 months after stopping cyclophosphamide.

### **Hydroxychloroquine**

Hydroxychloroquine can be continued during pregnancy and breastfeeding.

Men who are trying to conceive with their partner can continue to take hydroxychloroquine.

### **Intravenous Immunoglobulin (IVIG)**

IVIG may be continued during pregnancy and breastfeeding.

Men who are trying to conceive with their partner can continue to take IVIG.

### **Leflunomide**

Leflunomide is not recommended during pregnancy and breastfeeding.

You should stop Leflunomide and have a Cholestyramine washout six weeks to three months before conception. Also, you should discuss with your doctor as you will need to have a blood test on two separate occasions to ensure that there is no trace of Leflunomide in your body.

Men who are trying to conceive with their partner can continue to take Leflunomide.

### **Methotrexate**

Methotrexate is not recommended during pregnancy and breastfeeding.

Methotrexate should be stopped 1 month before conception.

Men who are trying to conceive with their partner can continue to take Methotrexate.

### **Mycophenolate (MMF)**

Mycophenolate is not recommended during pregnancy and breastfeeding as it is known to increase the risk of birth defects.

It should be stopped 6 weeks before a planned conception. It is not recommended in pregnancy.

Men who are trying to conceive with their partner can continue to take Mycophenolate.

### **Sulfasalazine**

Sulfasalazine can be continued during pregnancy, but patients should supplement with an increased dose of folic acid (5mg daily). Note this is a higher dose than recommended for the general population in pregnancy, which is just 400 micrograms daily. Sulfasalazine may also be continued during breastfeeding but can occasionally cause upset stomach in the infant, so should be avoided if baby is ill, stressed or premature.

Sulfasalazine can also reduce male fertility (meaning less ability to father a child), this is reversible. Men who are trying to conceive with their partner can continue to take sulfasalazine, but if conception is delayed by more than 1 year then it is recommended to stop sulfasalazine.

### **Tacrolimus**

Tacrolimus may be continued throughout pregnancy if the potential benefit outweighs the risks to the baby. If you are on Tacrolimus and considering pregnancy speak to your consultant about whether it should be continued or not. You should continue to have regular blood tests and get your blood pressure monitored regularly whilst on tacrolimus and pregnant. Tacrolimus may be continued during breastfeeding. Men who are trying to conceive with their partner can continue to take tacrolimus.

## **What are the benefits of Biologic Medicines?**

Biologics are synthetic proteins which inhibit the activity of inflammatory molecules in the joints.

During the later stages of pregnancy, antibodies from the mother are transported across the placenta to help give the baby some protection. This often means that biologic medicines which are antibodies are also transported across the placenta into the baby during the later stage of pregnancy.

Biologic medicines might be present in the breast milk of mothers. It is thought that many biologics can be continued during breast-feeding, although there isn't much data on their safety.

## **Will taking biologic medicines affect my unborn baby? Which biologic medicines are harmful to my unborn baby?**

There are biologic medicines that are safe to use during pregnancy and a few need to be discontinued because of their harmful effects to the unborn baby or not enough studies done with the particular medicine.

For information on individual medicines please see biologic lists below.

## **Biologic Lists**

### **Anti-Tumour Necrosis Factor (Anti-TNF)**

The current guidelines suggest that if your disease is very active in the 3<sup>rd</sup> trimester (the last three months of a pregnancy), it is possible to continue anti-TNF treatment up to 30 or 34 weeks of pregnancy and this should be discussed with your doctor. Specific anti-TNF are discussed below.

If anti-TNF medicines are continued throughout all pregnancy, your baby should not have a live vaccine until they are six months old as very small amounts of the drug may pass into your baby's body and could lower their immune system slightly.

Babies born to mothers who were taking certolizumab throughout pregnancy do not need to avoid live vaccines and can maintain the usual vaccination schedule.

Anti-TNF medicines may be continued during breastfeeding- as mentioned above small amounts of the drug may be present in breast milk and continuing biologic is likely to be safe. But if you are thinking of breastfeeding when on a biologic, you should discuss with your consultant. Men who are trying to conceive with their partner can continue to take anti-TNF treatments.

#### **Adalimumab (Amgevita, Imraldi and Humira)**

Women can take Adalimumab during the 1<sup>st</sup> trimester (first three months of a pregnancy) and 2<sup>nd</sup> trimester (2<sup>nd</sup> three months of a pregnancy) but may want to avoid or reduce their dose during the last trimester (last three months of a pregnancy). However, if your disease is active, you may be able to continue adalimumab until 30 to 34 weeks after discussion with your Rheumatologist.

Men who are trying to conceive with their partner can continue to take anti-TNF treatments.

#### **Etanercept (Benepali, Erelzi and Enbrel)**

The current guidelines state that you can carry on taking etanercept during the first six months of pregnancy. The amount of etanercept that cross the placenta in the third trimester is very small. If your disease is active, you may be able to continue etanercept until 30 to 34 weeks.

Men who are trying to conceive with their partner can continue to take anti-TNF treatments.

#### **Certolizumab Pegol (Cimzia)**

Certolizumab Pegol (Cimzia) does not cross the placenta and therefore can be prescribed throughout the pregnancy if clinically needed. However, it should be stopped two weeks before delivery to reduce the risk of infection in the mother during the delivery period.

Men who are trying to conceive with their partner can continue to take anti-TNF treatments.

#### **Golimumab**

Women can take golimumab during the 1<sup>st</sup> and 2<sup>nd</sup> trimester (first six months of a pregnancy) but may want to avoid or reduce their dose during the last trimester. However, if your disease is active, you may be able to continue golimumab until 30 to 34 weeks after discussion with your Rheumatologist.

Men who are trying to conceive with their partner can continue to take anti-TNF treatments.

#### **Infliximab**

Women can take infliximab during the 1<sup>st</sup> and 2<sup>nd</sup> trimester (first six months of a pregnancy) but may want to avoid or reduce their dose during the last trimester. However, if your disease is active, you may be able to continue infliximab until 30 to 34 weeks after discussion with your Rheumatologist.

Men who are trying to conceive with their partner can continue to take anti TNF treatments.

### **Rituximab**

This drug is not usually recommended in pregnancy. When use in pregnancy is being considered, the discussion differs for each patient and the possibility of risks and benefits to the mother and baby are estimated based on limited available data. If you are planning pregnancy you need to discuss this drug with your Rheumatologist.

Rituximab may be continued during breastfeeding; as mentioned above if small amounts of the drug are found in breast-milk, they are likely to be broken down in the baby's stomach anyway.

Men who are trying to conceive with their partner can continue to take Rituximab.

### **Belimumab**

Belimumab is a relatively new medicine with less overall experience of its use. Depending on risk and benefit, Belimumab may be used until week 34 of a pregnancy for Systemic Lupus Erythematosus (SLE). If you are planning pregnancy, you need to discuss this drug with your Rheumatologist.

Belimumab may be continued during breastfeeding; as mentioned above if small amounts of the drug are found in breast-milk, they are likely to be broken down in the baby's stomach anyway.

Men who are trying to conceive with their partner can continue to take Belimumab, but there is less data available on this.

### **Anakinra**

Anakinra is a less common treatment option and data is limited but reassuring. It may be stopped or continued in pregnancy depending on your individual circumstances. If you are planning pregnancy, you need to discuss this drug with your Rheumatologist.

Anakinra may be continued during breastfeeding; as mentioned above if small amounts of the drug are found in breast milk, they are likely to be broken down in the baby's stomach anyway.

Men who are trying to conceive with their partner can continue to take Anakinra, but there is less data available on this.

### **Tocilizumab**

Data about using Tocilizumab during pregnancy is limited because it is a slightly newer treatment option. It may be stopped or continued in pregnancy depending on your individual circumstances. When use in pregnancy is being considered, the discussion differs for each patient and the possibility of risks and benefits to the mother and baby are estimated based on limited available data.

If you are planning pregnancy, you need to discuss this drug with your Rheumatologist.

Tocilizumab may be continued during breastfeeding; as mentioned above if small amounts of the drug are found in breast milk, they are likely to be broken down in the baby's stomach anyway.

Men who are trying to conceive with their partner can continue to take Tocilizumab, but there is less data available on this.

### **Sarilumab**

As for Tocilizumab, data about using Sarilumab during pregnancy is limited because it is a slightly newer treatment option. It may be stopped or continued in pregnancy and while breastfeeding depending on your individual circumstances. When use in pregnancy is being considered, the discussion differs for each patient and the possibility of risks and benefits to the mother and baby are estimated based on limited available data.

If you are planning pregnancy, you need to discuss this drug with your Rheumatologist.

Sarilumab may be continued during breastfeeding; as mentioned above if small amounts of the drug are found in breast milk, they will be broken down in the baby's stomach anyway.

Men who are trying to conceive with their partner can continue to take sarilumab, but there is less data available on this.

### **Secukinumab and Ixekizumab**

These are newer biologic medicines and data about their use in pregnancy is limited. Secukinumab and ixekizumab may be stopped or continued in pregnancy depending on your individual circumstances. When use in pregnancy is being considered, the discussion differs for each patient and the possibility of risks and benefits to the mother and baby are estimated based on limited available data. If you are planning pregnancy, you need to discuss this drug with your Rheumatologist.

Secukinumab and ixekizumab may be continued during breastfeeding; as mentioned above if small amounts of the drug are found in breast milk, they are likely to be broken down in the baby's stomach anyway.

Men who are trying to conceive with their partner can continue to take either secukinumab or ixekizumab but there is less data available on this.

### **Ustekinumab and Guselkumab**

Ustekinumab and guselkumab may be stopped or continued in pregnancy depending on your individual circumstances. When use in pregnancy is being considered, the discussion differs for each patient and the possibility of risks and benefits to the mother and baby are estimated based on limited available data. If you are planning pregnancy, you need to discuss this drug with your Rheumatologist.

These medicines may be continued during breastfeeding; as mentioned above if small amounts of the drug are found in breast milk, they are likely to be broken down in the baby's stomach anyway.

Men who are trying to conceive with their partner can continue to take either ustekinumab or guselkumab but there is less data available on this.

### **Abatacept**

As with the medicines above, abatacept may be stopped or continued in pregnancy depending on your individual circumstances. When use in pregnancy is being considered, the discussion differs for each patient and the possibility of risks and benefits to the mother and baby are estimated based on limited available data. If you are planning pregnancy, you need to discuss this drug with your Rheumatologist.

Abatacept may be continued during breastfeeding; as mentioned above if small amounts of the drug are found in breast milk, they are likely to be broken down in the baby's stomach anyway.

Men who are trying to conceive with their partner can continue to take abatacept but there is less data available on this.

## **Janus kinase inhibitor (JAKi)**

JAK inhibitors are a group of relatively new DMARDs that come in a tablet form and are short acting. Examples of JAK inhibitors are baricitinib, filgotinib, tofacitinib and upadacitinib. These medicines will cross the placenta from the beginning of pregnancy and so they must not be used in people planning to conceive. It is recommended that JAKi medications are stopped at least 2 weeks before trying to conceive.

Taking JAK inhibitors is not recommended during pregnancy or breastfeeding until further information is available.

Men who are trying to conceive with their partner can continue to take JAK inhibitors but should be aware that there is less data available on this at the moment.

### **Apremilast (Phosphodiesterase 4 inhibitor)**

It is not recommended in pregnancy and breast feeding.

There is no data on paternal exposure, likely harmful.

If you are planning pregnancy, you need to discuss this drug with your Rheumatologist.

### **Useful resource**

There is a resource online which shows which drugs can be taken during each stage of pregnancy and breastfeeding. This was published as part of an article by the British Society for Rheumatology.

You can view the table by using the below web address or by scanning the QR code with the camera on your smartphone.

<https://academic.oup.com/view-large/378431611>



You can use this link to read the full article:

British Society for Rheumatology guideline on prescribing drugs in pregnancy and breastfeeding: immunomodulatory anti-rheumatic drugs and corticosteroids

<https://academic.oup.com/rheumatology/advance-article/doi/10.1093/rheumatology/keac558/6783014?login=true>



### **Research**

The British Society for Rheumatology Biologics Register - Rheumatoid Arthritis (BSRBR-RA) has been monitoring the long-term safety of biologics that are prescribed to people who have rheumatoid arthritis in the UK. This includes drugs that are taken before and during pregnancy. To date, there are more than 20,000 patients on the register, for which the 15-year update has identified many studies that were published using the data, which also includes those who were exposed to anti-TNF drugs in pregnancy. The aim of the BSRBR-RA is to better inform conclusions on the long-term safety of the biologics, by continuing to collect data until 2028, to create a rich database.

This PIL has used information from BSRBR-RA to help supplement the guidance.

### **Notes**

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## Useful links

Versus Arthritis: [www.versusarthritis.org/media/22936/pregnancy-and-arthritis-information-booklet.pdf](http://www.versusarthritis.org/media/22936/pregnancy-and-arthritis-information-booklet.pdf)

National Rheumatoid Arthritis Society: <https://nras.org.uk/>

Arthur's Place: <https://arthursplace.co.uk/life/about-us/2016/06/16/services/>

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