Pre-conceived chats

The CIMZIA® family planning guide

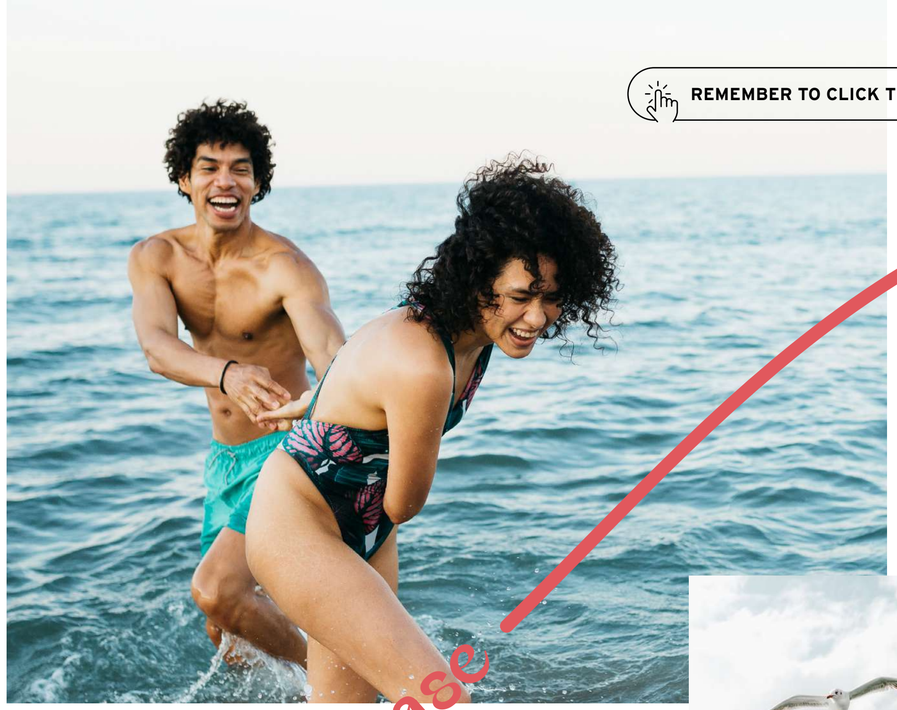
START HERE →

Please refer to the final page of this material for the full approved indications and posology of CIMZIA®.
Adverse event reporting information can be found on the final page of this material. A link to the CIMZIA® prescribing information can be found here.

IE-CZ-2300033 Date of preparation: March 2024

cimzia®
(certolizumab pegol)

Treatment planning for women with rheumatic disease



Disease control is the priority when it comes to your patients.

That's why, from diagnosis onwards, it's important to have a good understanding of their long-term plans around family planning, no matter what they may look like. After all, with life being full of twists and turns, you never know when your patient's life journey might include a bump or two.

A fully informed treatment plan can support your patients in achieving the best disease control possible. However, it can be difficult initiating these conversations, and even harder to ensure all the relevant information is discussed at the right time.

So, let's talk about it.

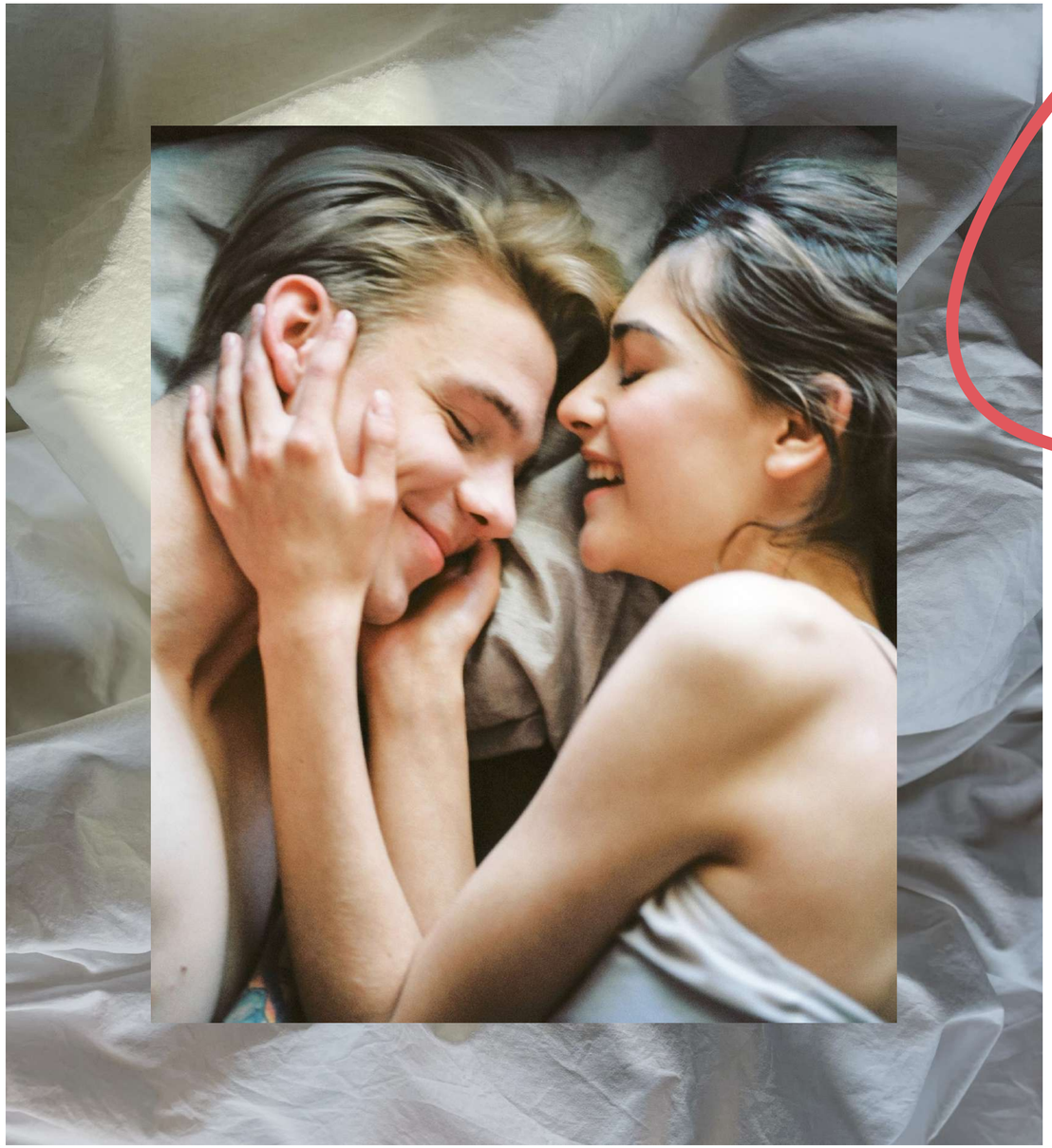
KEY QUESTIONS TO THINK ABOUT

Question 01
What do their own aspirations around pregnancy look like?

Question 02
Are they fully informed of the risks of rheumatic disease flares and their potential implications for fertility and pregnancy outcomes?

Question 03
What might their future plans mean for treatment switching, and vice versa?

Question 04
If they're not planning pregnancy what does their contraceptive plan look like? How effective is it for supporting their decision?



Your patient might not be thinking about starting a family. Or she might be thinking about it all the time. Whatever stage of life she's at, everyone will have different future plans. So, to find the right treatment for her, you'll need to start a conversation around family planning.

This guide will help you focus on your patient and her current journey living with a rheumatic disease.

It has been put in place to help you build a relationship with your patient, empowering you to better understand her goals and future aspirations. By talking through everything in this guide, you can help your patient make the best decisions for herself today – and tomorrow.

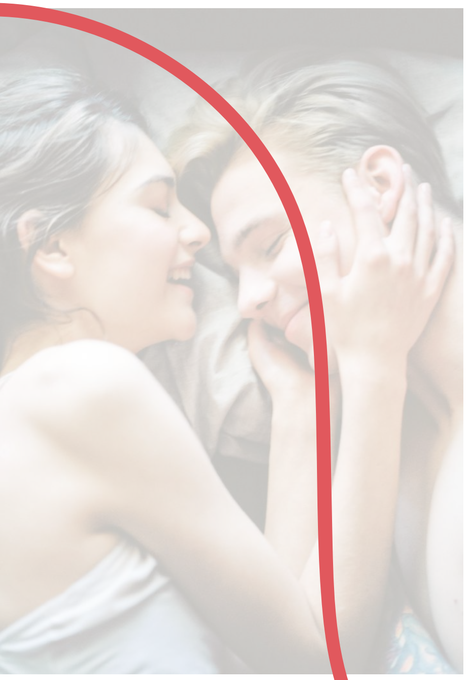
Whether it's a case of now, next year or never-ever, it's important to know where your patients are on the family planning pathway. With this in mind, you can tailor your questions around their current and future plans:

- Is pregnancy completely off the radar for them right now?
- What are their longer-term goals around having a family?
- Is it something they see as a future or near-future goal?
- Are they actively trying or currently pregnant?

The benefits of shared decision making for patients:

- Greater satisfaction with treatment decisions[NHS]
- More likely to adhere to evidence-based treatment[NHS]
- Fewer regrets about the treatment decisions[NHS]

Divided into four sections, this tool will act as a roadmap for you to help your patients wherever they are on their life journey. Each section will function as a stop on their journey, from not planning for pregnancy, thinking about it, or trying and during.



Not planning pregnancy
For when your patients don't have families on their radar.

EXPLORE →

During
For when your patients are currently pregnant or recently post-partum.

EXPLORE →

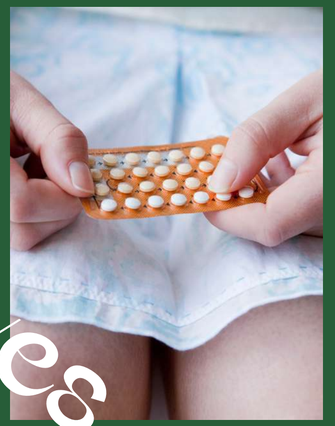
Planning in the near future
For when your patients have a desire to start a family in the coming years.

EXPLORE →

Actively trying
For when your patients have their sights set on starting a family.

EXPLORE →

Coils, condoms and other contraceptives



SECTION 01

NOT PLANNING PREGNANCY

If your patient has no desires for pregnancy right now, it's still essential to establish the following:

QUESTION 01	Is her disease controlled?
QUESTION 02	Is she using contraceptive methods? And if so, which?
QUESTION 03	Is there any potential for her to want to conceive in the future?
QUESTION 04	Is she open to ongoing conversations on whether her goals around pregnancy have changed, and how her treatment plan could change to accommodate?

CONTROL, CONSTRAINTS AND CHECK-UPS

Is her disease controlled?

"Yes, I am experiencing improvement in symptoms with my current treatment plan."

When it comes to treating your patient, her disease control is your utmost priority. Therefore, it is important to revisit this conversation with your patient regularly.

Some treatments may be considered less suitable for pregnancy, therefore it's critical to know in plenty of time if she is thinking about pregnancy, so that any changes can happen proactively.[BSR]

Switching treatment can increase the risk of disease flares, possibly affecting fertility, and should therefore happen prior to conception.[STE,PRO]

CONTENT BANK

RISK OF DISEASE FLARES | INFERTILITY

"No, my condition is flaring/not controlled with my current treatment plan."

When it comes to treating your patient, her disease control is your utmost priority. Therefore, it is important to explain the implications if her treatment isn't controlled.

Uncontrolled disease could have implications for fertility, as well as adverse pregnancy outcomes, if her plans for family were to change.[PRO,MAG,MEI]

Consider re-evaluating her treatment plan, to ensure her adequate disease control.[BSR]

CONTENT BANK

INFERTILITY | ADVERSE PREGNANCY OUTCOMES

COILS, CONDOMS AND OTHER CONTRACEPTION

Is she using contraceptive methods? And if so, which?

"I am not currently using any type of contraception."

Your patients might not have babies on their mind but without contraception, the risk of falling pregnant is higher.

Some treatments may be considered less suitable than others for pregnant females. Therefore, it's important to convey the potential implications of her current treatment plan on pregnancy.[BSR]

If pregnancy is not a goal for her right now, advise her on the benefits of more long-term contraception in mitigating the risk of pregnancy.[NIC]

"I am currently using [X contraceptive method]."

Wherever your patient may be on her life journey, it's important to explain that there's still a possibility of conception with contraception.

Different contraceptive methods have varying degrees of effectiveness.[NIC]

If pregnancy is not a goal for her right now, advise her on the benefits of more long-term contraception in mitigating the risk of pregnancy.[NIC]

Some treatments may be considered less suitable than others for pregnant females. It's therefore important to convey to her:

- The potential implications of her current treatment plan on pregnancy[BSR]
- What her ideal treatment plan could look like if an unplanned pregnancy were to occur

CONTENT BANK

CONTRACEPTIVE METHOD EFFECTIVENESS

FROM CONTRACEPTION TO CONCEPTION

Is there any potential for her to want to conceive in the future?

"No, I have absolutely no plans for pregnancy in the future."

If her disease is well controlled, then there's no need to change her current plan. However, conversations around contraception are important if she currently has no plans for a family.

"Yes/unsure/don't want to rule it out."

When it comes to treating your patient, her disease control is your utmost priority. Therefore, it is important to revisit this conversation with your patient regularly.

If her disease is adequately controlled, then let her know there is currently no need to change her treatment plan.[BSR]

If biologics are to be initiated, convey the implications:

- Delays to the infant's vaccination schedule[BSR]
- Some risk of adverse pregnancy outcomes[BSR]
- Placental transfer in 3rd trimester[BSR]

Treatment switching can increase the risk of disease flares and possibly infertility, so it's vital that the implications of treatment are considered at the point of initiation.[STE,PRO]

That's why it's also important to revisit the conversation if her plans around having a family change – so any changes to her treatment can happen proactively prior to conception, to help mitigate risk.

CONTENT BANK

DELAY TO INFANT VACCINATION | RISK OF ADVERSE PREGNANCY OUTCOMES | SWITCHING TREATMENT AND DISEASE FLARES | INFERTILITY | Fc- AND NON-Fc CONTAINING BIOLOGICS

A GOOD CONVERSATION NEVER STOPS

"I am happy to have semi-regular check-ins to discuss my situation and treatment plan."

Your patient's future plans and goals may change over time, or she may even get an unexpected surprise along the way. Therefore, it is imperative to have frequent conversations around family planning.

- Ensure her disease is adequately controlled, and that her treatment plan is best tailored to achieve this.
- Establish if her plans around pregnancy have changed, and offer her the chance to adjust her treatment plan in plenty of time, to mitigate any potential risks.

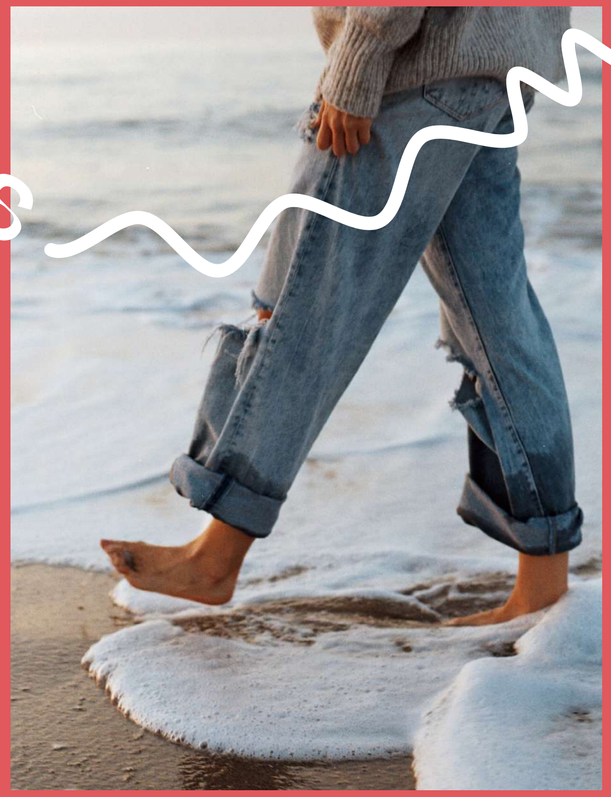
"I would rather not have regular check-ins due to the inconvenience."

It's important to frequently discuss family planning to ensure her disease is adequately controlled, and that her treatment plan is best tailored to achieve this.

- Establish if her plans around pregnancy have changed, and offer her the chance to adjust her treatment plan in plenty of time, to mitigate any potential risks.
- Try to explore the patient's reasons for hesitancy, and whether anything can be done to help accommodate.

Is she open to ongoing conversations on whether her goals around pregnancy have changed, and how her treatment plan could change to accommodate?

Hopes, dreams and future plans



SECTION 02

PLANNING IN THE NEAR FUTURE

If your patient has family plans on their radar in the next couple of years, you can be proactive in ensuring her treatment plan supports her future goals.

QUESTION 01	Is she experiencing disease control?
QUESTION 02	How does she feel about receiving her treatment on the lead up to, or during pregnancy?
QUESTION 03	Is she concerned about the potential side effects of her treatment on pregnancy and her infant?

HER ASPIRATIONS FOR THE FUTURE

Is she experiencing disease control?

"Yes, I am experiencing improvement in symptoms with my current treatment plan."

Let your patient know that her disease control is your priority, and discuss the implications of her current treatment plan on pregnancy and treatment switching.

Discuss the implications of using Fc-containing biologics during pregnancy:

- Placental transfer[BSR]
- Increased risk of infections in the infant 1–2 years after birth[BSR]
- Delays to the infant vaccination schedule[BSR]

Discuss the potential benefits of CIMZIA®:

- According to the CRIB study, there is minimal to no placental transfer[BSR,CIM,CRI]
- No evidence for adverse pregnancy outcomes or congenital malformations[BSR,CIM]

Switching treatments can induce disease flares, so any changes to her treatment plan should happen prior to conception to mitigate risk of adverse pregnancy outcomes and infertility.[MAG,MEI,PRO,STE]

"No, my condition is flaring/ not controlled with my current treatment plan."

Let your patient know that her disease control is your priority.

Explain the importance of establishing disease control, and the impact of disease control on fertility and pregnancy outcomes. [MAG,MEI,PRO,DAN,STE]

Consider re-evaluating her treatment plan, to ensure adequate disease control and support plans for conception.

Discuss the potential benefits of CIMZIA®:

- According to the CRIB study, there is minimal to no placental transfer[BSR,CIM,CRI]
- No evidence for adverse pregnancy outcomes or congenital malformations[BSR,CIM]

CONTENT BANK

PLACENTAL TRANSFER | RISK OF INFANT INFECTION AFTER BIRTH | DELAY TO INFANT VACCINATION SCHEDULE | RISK OF ADVERSE PREGNANCY OUTCOMES | SWITCHING TREATMENT AND DISEASE FLARES | INFERTILITY | Fc- AND NON-Fc CONTAINING BIOLOGICS

TALKING THROUGH TREATMENT IN THE RUN-UP TO PREGNANCY

How does she feel about receiving treatment in the lead up to, or during her pregnancy?

"I want my pregnancy to be entirely natural and don't wish to receive treatment in the lead up to, or during pregnancy."

Your patient may be feeling hesitant to take treatment in the lead up to her pregnancy.

Understand her reasons but explain the implications of uncontrolled rheumatic disease:

- → Reduced fertility[PRO]
- → Increased risk of adverse pregnancy outcomes such as pre-eclampsia, low birth weight and pre-term birth[MAG,MEI]

"I'd be ok receiving treatment during pregnancy – but I need more information."

There's a number of treatment options but some may be preferable to use during pregnancy.

Discuss the implications of using Fc-containing biologics during pregnancy:

- → Placental transfer[BSR]
- → Increased risk of infections in the infant 1–2 years after birth[BSR]
- → Delays to the infant vaccination schedule

Discuss the potential benefits of CIMZIA®:

- → According to the CRIB study, there is minimal to no placental transfer[CRI]
- → No evidence for adverse pregnancy outcomes or any congenital malformations[BSR,CIM]

Switching treatments can induce disease flares, so any changes to her treatment plan should happen prior to conception to mitigate risk of adverse pregnancy outcomes and infertility.[MAG,MEI,PRO,STE,BSR]

CONTENT BANK

INFERTILITY | ADVERSE PREGNANCY OUTCOMES | PLACENTAL TRANSFER | RISK OF INFANT INFECTION AFTER BIRTH | DELAY TO INFANT VACCINATION SCHEDULE | RISK OF ADVERSE PREGNANCY OUTCOMES | SWITCHING TREATMENT AND DISEASE FLARES

Is she concerned about the potential side effects of her treatment on pregnancy and her infant?

FOR YOUR PATIENT'S PEACE OF MIND

"I am worried about the side effects that different treatments could have on my baby."

When she starts thinking about bringing a little bundle of joy into the world, she may have concerns regarding her treatment and its effect on her new-born.

Fc-containing biologics:

- Presence of an Fc-region facilitates active placental transfer[BSR]
- Based on data from >12,000 pregnancies, TNF-inhibitors are considered compatible for use during pregnancy[BSR]
- However, some studies have found an increased risk of infections in the infant 1-2 years after birth[BSR]

CIMZIA®:

- According to the CRIB study, CIMZIA® is unable to cross the placenta as it lacks an Fc-region, and therefore has minimal to no transfer to the foetus[CIM,BSR,CRI]
- In >1,300 pregnancies, no evidence for adverse pregnancy outcomes or congenital malformations was found with CIMZIA®[CIM]

CONTENT BANK

- FC-REGION PLACENTAL TRANSFER
- TNF-INHIBITORS AND PREGNANCY
- RISK OF INFANT INFECTION AFTER BIRTH
- CIMZIA® UNABLE TO CROSS THE PLACENTA
- RISK OF ADVERSE PREGNANCY OUTCOMES
- Fc- AND NON-Fc CONTAINING BIOLOGICS

Conceiving on her current treatment

SECTION 03

ACTIVELY TRYING

If your patient's told you she's trying for a baby at the moment, it's really important to discuss how her current treatment can safely support both disease control and her pregnancy. It's crucial to work out:

QUESTION 01	Is she experiencing disease control?
QUESTION 02	Is she concerned about the potential side effects of her treatment on pregnancy and her infant?
QUESTION 03	Has she considered how treatment received during pregnancy might affect her infant's vaccination schedule?

CONTROL, CONSTRAINTS AND CHECK-UPS

Is she experiencing disease control?

"Yes, I am experiencing improvement in symptoms with my current treatment plan."

When it comes to treating your patient, her disease control is your priority. Therefore, it's important to consider what treatment plan is best for her.

The potential implications of using Fc-containing biologics during pregnancy:

- Placental transfer[BSR]
- Increased risk of infections in the infant 1–2 years after birth[BSR]
- Delays to the infant vaccination schedule[BSR]

Discuss the potential benefits of CIMZIA®:

- According to the CRIB study there is minimal to no placental transfer[BSR,CIM,CRI]
- No evidence for adverse pregnancy outcomes or congenital malformations[BSR,CIM]

Switching treatments can induce disease flares, so any changes to her treatment plan should happen prior to conception to mitigate risk of adverse pregnancy outcomes and infertility.[MAG,MEI,PRO,STE,BSR]

"No, my condition is flaring/ not controlled with my current treatment plan."

When it comes to treating your patient, her disease control is your utmost priority. Therefore, it's important to explain the implications if her treatment isn't controlled.

Explain that uncontrolled disease could increase her risk of long-term, irreversible health complications, as well as the risk of both infertility, and adverse pregnancy outcomes.[MAG,MEI,PRO,DAN]

Discuss re-evaluating her treatment plan, in order to ensure adequate disease control.

Convey the potential benefits of CIMZIA®:

- According to the CRIB study, there is minimal to no placental transfer[BSR,CIM,CRI]
- No evidence for adverse pregnancy outcomes or congenital malformations[BSR,CIM]

CONTENT BANK

PLACENTAL TRANSFER | RISK OF INFANT INFECTION AFTER BIRTH | DELAY TO INFANT VACCINATION SCHEDULE | RISK OF ADVERSE PREGNANCY OUTCOMES | SWITCHING TREATMENT AND DISEASE FLARES | INFERTILITY | Fc- AND NON-Fc CONTAINING BIOLOGICS

When she starts thinking about bringing a little bundle of joy into the world, she may have concerns regarding her treatment and its effect on her new-born.

Based on data from >12,000 pregnancies, TNF-inhibitors are considered compatible for use during pregnancy, however:[BSR]

→ WSome studies have found increased risk of infections in the infant 1–2 years after birth[BSR]

According to the CRIB study, CIMZIA® is unable to cross the placenta and therefore has minimal to no transfer to the foetus.[BSR,CIM,CRI]

In >1,300 pregnancies, no evidence for adverse pregnancy outcomes or congenital malformations was found with CIMZIA®.[CIM]

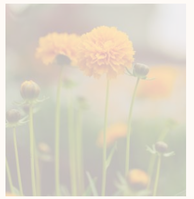
Treatment switching can induce disease flares, which increases the risk of adverse pregnancy outcomes and infertility. Treatment switching should therefore only be considered where risk of disease flaring is low.[MAG,STE,MEI,PRO,BSR]

CONTENT BANK

- TNF-INHIBITORS AND PREGNANCY
- INFERTILITY
- RISK OF INFANT INFECTION AFTER BIRTH
- CIMZIA® UNABLE TO CROSS THE PLACENTA
- RISK OF ADVERSE PREGNANCY OUTCOMES
- SWITCHING TREATMENT AND DISEASE FLARES
- ADVERSE PREGNANCY OUTCOMES
- Fc- AND NON-Fc CONTAINING BIOLOGICS

ANSWERING HER CONCERNS ABOUT TREATMENT DURING PREGNANCY

Is she concerned about the potential side effects of her treatment on pregnancy and her infant?



"I am worried about the side effects that different treatments could have on my baby."

EXPLAINING TREATMENT'S IMPLICATIONS FOR HER LITTLE ONE'S VACCINATIONS

Has she considered how treatment received during pregnancy might affect her infant's vaccination schedule?

*CIMZIA® SPC states: It is recommended to wait a minimum of 5 months following the mother's last CIMZIA® administration during pregnancy before administration of live or live-attenuated vaccines (e.g. BCG vaccine), unless the benefit of the vaccination clearly outweighs the theoretical risk of administration of live or live-attenuated vaccines to the infants.[CIM]

"I was unaware that treatment could affect my infant's vaccination schedule. I am worried about how my treatment plan will affect my infant's vaccination schedule."

Let her know the implications of using either Fc-biologics or CIMZIA® on her baby's vaccination schedule:

- Using Fc-containing biologics throughout pregnancy means delaying the infant's live vaccination schedule until 6 months of age.[BSR]
- Fc-biologics can be stopped during the 2nd or 3rd trimester of pregnancy to ensure a normal vaccination schedule.[BSR]
- As per BSR guidance, CIMZIA® can be used throughout pregnancy without delays to the infant vaccination schedule.*[,BSR,CIM]
- Re-iterate that treatment switching can induce disease flares, which increases the risk of adverse pregnancy outcomes and infertility. Treatment switching should therefore only be considered where risk of disease flaring is low.[MAG,STE,MEI,PRO,BSR]

CONTENT BANK

- DELAY TO INFANT VACCINATION SCHEDULE
- FC-BIOLOGICS STOPPAGE DURING PREGNANCY
- NO DELAY TO INFANT VACCINATION WITH CIMZIA®*
- SWITCHING TREATMENT AND DISEASE FLARES
- INFERTILITY
- ADVERSE PREGNANCY OUTCOMES
- Fc- AND NON-Fc CONTAINING BIOLOGICS

The birds, the bees and the babies

SECTION 04

DURING

If your patient has arrived at the pregnancy stop on her journey, it's vital to discuss treatment options for both her and her infant's health. It's key to establish:

QUESTION 01	Is she experiencing disease control?
QUESTION 02	Is she concerned about the potential side effects of her treatment on pregnancy and her infant?
QUESTION 03	Has she considered how treatment received during pregnancy might affect her infant's vaccination schedule?
QUESTION 04	Has she considered how different treatments might transfer to her infant through breastfeeding?

CONTROL, CONSTRAINTS AND CHECK-UPS

Is she experiencing disease control?

"Yes, I am experiencing improvement in symptoms with my current treatment plan."

When it comes to treating your patient, her disease control is your priority. Therefore, it's important to consider what treatment plan is best for her.

The potential implications of using Fc-containing biologics during pregnancy:

- Placental transfer[BSR]
- Increased risk of infections in the infant 1–2 years after birth[BSR]
- Delays to the infant vaccination schedule[BSR]

Switching treatments can induce disease flares, so any changes to her treatment plan should happen prior to conception to mitigate risk of adverse pregnancy outcomes and infertility.[MAG,MEI,PRO,STE]

"No, my condition is flaring/ not controlled with my current treatment plan."

When it comes to treating your patient, her disease control is your utmost priority. Therefore, it's important to explain the implications if her treatment isn't controlled.

Explain that uncontrolled disease could increase her risk of long-term, irreversible health complications, as well as the risk of both infertility, and adverse pregnancy outcomes.[MAG,MEI,PRO,DAN]

Discuss re-evaluating her treatment plan, in order to ensure adequate disease control.

Convey the potential benefits of CIMZIA®:

- According to the CRIB study, there is minimal to no placental transfer[BSR,CIM,CRI]
- No evidence for adverse pregnancy outcomes or congenital malformations[BSR,CIM]

CONTENT BANK

PLACENTAL TRANSFER | RISK OF INFANT INFECTION AFTER BIRTH | DELAY TO INFANT VACCINATION SCHEDULE | RISK OF ADVERSE PREGNANCY OUTCOMES | SWITCHING TREATMENT AND DISEASE FLARES | INFERTILITY | Fc- AND NON-Fc CONTAINING BIOLOGICS

CONCERNS AND REASSURANCE

Is she concerned about the potential side effects of her treatment on pregnancy and her infant?

"I am worried about the side effects that different treatments could have on my baby."

When she starts thinking about bringing a little bundle of joy into the world, she may have concerns regarding her treatment and its effect on her new-born.

Based on data from >12,000 pregnancies, TNF-inhibitors are considered compatible for use during pregnancy, however: [BSR]
- → Some studies have found increased risk of infections in the infant 1–2 years after birth[BSR]

According to the CRIB study, CIMZIA® is unable to cross the placenta and therefore has minimal to no transfer to the foetus.[BSR,CIM,CRI]

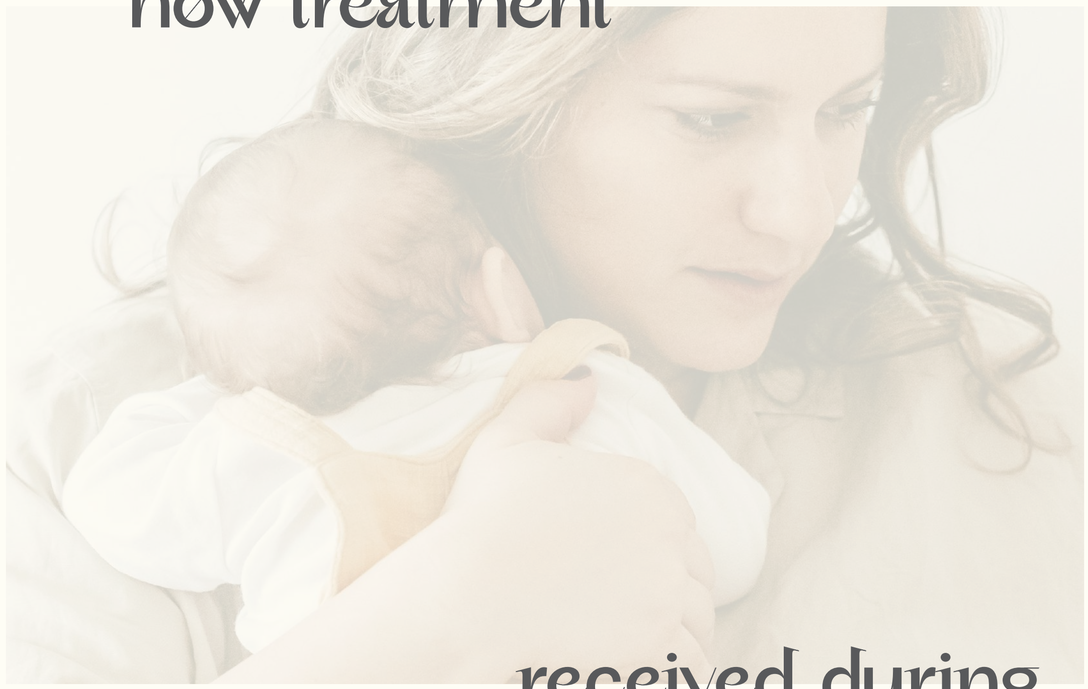
In >1,300 pregnancies, no evidence for adverse pregnancy outcomes or congenital malformations was found with CIMZIA®.[CIM]

Treatment switching can induce disease flares, which increases the risk of adverse pregnancy outcomes and infertility. Treatment switching should therefore only be considered where risk of disease flaring is low.[MAG,STE,MEI,PRO,BSR]

CONTENT BANK

TNF-INHIBITORS AND PREGNANCY · RISK OF INFANT INFECTION AFTER BIRTH · CIMZIA® UNABLE TO CROSS THE PLACENTA · ADVERSE PREGNANCY OUTCOMES · RISK OF ADVERSE PREGNANCY OUTCOMES · INFERTILITY · SWITCHING TREATMENT AND DISEASE FLARES · Fc- AND NON-Fc CONTAINING BIOLOGICS

Has she considered how treatment



received during pregnancy might affect her infant's vaccination schedule?

***CIMZIA® SPC states: It is recommended to wait a minimum of 5 months following the mother's last CIMZIA® administration during pregnancy before administration of live or live-attenuated vaccines (e.g. BCG vaccine), unless the benefit of the vaccination clearly outweighs the theoretical risk of administration of live or live-attenuated vaccines to the infants.[CIM]**

EXPLAINING TREATMENT IMPLICATIONS FOR HER LITTLE ONE'S VACCINATIONS

"I was unaware that treatment could affect my infant's vaccination schedule. I'm worried about how my treatment plan will affect my infant's vaccination schedule."

Let her know the implications of using either Fc-biologics or CIMZIA® on her baby's vaccination schedule:

- Using Fc-containing biologics throughout pregnancy means delaying the infant's live vaccination schedule until 6 months of age.[BSR]
- Fc-biologics can be stopped during the 2nd or 3rd trimester of pregnancy to ensure a normal vaccination schedule.[BSR]
- As per BSR guidance, CIMZIA® can be used throughout pregnancy without delays to the infant vaccination schedule.*[,BSR,CIM]
- Re-iterate that treatment switching can induce disease flares, which increases the risk of adverse pregnancy outcomes and also infertility. Treatment switching should therefore only occur if at a low risk of disease flares.[STE,MAG,MEI,BSR]

CONTENT BANK

DELAY TO INFANT VACCINATION SCHEDULE | FC-BIOLOGICS STOPPAGE DURING PREGNANCY | NO DELAY TO INFANT VACCINATION WITH CIMZIA®* | INFERTILITY | ADVERSE PREGNANCY OUTCOMES | SWITCHING TREATMENT AND DISEASE FLARES | Fc- AND NON-Fc CONTAINING BIOLOGICS

BABIES. BOTTLES AND BREASTFEEDING

Has she considered how different treatments might transfer to her infant through breastfeeding?

"Can I still breastfeed if I take [X-drug] during pregnancy? I hadn't considered this possibility..."

Your patient may have worries about her treatment's effect on breastfeeding, re-assure her that TNF-inhibitors are considered compatible with breast milk exposure.[BSR]

Some studies have reported presence of Fc-containing biologics in breast milk.[BSR] However, no side effects were reported in these breastfed infants.[BSR]

CIMZIA® demonstrates minimal transfer into breast milk.[BSR,CIM]

CONTENT BANK

COMPATIBLE WITH BREAST MILK EXPOSURE | MINIMAL TRANSFER INTO BREAST MILK | FC-BIOLOGICS IN BREAST MILK | Fc- AND NON-Fc CONTAINING BIOLOGICS

Content Bank

→

On the following pages you can find additional information on a number of different topics. This content can help guide you and your patient on the best treatment decision for her today – and tomorrow.

FC- AND NON-FC CONTAINING BIOLOGICS

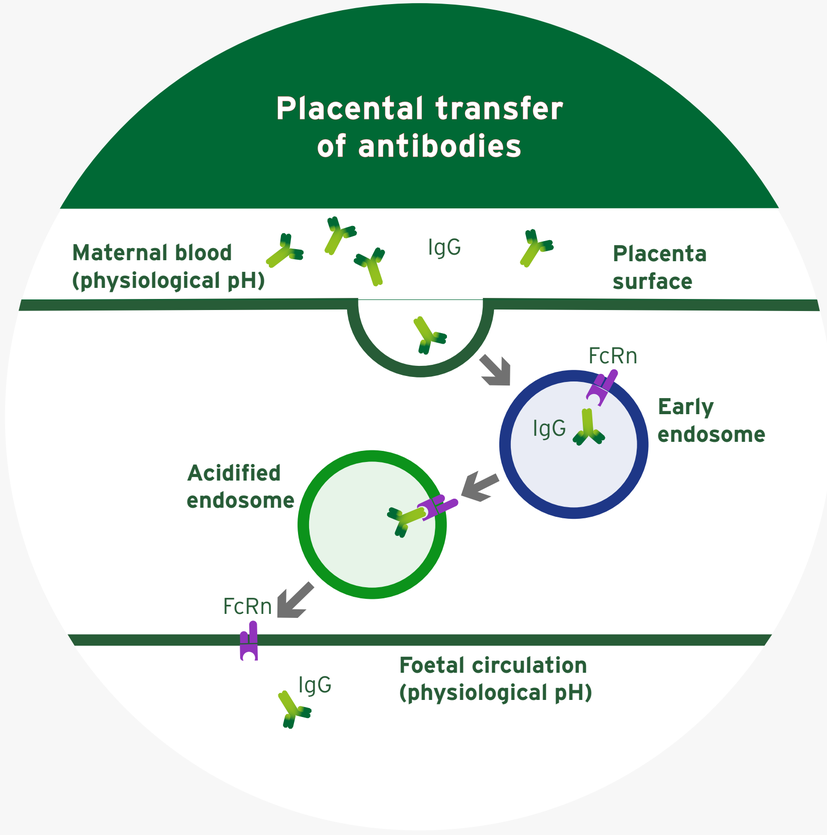
Biologic anti-TNF inhibitors are antibody-based treatments, which target the inflammatory cytokine – TNFa[BSR]

Antibodies comprise an F(ab) region and an Fc-region[ABC]

Presence of an Fc-region facilitates active placental and breast milk transfer*,[BSR]

Biologic anti-TNF inhibitors are antibody-based treatments, which target the inflammatory cytokine – TNFa[BSR]

According to the CRIB study, CIMZIA® is an anti-TNF antibody which lacks the Fc-region, meaning that there is minimal to no placental and breast milk transfer[BSR,CRI]



EFFICACY OF DIFFERENT CONTRACEPTIVE METHODS

CONTRACEPTIVE METHOD[NICE]	PERCENTAGE OF WOMEN EXPERIENCING AN UNINTENDED PREGNANCY WITHIN THE FIRST YEAR OF TYPICAL USE[NIC]	CONTRACEPTIVE METHOD[NIC]	PERCENTAGE OF WOMEN EXPERIENCING AN UNINTENDED PREGNANCY WITHIN THE FIRST YEAR OF TYPICAL USE[NIC]
Levonorgestrel intrauterine system (long-term contraception)	0.2%	Combined vaginal ring	9%
Progestogen-only implant (long-term contraception)	0.05%	Combined transdermal patch	9%
Male sterilisation (long-term contraception)	0.15%	Male condom	18%
Female sterilisation (long-term contraception)	0.5%	Female condom	21%
Copper intrauterine device	0.8%	Withdrawal method	22%
Progestogen-only injectables	6%	Fertility awareness methods	24%
Combined oral contraceptives and progestogen-only pills	9%	No method	85%

TREATMENT SWITCHING AND RISK OF DISEASE FLARES

In an analysis of
136 pregnant patients with rheumatic disease, discontinuation of TNF-inhibitors in early pregnancy was a risk factor for disease flares during pregnancy.[STE]

Patients with
rheumatoid arthritis and axial spondyloarthritis who discontinued their treatment demonstrated an over 3x increased relative risk of disease flares.[STE]

Therefore,
temporary discontinuation when switching treatments may increase the risk of disease flares in patients with rheumatic diseases.[STE]

RISK OF INFERTILITY WITH UNCONTROLLED RHEUMATIC DISEASE

Several large studies have demonstrated that women with rheumatoid arthritis have smaller families and are slower to conceive than other women.[PRO]

Infertility in women with rheumatoid arthritis is a remarkably common phenomenon and may require women to be referred to an endocrinologist.[PRO]

Sexual function in women with rheumatoid arthritis is often hampered by pain, decreasing the opportunity for conception.[PRO]

RISK OF ADVERSE PREGNANCY OUTCOMES WITH UNCONTROLLED RHEUMATIC DISEASE

PSORIATIC ARTHRITIS

Analysis of 2,332 pregnancies in women with psoriatic arthritis indicated an increased risk of:

- ↑ Pre-eclampsia
- ↑ Pre-term birth

AXIAL SPONDYLOARTHRITIS

Analysis of 335 pregnancies in women with axial spondyloarthritis indicated an increased risk of:

- ↑ Pre-eclampsia
- ↑ Pre-term birth
- ↑ Low birth weight[MAG]

GENERALLY SPEAKING, STUDIES INDICATE THAT AXIAL SPONDYLOARTHRITIS AND PSORIATIC ARTHRITIS PREGNANCIES ARE ASSOCIATED WITH HIGHER RATES OF COMPLICATIONS OVERALL.[MEI,MAG]

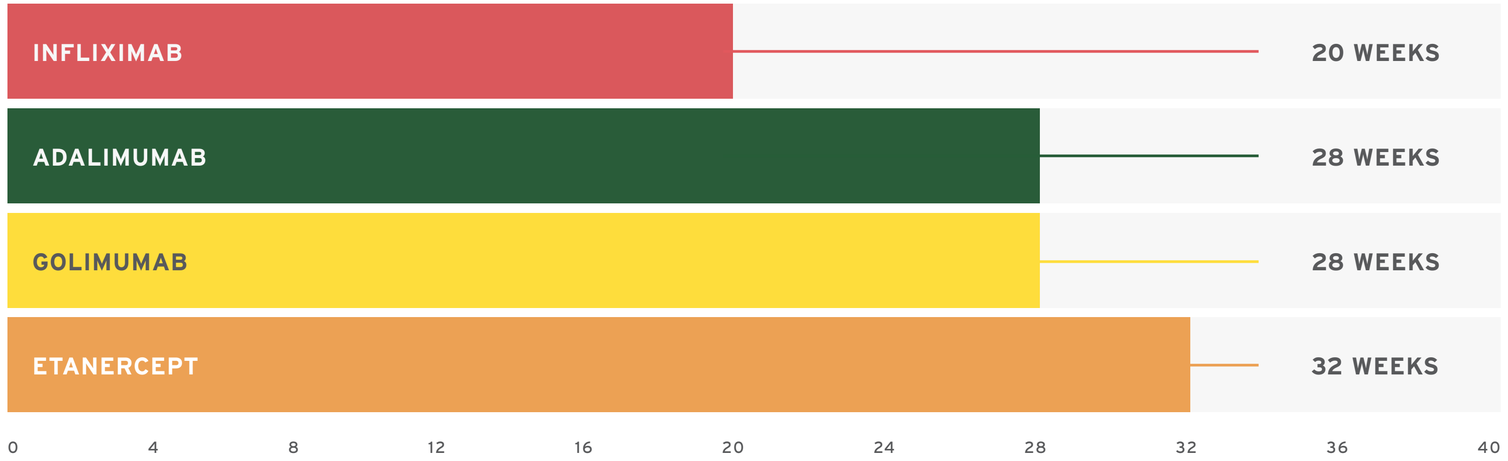
BSR GUIDELINES – INFANT VACCINATION SCHEDULE WITH MATERNAL EXPOSURE TO BIOLOGIC TNF-INHIBITORS[BSR,CIM]

BIOLOGIC TNF-INHIBITOR[BSR]	DELAY TO INFANT LIVE VACCINATION STATUS IF ADMINISTERED THROUGHOUT PREGNANCY?[BSR]
CIMZIA® (certolizumab pegol)	NO
Infliximab	YES – if the last dose is after 20 weeks of pregnancy
Adalimumab	YES – if the last dose is after 28 weeks of pregnancy
Golimumab	YES – if the last dose is after 28 weeks of pregnancy
Etanercept	YES – if the last dose is after 32 weeks of pregnancy

Please note: Despite BSR guideline recommendations, the CIMZIA® SmPC recommends to wait >5 months after the mother's last dose during pregnancy before administration of live or live-attenuated vaccines to the infant, unless the benefit of the vaccination clearly outweighs the theoretical risk.[CIM]

TREATMENT SWITCHING TO ENSURE A NORMAL VACCINATION SCHEDULE[BSR]

To ensure the infant can have a normal vaccination schedule, women at a low risk of disease flare can stop:[BSR]



Infliximab, adalimumab, etanercept or golimumab may be continued throughout pregnancy to maintain disease control; in these circumstances, live vaccines should be avoided in infants until they are 6 months of age.[BSR]

FC- AND NON-FC CONTAINING BIOLOGICS
CONTRACEPTIVE METHOD EFFECTIVENESS
SWITCHING TREATMENT AND DISEASE FLARES
INFERTILITY
ADVERSE PREGNANCY OUTCOMES
DELAY TO INFANT VACCINATION SCHEDULE
FC-BIOLOGICS STOPPAGE DURING PREGNANCY
RISK OF INFANT INFECTION AFTER BIRTH
RISK OF ADVERSE PREGNANCY OUTCOMES
PLACENTAL TRANSFER
FC-REGION PLACENTAL TRANSFER
TNF-INHIBITORS AND PREGNANCY
CIMZIA® UNABLE TO CROSS THE PLACENTA
NO DELAY TO INFANT VACCINATION WITH CIMZIA®
MINIMAL TRANSFER INTO BREAST MILK
COMPATIBLE WITH BREAST MILK EXPOSURE
FC-BIOLOGICS IN BREAST MILK

USE OF INFLIXIMAB, ADALIMUMAB, GOLIMUMAB OR ETANERCEPT DURING PREGNANCY[BSR]

Data from >12,000 pregnancy exposures to TNF-inhibitors, did not indicate an increased risk of pre-term birth, miscarriage, low birth weight or congenital malformations.[BSR]

Treatments which contain an Fc-region include adalimumab, infliximab, etanercept and golimumab. Persistent drug levels in infant's bloodstream may last <12 months.[BSR]

Presence of an Fc-region facilitates both placental and breast milk transfer.[BSR,CRI]

Some studies have shown that children exposed in-utero to TNF-inhibitors have an increased risk of infections 1–2 years after birth.[BSR]

One study indicated that in etanercept-exposed pregnancies, the proportion of infants with major birth defects was more than twice as high vs. in non-exposed pregnancies (9.4% [N=370] vs. 3.5% [N=164]).[BSR]

TNF-inhibitors are considered compatible with breast milk exposure.[BSR] Presence of etanercept and infliximab in breast milk has been reported in some studies, but not others – no adverse events were reported in any of these breastfed infants.[BSR]

CIMZIA® IN WOMEN OF CHILD-BEARING AGE WITH RHEUMATIC DISEASES

cimzia® (certolizumab pegol)

Demonstrates minimal to no placental transfer.[BSR,CRI]
According to the CRIB study, CIMZIA® lacks the Fc-region required for placental transfer.

Is compatible with all three trimesters of pregnancy.[BSR]

Has shown no signal for adverse pregnancy outcomes or congenital malformations.[CIM,BSR]
Based on evaluation of >1,300 CIMZIA® exposed pregnancies.[CIM]

Demonstrates minimal transfer into breast milk.[CIM,BSR]
Based on evaluation of 17 mothers breastfeeding while taking CIMZIA.®[CIM,BSR]

Can be used throughout pregnancy without delays to the infant vaccination schedule – as per BSR guidance.[BSR]

Please note: Despite BSR guideline recommendations, the CIMZIA® SmPC recommends to wait >5 months after the mother's last dose during pregnancy before administration of live or live-attenuated vaccines to the infant, unless the benefit of the vaccination clearly outweighs the theoretical risk.[CIM]

Mandatory information

Indication

CIMZIA® is indicated in combination with methotrexate, for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. CIMZIA® can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.[CIM]

For the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[CIM]

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk for the UK and hpra.ie/homepage/about-us/report-an-issue for Ireland. Or, via the MHRA Yellow Card App in the Google Play or Apple App Store. Adverse events should also be reported to UCB Pharma Limited.

Glossery of terms

BSR	British Society of Rheumatology
DMARD	Disease modifying anti-rheumatic drug
Fc	Fragment crystallizable
SmPC	Summary of Product Characteristics
TNF	Tumour Necrosis Factor
TNFa	Tumour Necrosis Factor Alpha

References

ABC ABCAM. Antibody structure and isotypes. Available at: https://docs.abcam.com/pdf/antibody-guide/antibody-structure-and-isotypes.pdf#:~:text=Antibodies%20exist%20as%20one%20or%20more%20copies%20of,which%20are%20different%20in%20their%20sequence%20and%20length. Accessed: May 2023.

BSR Russel DM et al. Rheumatology 2022; 00: 1–41.

CIM CIMZIA® (certolizumab pegol) SmPC. Available from: https://www.medicines.org.uk/emc/product/4450/smpc. Accessed: May 2023.

CRI Mariette X et al. Ann Rheum Dis 2018; 77: 228–233.

DAN Danve A et al. Clin Rheum 2019; 8: 625–634.

MAG Maguire S et al. Semin Arthritis Rheum 2022; 54: 151993.

MEI Meissner Y et al. Semin Arthritis Rheum 2021; 51(3): 530–538.

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NIC NICE. How effective are the available contraceptive methods? Available at: https://cks.nice.org.uk/topics/contraception-assessment/background-information/comparative-effectiveness-of-contraceptive-methods/. Accessed: May 2023.

PRO Provost M et al. Curr Opin Rheumatol2 014; 26(3): 308–314.

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