



EUROPEAN
ACADEMY OF
DERMATOLOGY &
VENEREOLOGY

Information Leaflet
for Patients

Use of Biologics for Psoriasis during Pre-conception, Pregnancy, & Breastfeeding



The aim of this leaflet

This leaflet has been written to help you understand more about the use of biological drugs or “biologics” for the treatment of psoriasis when you want to become pregnant, or if you are pregnant or breastfeeding. It tells you what needs to be considered regarding this treatment before, during, and after your pregnancy and where you can find out more about it.

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What is a biologic (biological drug)?

Biologics are drugs that are produced by living cells or bacteria. There are various biologics, and some are very effective for the treatment of autoimmune or inflammatory diseases like rheumatoid arthritis, Crohn's disease, and moderate-to-severe psoriasis. Sometimes a "biosimilar" is used, which means that it is interchangeable with a biological product. For the treatment of psoriasis, etanercept (Enbrel® and biosimilar), adalimumab (Humira®), infliximab (Remicade® and biosimilars), certolizumab pegol (Cimzia®), ustekinumab (Stelara®), secukinumab (Cosentyx®), ixekizumab (Taltz®), brodalumab (Kytream®), bimekizumab (Bimzelx®), guselkumab (Tremfya®), risankizumab (Skyrizi®) and tildrakizumab (Ilumetri®) are currently available in Europe. Biologics are either administered by injection or in a drip

How does a biologic work?

In psoriasis, the immune system produces far too many inflammatory proteins (cytokines) which cause the skin lesions. Biological drugs specifically block or inhibit the activity of these inflammatory proteins, interrupting the inflammatory process, and may lead to an improvement of your psoriasis.

Can I use a biological drug when I want to become pregnant

Anti-Tumour Necrosis Factor (TNF) Inhibitors are a type of biological therapy that helps to stop inflammation in psoriasis and other diseases. Limited experience with the anti-TNF Inhibitors etanercept, adalimumab, and infliximab suggests that treatment with these drugs does not reduce fertility in men or women. However, for ustekinumab, secukinumab, ixekizumab, brodalumab, guselkumab, risankizumab, and tildrakizumab (which are newer drugs), this has not been shown yet. However, because of the limited experience, women who plan to become pregnant are advised to stop treatment with a biological drug. For the biologics mentioned above, it is advised that treatment be stopped for at least six months before attempting to become pregnant (stopping contraceptive measures). However for etanercept, treatment should be discontinued at least one

month prior to conception. Please consult your dermatologist when you plan to become pregnant to discuss this further

What happens when I am being treated with a biologic and discover that I am pregnant?

There are currently limited data (meaning not enough studies) available on the use of biologics during pregnancy, primarily from patients with inflammatory bowel disease and rheumatoid arthritis who were treated with anti-TNF Inhibitors. Based on the experience of women who became pregnant while taking a biological treatment, the use of these drugs appeared to be safe up to three months into pregnancy and was not associated with any adverse outcomes in the newborn. Therefore, while on biological treatment, there is no need to end the pregnancy. However, if possible the treatment should be stopped, and detailed ultrasound examination of the unborn child should be offered to confirm normal development.

It is important to note that after the first trimester, the biologic can be actively transferred from the mother to the baby and may cause changes in the development of the child's immune system, the long term effects of which are unknown.

Can I (re)start treatment with a biologic when I am breastfeeding?

Biologics can be transferred to breast milk in very small amounts. However, there is no evidence that biological treatment in the breastfeeding mother can cause harm to the newborn. Therefore, if needed, the biological treatment may be started while the mother is still breastfeeding.

Which drugs are recommended when my psoriasis is so severe that I have to be treated during pregnancy?

Treatment with topical agents or a systemic drug (such as Cyclosporine) may be needed. Please see our Task Force leaflet on "Psoriasis in pregnancy" for general advice.

In cases of more severe psoriasis in pregnancy requiring biological therapy, the anti-TNF-alpha agent certolizumab pegol (Cimzia®) should primarily be considered as it does not cross the placenta in significant

amounts. A second line option to consider would include the anti-TNF-alpha agent etanercept. Etanercept crosses the placenta less than the other newer anti-TNF Inhibitors listed above, and in addition more information is available regarding its long-term safety in pregnancy.

Importantly, due to the placental transfer of most biologics during the pregnancy, there is a potential for your infant to be born with a decreased immune response (ability to fight infections). Therefore, the administration of "live" virus vaccinations should be avoided for at least 6 months after delivery. Inactive vaccinations can follow the standard schedule as recommended.

You should discuss these matters with your own clinician. Specialised clinics for patients using biologics are available in larger hospitals. Ideally, your clinician should refer you to a specialised clinic if you are taking a biological drug during your pregnancy.

While every effort has been made to ensure that the information given in this leaflet is accurate, not every treatment will be suitable or effective for every person. Your own clinician will be able to advise in greater detail.