PATIENT INFORMATION LEAFLET: 
Use of Biologics for Psoriasis during Pre-conception, Pregnancy & Breastfeeding

The aim of this leaflet
This leaflet has been written to help understand more about the use of biologic drugs or ‘biologics’ for the treatment of psoriasis when you want to become pregnant, 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.

What is a biologic?
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. For the treatment of psoriasis, etanercept (Enbrel®), adalimumab (Humira®), infliximab (Remicade®), ustekinumab (Stelara®), secukinumab (Cosentyx®) and ixekizumab (Taltz®) 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. Biologic drugs specifically block or inhibit the activity of these inflammatory proteins and interrupt the inflammatory process and may lead to an improvement of your psoriasis.

Can I use a biologic drug when I want to become pregnant?
Limited experience with the anti-Tumor Necrosis Factor (TNF) drugs etanercept, adalimumab and infliximab suggests that treatment with these drugs does not reduce the fertility of men and women. For ustekinumab, secukinumab and ixekizumab (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 biologic drug. For all biologics mentioned it is advised that treatment should be stopped for at least six months before attempting to become pregnant (stopping contraceptive measures). Only 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 available on the use of biologics during pregnancy, primarily from patients with inflammatory bowel disease and rheumatoid arthritis who were treated with anti-TNF drugs. Based on the experience of women who became pregnant while taking biologic 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, whilst on biologic treatment, there is no need to terminate the pregnancy but if possible this treatment should be stopped and detailed ultrasound examination of the unborn child should be offered to confirm normal development. 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 this 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 biologic treatment in the breastfeeding mother to cause harm to the newborn. Therefore, if needed, the biologic 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?
In this case the anti-TNF-alpha agents and more specifically, etanercept (which has less placental transfer to the unborn child) should be considered over the newer drugs such as ustekinumab, secukinumab and ixekizumab due to the increased availability of long-term safety data. Also, another anti-TNF biologic, certolizumab pegol (Cimzia®), which is used for the treatment of rheumatoid arthritis, should be considered, as it does not cross the placenta in significant amounts. However, since it is not (yet) registered for the treatment of psoriasis, it may not be reimbursed by your health insurance company.
Importantly, due to the placental transfer of the biologic during the pregnancy there is a potential for an impaired immune response of your infant. Therefore, the administration of live 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 doctor. Usually specialised clinics for patients using biologics are available in the larger hospitals, your doctor will be able to refer to them.

Where can I find more information about the use of biologics in 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 doctor will be able to advice in greater detail.
This leaflet has been prepared by the EADV Task Force “Skin Diseases in Pregnancy”, it does not necessarily reflect the official opinion of the EADV.

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