Women with Psoriasis – Disease Activity and Treatment Choice Pre-, During and Post-Pregnancy for Women with PSO, and the Impact of Family Planning

Slides intended for HCPs only

Inspired by **patients.**
Driven by **science.**

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Family Planning is Important for Women with PSO

~50% (n=72) of WoCBA with PSO report a desire to conceive[1]

50% (n=278) of WoCBA reported experience with family planning[2]

14% (n=79) trying to conceive or expecting to start soon

5% (n=26) currently pregnant

31% (n=173) who had given birth in the last 5 years

~50%

of all pregnancies are unplanned[3]

~20%

of patients with moderate-to-severe PSO are women of childbearing age[4,5]

KEY MESSAGE

Healthcare professionals should initiate timely family planning conversations in each patient of reproductive age, even before the patient expresses a pregnancy wish.[6]

Inspired by patients.
Driven by science.

1. Stephan B et al. EADV 2023. Abstract 5406. 2. McBride SR et al. Int J Womens Dermatol. 2021;7(5):697–707. 3. Gottlieb AB et al. Int J Womens Dermatol. 2019;5(3):141–150. 4. Kimball AB et al. JAMA Dermatol. 2021;157(3):301–306. 5. Hernández-Fernández CP et al. Acta Derm Venereol. 2021;101:adv00354. 6. Sammaritano LR et al. Arthritis Rheumatol. 2020;72(4):529–556.

Female Perception of PSO Treatment During Family Planning

Not all PSO treatments are compatible with pregnancy, many of which are due to placental transfer[1–5]

5%

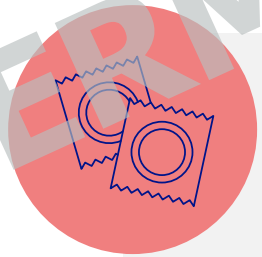
of medications have been adequately monitored, tested and labelled with safety information for use in pregnant and breastfeeding women[6]

In comparison to the general population, patients with moderate-to-severe PSO have **lower fertility rates** ($p < 0.001$)[7]

KEY MESSAGE Lacking information on the safety of PSO treatments during pregnancy may be of concern to patients and may lead to reduced fertility rates.[10,11]

Advice for HCPs

It is recommended to identify and evaluate early any comorbidities which may have an effect on pregnancy outcomes, such as metabolic syndrome and depression[2,8]



Advice for women of childbearing age starting a biologic therapy:[9]

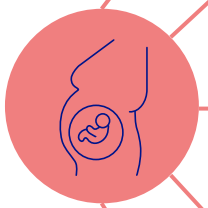
- ✓ Use effective contraception
- ✓ Discuss conception plans with the supervising consultant and adjust treatment if needed

There are no known interactions between biologic therapies and contraceptive methods[9]

Some systemic treatments, however, are potentially teratogenic and should be discontinued before conception[8]

1. Cimzia® EU SmPC. Available at: https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf. Accessed on April 2024. 2. EuroGuiDerm Guideline for the Systemic Treatment of Psoriasis Vulgaris. Available at: https://guidelines.edf.one//guidelines/psoriasis-guideline. Accessed on April 2024. 3. Cosentyx® EU SmPC. Available online at: https://www.ema.europa.eu/en/documents/product-information/cosentyx-epar-product-information_en.pdf. Accessed on April 2024. 4. Taltz® EU SmPC. Available online at: https://www.ema.europa.eu/en/documents/product-information/taltz-epar-product-information_en.pdf. Accessed on April 2024. 5. Kyntheum® EU SmPC. Available online at: https://www.ema.europa.eu/en/documents/product-information/kyntheum-epar-product-information_en.pdf. Accessed on April 2024. 6. ConcePTION. Background. Available online at: https://www.imi-conception.eu/background/. Accessed on April 2024. 7. Chen T-C et al. JAMA Dermatol. 2023;159(7):736–744. 8. Belinchón I et al. Actas Dermosifiliogr (Engl Ed). 2021;112:225–241. 9. Smith CH et al. Br J Dermatol. 2020;183(4):628–637. 10. Gottlieb AB et al. Int J Womens Dermatol. 2019;5(3):141–150. 11. Götestam Skorpen C et al. Ann Rheum Dis. 2016;75:795–810.

Concerns of Women with Psoriatic Disease Before Pregnancy



60% were concerned that treatment could harm the baby[1a]

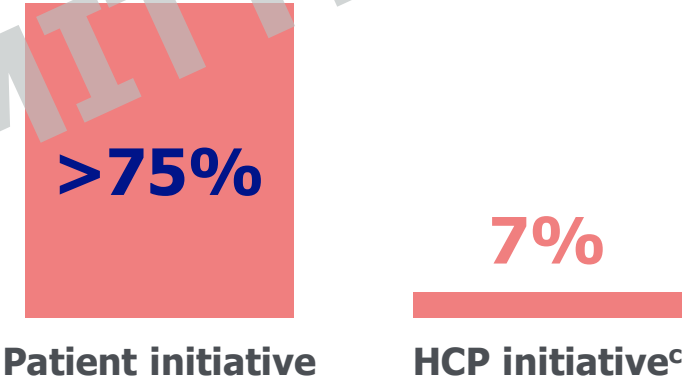
35% of women with PSO reported that their PSO affected their desire to become pregnant or delayed their decision to become a mother[1a]

20.5% felt that the disease could restrict them from caring for their child appropriately[1a]

55–65% were worried that PSO would worsen if their treatment was withdrawn or switched before pregnancy, during pregnancy, or during breastfeeding[1a]

76% of women fear passing on PSO to their child[2]

Most women with psoriatic disease had to initiate discussions around family planning with their HCP:[3b]



KEY MESSAGE Timely initiation of discussions about family planning and ongoing dialogue with healthcare professionals are critical for all women of childbearing age.[3]

[a]Survey administered to women aged 18 to 45 years with plaque PSO who were candidates for systemic treatment. 153 women from 11 Spanish centres were surveyed. [b]The Patient Journey survey was conducted across women of childbearing age (18–45 years) from the US, Japan, and Germany, France, UK, Italy, Spain (EU5). There were 367 survey participants with PSO, and 142 with PsA. [c]Data from NPF survey.

1. Jiménez Gómez Á et al. Actas Dermosifiliogr. 2024;115(1):10–20. 2. Feldman SR et al. Dermatol Online J. 2014;20(8):13030/qt48r4w8h2. 3. Gottlieb A et al. Int J Womens Dermatol. 2019;5(3):141–150.

Family Planning: Guidelines for Healthcare Professionals

Conception plans should be explored when identifying contraindications to therapies[1]

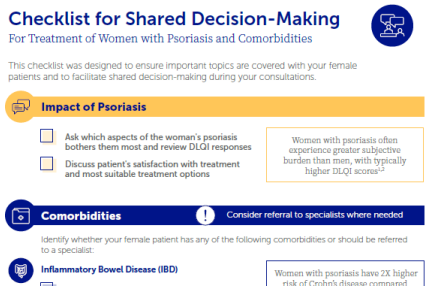
Pre-conception counselling should be offered to all patients with PSO, so they can make informed decisions with their dermatologists and avoid unnecessary delays in conception[2]

Providing this information early in the patient-physician relationship may increase communication, reduce unnecessary treatment cessation and provide patients with more tailored treatment plans during pregnancy[3]

Advice for HCPs

Use a checklist to ensure all important topics, e.g. checking for comorbidities (which can impact family planning for WoCBA)[4] are covered with your patient

Advice should be provided from across specialities[5] and should be tailored to each patient


Checklist for Shared Decision-Making
For Treatment of Women with Psoriasis and Comorbidities
This checklist was designed to ensure important topics are covered with your female patients and to facilitate shared decision-making during your consultations.
Impact of Psoriasis
Ask which aspects of the woman's psoriasis bothers them most and review DLQI responses
Discuss patient's satisfaction with treatment and most suitable treatment options
Women with psoriasis often experience greater subjective burden than men, with typically higher DLQI scores[1,2]
Comorbidities
Consider referral to specialists where needed
Identify whether your female patient has any of the following comorbidities or should be referred to a specialist:
Inflammatory Bowel Disease (IBD)
Women with psoriasis have 2X higher risk of Crohn's disease compared

KEY MESSAGE

Women who are planning pregnancy should understand:[1]

- The importance of controlling severe or unstable PSO to maintain maternal health
- The known effects of biologic therapies on pregnancy outcomes

1. Smith CH et al. Br J Dermatol. 2020;183(4):628–637. 2. Belinchón I et al. Actas Dermosifiliogr (Engl Ed). 2021;112:225–241. 3. Yeung J et al. J Cut Med Surg. 2020;24(IS):3S–14S. 4. Johansen CB et al. Int J Womens Dermatol. 2021;7:246–258. 5. EuroGuiDerm Guideline for the Systemic Treatment of Psoriasis Vulgaris. Available at: https://guidelines.edf.one//guidelines/psoriasis-guideline. Accessed on April 2024.

Pregnancy Can Have an Unpredictable Effect on PSO[1]

	PSO Evolution During Pregnancy[2]
Improved	32.3–63.3%[a]
Stable	17.6–55.9%[b]
Worsening	8.9–26.4%[c]

KEY MESSAGE Treatment plans should be discussed before pregnancy to ensure disease control during pregnancy (if needed).[3]

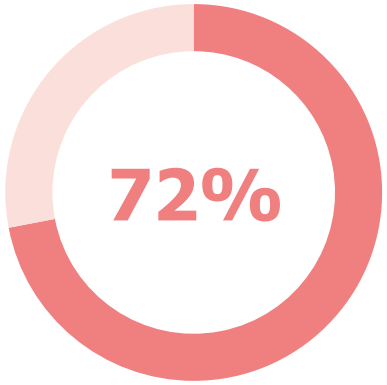
[a]As published in 2021. Range calculated from 8 studies, with total n number provided by 6 studies (n=227).
[b]As published in 2021. Range calculated from 8 studies, with total n number provided by 6 studies (n=147).
[c]As published in 2023. Range calculated from 7 studies, with total n number provided by 6 studies (n=72).

1. EuroGuiDerm Guideline for the Systemic Treatment of Psoriasis Vulgaris. Available at: https://guidelines.edf.one//guidelines/psoriasis-guideline. Accessed on April 2024. 2. Simionescu AA et al. Medicina. 2021;57(8):804. 3. Götestam Skorpen C et al. Ann Rheum Dis. 2016;75:795–810.

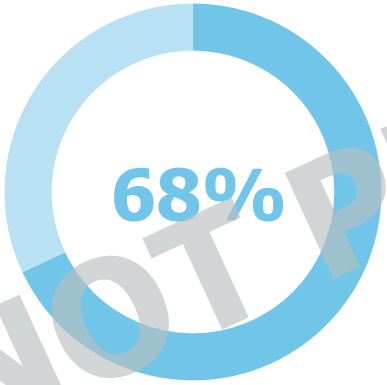
Women's Experience of PSO During Pregnancy

During pregnancy, women with CIDs experience anxiety throughout pregnancy regarding adverse pregnancy outcomes and disease flares, as well as concerns regarding the effect of treatment on children exposed in utero[1]

Among women who were pregnant or had given birth in the last 5 years:[2a]

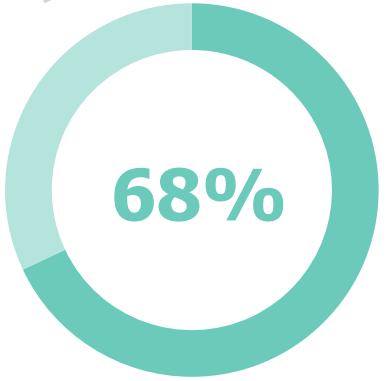


Experienced skin flares during pregnancy (105/145)



Experienced joint flares during pregnancy (98/145)

Among women who had given birth in the last 5 years:[2a]



Experienced disease flares since giving birth (109/161)

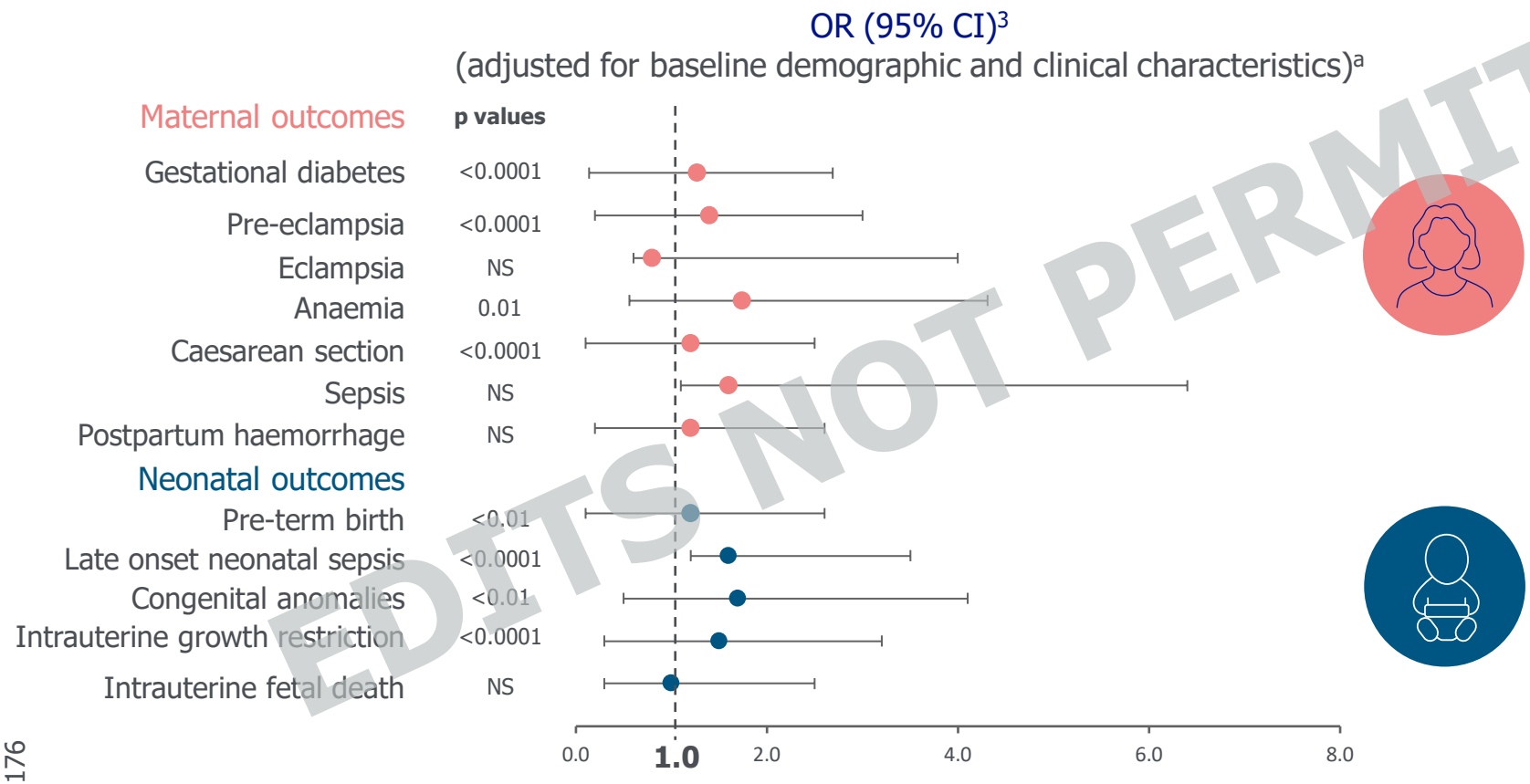
KEY MESSAGE In women with psoriatic disease, many flare during pregnancy and postpartum.[2]

[a]Multinational survey across 11 European countries completed by female members of patient associations/panels aged 18–45 years. Overall survey responders (n=573) had a diagnosis of PSO (n=236), PsA (n=173) or PSO+PsA (n=164). Data presented include women with PSO, PsA and PSO+PsA.

1. Flanagan EK et al. JGH Open. 2021;5:28–33.
2. McBride SR et al. Int J Womens Dermatol. 2021;7(5):697–707.

Maternal and Neonatal Outcomes of Births to Women with PSO

Compared to pregnancies in women without PSO, pregnancies in patients with PSO have a higher risk of pregnancy loss (OR, 1.06; 95% CI, 1.03–1.10)[1]



American population-based, retrospective cohort study using 1999–2015 United States' Healthcare Cost and Utilisation Project Nationwide Inpatient Sample. N=13,788,807 patients without PSO; n=3,737 patients with PSO. [a]Includes maternal age, race, median household income (quartiles), insurance type, hospital type, obesity, smoker and comorbidities. NS: not statistically significant. [b]Data from a Danish register-based case-control study of adverse pregnancy outcomes (N=42,041). OR of ectopic pregnancy was significantly higher in women with moderate-to-severe PSO than in women without PSO (OR=2.77).

Ectopic pregnancy is the leading cause of maternal morbidity and mortality in the first trimester of pregnancy. Women with moderate-to-severe PSO have a 2.48% higher absolute risk of ectopic pregnancy compared to women without PSO so it is important that this is monitored[2b]

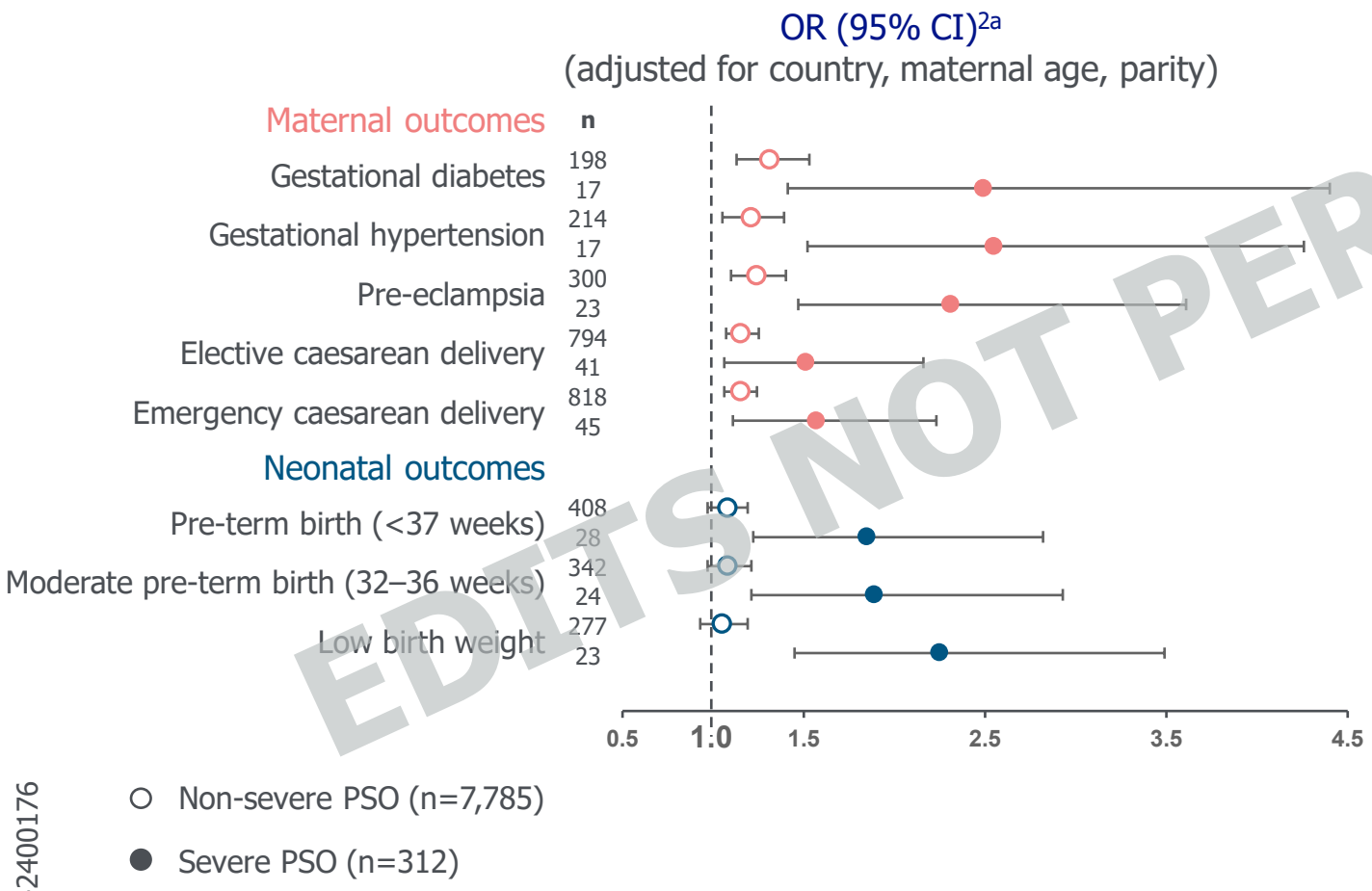
KEY MESSAGE

Women with PSO and their newborns appear more prone to adverse pregnancy outcomes than women without PSO and their newborns.[3]

1. Chen T-C et al. JAMA Dermatol. 2023;159(7):736–744.
2. Johansen CB et al. J Am Acad Dermatol Int. 2022;7:146–155.
3. Krim D et al. J Matern Fetal Neonatal Med. 2021:1–8.

The Severity of PSO Can Impact Pregnancy Outcomes

Disease severity is correlated with increased skin and serum levels of proinflammatory cytokines[1]



Obesity, diabetes, hypertension and depression were more common in patients with PSO. Alongside other lifestyle factors, such as high BMI, they are also associated with increased risks of adverse pregnancy outcomes[2,3]

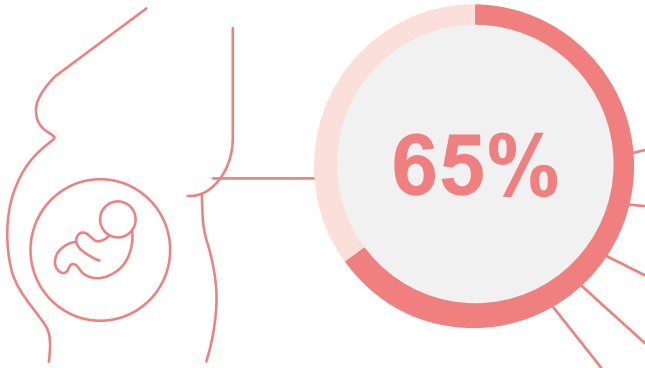
KEY MESSAGE

Beyond the disease itself, disease severity was a predictor of adverse neonatal pregnancy outcomes.[2] Comorbidities associated with PSO can also increase the risk of adverse pregnancy outcomes.[2,3]

Danish and Swedish population-based cohort study. [a]N=8,097 deliveries in 6,103 women with PSO. Pregnancies without PSO as reference.

1. Di Cesare A et al. Biomedicines. 2022;10(11);2879.
2. Bröms G et al. Acta Derm Venereol. 2018;98(8):728–734.
3. De Simone C et al. G Ital Dermatol Venereol. 2020;155(4):434–440.

Women's Concerns with Treatment During Pregnancy



Of patients who had given birth in the last five years, stopped treatment during pregnancy

Of those who stopped treatment:

79% Did so out of fear of harming their baby[1]

≥65% Did not have a plan for flare management during pregnancy[1]

44% Experienced a worsening in the severity of their disease[1]

33% Stopped due to misinformation[2]

24% Decided themselves to stop treatment[2]

KEY MESSAGE

Most women stopped taking treatment during pregnancy due to concerns over harming the baby, and advice on flare management during pregnancy was limited.[1]

Data from US NPF survey (n=141).

1. Gottlieb A et al. Int J Womens Dermatol. 2019;5(3):141–150.
2. De Simone C et al. G Ital Dermatol Venereol. 2020;155(4):434–440.

Discontinuation of Biologics may lead to Worsening of the Disease During Pregnancy

In a retrospective study, of 307 women living with PSO that were treated with biologics in 5 Dermatologic Center of University Hospitals:[1]

14 pregnancies to 12 women were exposed to a biologic (at least 1 administration during pregnancy)

Pregnancy Outcomes

10 healthy children were delivered:

- 9 spontaneous deliveries
- 1 cesarean section
- All children had a normal birth weight
- No congenital abnormalities and no cognitive disorders or other diseases were observed in children, including PSO

Biologic Treatment During Pregnancy

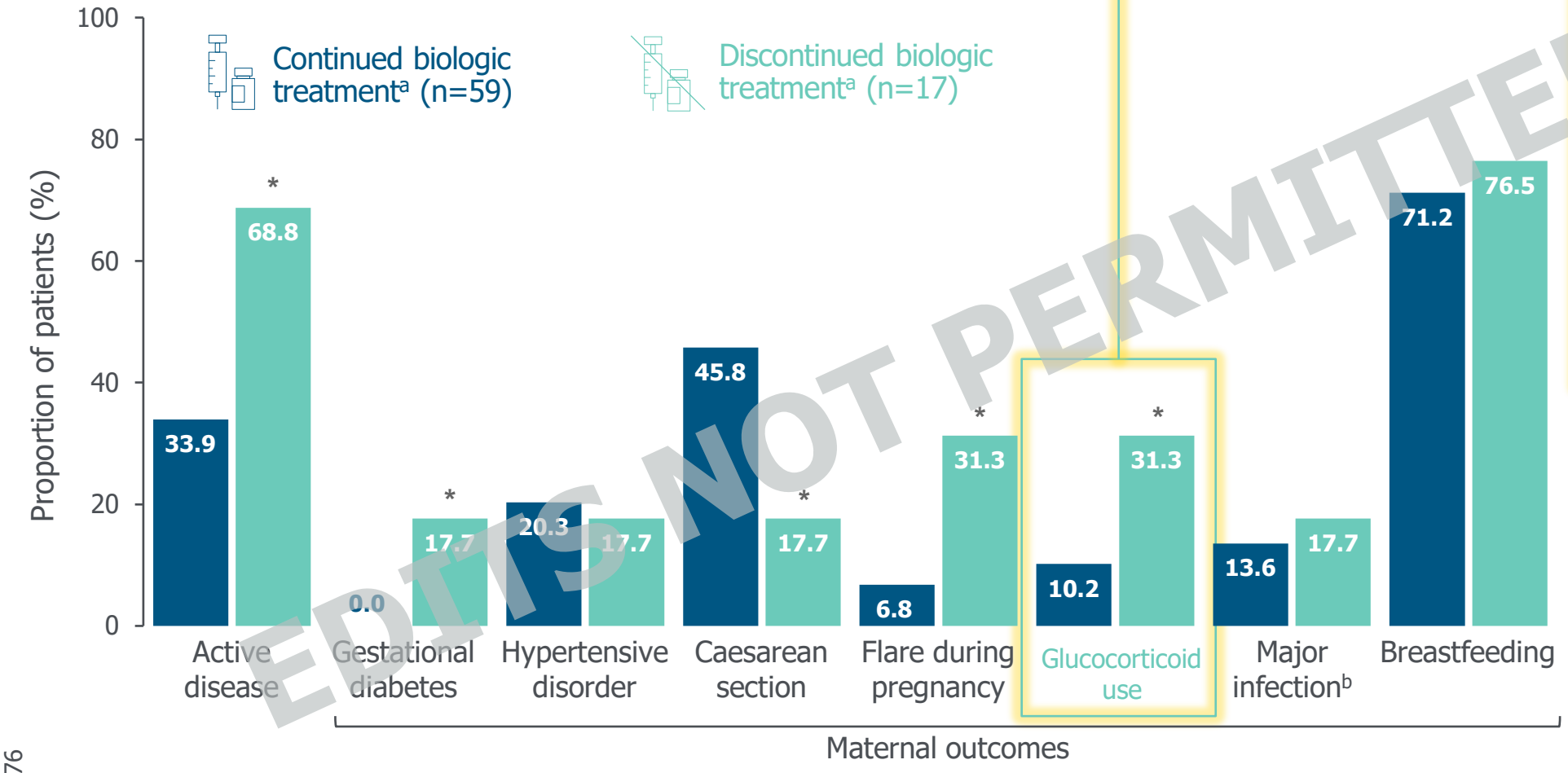
- All patients discontinued therapy when they discovered they were pregnant
- 1 woman discontinued treatment with IFX biosimilar but due to severe PSO and PsA, resumed therapy with CZP during pregnancy[a]
- In 8 women, PSO worsened during pregnancy

KEY MESSAGE Rates of flare in pregnant women with immune-mediated inflammatory diseases are higher in people who discontinue biologics (31.3%) than those who don't discontinue biologics (6.8%).[2]

[a]**According to the CZP SmPC, CZP should only be used during pregnancy if clinically needed.** For information about non-UCB products, consult the relevant country SmPC.

1. Odorici G et al. J Eur Acad Dermatol Venereol. 2019;33(10):e374–e377.
2. Allen K et al. Arch Gynecol Obstet. 2022;306(6):1929–1937.

Importance of Treatment Continuation for Pregnancy Outcomes



Stopping biologic treatment prior to conception can lead to increased glucocorticoid use,[1] which can increase the risk of:[2]

- Gestational diabetes
- Infection
- Preterm premature rupture of the membranes with higher doses

KEY MESSAGE

Pregnant women who discontinued biologics prior to conception are more likely to have active disease, gestational diabetes and disease flares. This can lead to higher rates of glucocorticoid use during pregnancy.[1]

According to the CZP SmPC, CZP should only be used during pregnancy if clinically needed. For information about non-UCB products, consult the relevant country SmPC. The use of CZP for the treatment of Crohn's Disease is currently not approved in the EU and is an unlicensed indication. Comparison of patients with immune mediated inflammatory diseases (IMIDs) who had prior biologic exposure but discontinued their biologics <3 months prior to conception with those who continued biologics throughout pregnancy. IMIDs included ankylosing spondylitis, Crohn's disease, PSO/psoriatic arthritis, rheumatoid arthritis and ulcerative colitis. [a]Biologic agents included infliximab, adalimumab, etanercept, certolizumab, vedolizumab, golimumab and anakinra. [b]Included chorioamnionitis, endometritis, surgical site infection, intra-abdominal abscess, pyelonephritis. *Statistically significant ($p<0.05$) difference between groups.

1. Adapted from Allen KD et al. Arch Gynecol Obstet. 2022;306(6):1929–1937. 2. Andreoli L et al. Autoimmun Rev. 2023;22(3):103259.

Impact of Biologic Exposure Throughout Pregnancy on Neonates

Neonatal exposure to biologics with an Fc portion increases during the 2nd and 3rd trimesters due to increasing FcRn expression[1–3]

Some biologics have been detected in intrauterine-exposed newborns up to 12 months after birth (usually 6–9 months)[4,5]

There are concerns that these agents could cause immunosuppression after birth. However, the current available literature is inconclusive:[6]

TNF-α plays a crucial role in the first line of defence against infection.[7,8] Anti-TNF-α agents have been hypothesised to facilitate defects in the interleukin-12/interferon-γ pathway, placing the infant at risk of infection[7]

There is mounting evidence that prenatal exposures alter epigenetic profiles and subsequent immune function in exposed offspring[9]

The results of a recent systematic literature review suggest that biologic drugs are generally well-tolerated and pose an acceptable risk to the fetuses/neonates[10]

However, a change in neonatal immune systems followed by in utero exposure to anti-TNFs has been reported,[7] and has been associated with an increased risk of neonatal infections within the first year of life.[11–13a] A decrease in Tregs due to in utero anti-TNF exposure is thought to facilitate hypersensitivity[7]

[a]Studies included a range of maternal disease, including inflammatory bowel disease, rheumatological diseases, psoriasis, liver disease and connective tissue disease.[11,12]
Treg: T-regulatory cell.

1. Lozano N et al. Am J Reprod Immunol. 2018;80(3):e12972. 2. Pfaller B et al. Allergy. 2021;76(1):71–89. 3. EuroGuiDerm Guideline for the Systemic Treatment of Psoriasis Vulgaris. Available at: https://guidelines.edf.one//guidelines/psoriasis-guideline. Accessed on April 2024. 4. Luo Y et al. Pediatr Allergy Immunol. 2023;34:e13911. 5. Weiss B et al. Front Pediatr. 2022;10:935034. 6. Gorodensky JH et al. J Rheumatol. 2023:50(12):1644–1645. 7. Esteve-Solé A et al. Front Immunol. 2017;8:1123. 8. Bickes M et al. FASEB J. 2019;33(10):10633–10647. 9. Bermick J and Schaller M. Pediatr Res. 2022;91(2):297–327. 10. Sánchez-García V et al. J Eur Acad Dermatol Venereol. 2023;37(10):1971–1990. 11. Bröms G et al. Aliment Pharmacol Ther. 2020;52:843–854. 12. Nørgård BM et al. Aliment Pharmacol Ther. 2020;52:829–842. 13. Barenbrug L et al. J Autoimmun. 2021;122:102676.

Live Vaccinations in Infants Exposed to Biologics

There are concerns that exposure to biologics could cause immunosuppression after birth, with anti-TNFs exposure during pregnancy being associated with increased risk of neonatal and paediatric infections.[1–3] However, the current available literature is inconclusive[4]

Guidelines therefore recommend against the use of live vaccinations in infants up to six months old whose mothers received biologic therapy beyond 16 weeks gestation[5,6]

- Newborn vaccinations may differ by country but include vaccinations against several diseases that could have long-term health impacts such as polio and hepatitis B[7,8]
- However, a study suggests vaccines are effective in infants exposed to biologics in utero[9]

KEY MESSAGE Further research and long-term outcomes data are required to confirm potential impacts of in utero exposure to anti-TNFs.

1. Bröms G et al. Aliment Pharmacol Ther. 2020;52:843–854. 2. Nørgård BM et al. Aliment Pharmacol Ther. 2020;52:829–842. 3. Barenbrug L et al. J Autoimmun. 2021;122:102676. 4. Gorodensky JH et al. J Rheumatol. 2023:50(12):1644–1645. 5. Smith C et al. Br J Dermatol. 2020;183(4):628–637. 6. EuroGuiDerm Guideline for the Systemic Treatment of Psoriasis Vulgaris. Available at: https://guidelines.edf.one//guidelines/psoriasis-guideline. Accessed on April 2024. 7. European Vaccination Information Portal. Vaccination schedules in the EU/EEA. Available online at: https://vaccination-info.eu/en/vaccination/when-vaccinate/vaccination-schedules-eueea. Accessed on April 2024. 8. NHS Inform. The 6-in-1 vaccine. Available online at: https://www.nhsinform.scot/healthy-living/immunisation/vaccines/the-6-in-1-vaccine. Accessed on April 2024. 9. Gisbert JP and Chaparro M. J Crohns Colitis. 2023;17(6):995–1009.

PSO Commonly Worsens Postpartum

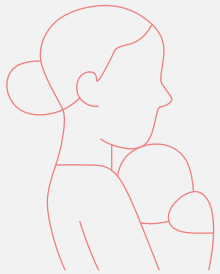
PSO Status Post-Partum	
Improved	1.1–10.7%[a]
Stable	11.1–48.4%[b]
Worsening	48.4–87.8%[c]

[a]Range calculated from 4 studies, with total n number provided by 4 studies (n=18). [b]Range calculated from 4 studies, with total n number provided by 4 studies (n=78). [c]Range calculated from 4 studies, with total n number provided by 4 studies (n=179).

Simionescu AA et al. Medicina. 2021;57(8):804.

Concerns of Women with Psoriatic Disease After Pregnancy

After pregnancy:



44% of mothers with PSO felt they had to choose between treatment and breastfeeding[1a]

17% of women with rheumatic disease develop postpartum depression, which is higher than women without rheumatic disease (13%)[2b]

Breastfeeding is critically important to the development of the neonatal intestinal microbiota, which plays an important role in maintaining health throughout life[3]

Women with psoriatic disease who had stopped all treatments were not likely to be advised on a postpartum treatment plan:[1]

~25%

No treatment plan[c]

KEY MESSAGE

Women with PSO may have a greater need for information, to avoid feeling they have to choose between treatment and breastfeeding.[1]

[a]The Patient Journey survey was conducted across women of childbearing age (18–45 years) from the US, Japan, and Germany, France, UK, Italy, Spain (EU5). There were 367 survey participants with PSO, and 142 with PsA. [b]Retrospective analysis including pregnant women with axSpA, PsA, or RA. [c]Data from US NPF survey (n=141).

1. Gottlieb A et al. Int J Womens Dermatol. 2019;5(3):141–150.
2. Shridharmurthy D et al. J Rheumatol. 2023;50(10):1287–1295.
3. Gopalakrishna KP et al. Nutrients. 2020;12(3):823.

Benefits of Breastfeeding

Reduced risk in child[1]

- Infections
- Obesity
- Type 1 and 2 diabetes
- Childhood leukaemia
- Sudden infant death syndrome
- Necrotising enterocolitis

Reduced risk in mother[2]

- Type 2 diabetes
- Breast cancer
- Ovarian cancer
- Postpartum depression (if not stopped early)

1. Brahm P and Valdés V. Rev Chil Pediatr. 2017;88(1):7–14.
2. James DC et al. J Am Diet Assoc. 2009;109(11):1926–1942.

References (1/4)

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Abbreviations

	Description
axSpA	Axial spondyloarthritis
BMI	Body mass index
CI	Confidence interval
CID	Chronic inflammatory disease
CZP	Certolizumab pegol
EU	European Union
Fc	Fragment crystallisable
FcRN	Neonatal Fc receptor
HCP	Healthcare professional
IFX	Infliximab
IMID	Immune mediated inflammatory diseases

	Description
NS	Not statistically significant
OR	Odds ratio
PsA	Psoriatic arthritis
PSO	Psoriasis
RA	Rheumatoid arthritis
SmPC	Summary of Product Characteristics
TNF	Tumor necrosis factor
UK	United Kingdom
US	United States
WoCBA	Women of childbearing age