Pregnancy, breastfeeding, and family planning

The current ethical framework of GCP guidelines deems it unethical to perform clinical trials in pregnant women. Therefore, there is no high-level evidence data on the efficacy and safety in this patient population. On the other hand, AE is the most common general skin disease in pregnancy. AE may either (i) worsen in women with a chronic condition, or (ii) may be reactivated in patients with a past AE history or (iii) may occur in women with no AE history (atopic eruption of pregnancy, AEP). Worsening of AE is mostly reported during the second and third trimesters, while AEP typically occurs during the first trimester.[1] There are no major clinical differences between classical AE worsening and AEP. Physiological skewness of the immune system towards a Th2-dominated response during pregnancy as well as physical and psychological stress during this period may contribute to AE worsening during pregnancy.

Little is known about treatment patterns during pregnancy, but patients and caregivers tend to reduce the use of topical and systemic therapies during pregnancy to avoid presumed harm to the fetus.[2] Consequently, undertreatment of AE during pregnancy may lead to serious QoL impairment but also to complications such as eczema herpeticum or staphylococcus aureus skin infections, and should therefore be avoided. We make recommendations based on the currently available evidence in relation to both topical and systemic therapies for the mother to ensure the health and well-being of the mother and the child throughout pregnancy.

Pregnant Women

In pregnant women with AE, we **recommend** TCS class II or III.	↑↑	**100%** Expert Consensus
In pregnant women with AE, we **suggest** that TCI may preferably be used on the face and intertriginous areas and on abdominal, breast and thigh skin, where the risk of striae formation increases with excessive use of TCS.	↑	**>75%** Expert Consensus
In pregnant women with AE, when topical treatments are insufficient, we **recommend** narrow-band UVB (311 nm) or broad spectrum UVB therapy if NB-UVB is unavailable.	↑↑	**>75%** Expert Consensus

In pregnant women with AE who require systemic treatment we **suggest** ciclosporin.	↑	**100%** Expert Consensus

In pregnant women with AE, we **recommend against** long term use of systemic corticosteroids - as we do in all AE patients.	↓↓	**100%** Expert Consensus
In pregnant women with AE, we **suggest** prednisolone only as short term rescue therapy for acute flares.	↑	

In pregnant women with AE, we **recommend against** the use of abrocitinib, baricitinib, upadacitinib and methotrexate.	↓↓	**100%** Expert Consensus

In pregnant women with AE, we **cannot make a recommendation** regarding the use of lebrikizumab, nemolizumab and tralokinumab due to the current lack of clinical data.	**0**	**100%** Expert Consensus
In pregnant women with AE, who require systemic treatment, we **suggest** dupilumab if the potential benefit justifies the potential risk to the fetus.	↑	

First line treatments

Emollients. Basic emollient therapy is key in the treatment of AE also during pregnancy and must be proposed to pregnant women with AE as a basic daily therapy. There is no firm evidence on which emollient should be used. However, emollients with a high lipid content and as few potentially harmful agents as possible are typically favored. Using emollients in a wet wrap technique is encouraged.[3]

TCS. Reactive or proactive use of TCS class II or III according to the fingertip unit role (see chapter 3) is recommended. A Cochrane systematic review updated in 2015 including 14 studies (5 cohort and 9 case-control studies) with 1,601,515 study subjects has examined the risk of TCS use in pregnancy. Overall, it has been deemed safe, with no causal associations between maternal exposure to TCS of all

potencies and pregnancy outcomes including mode of delivery, congenital abnormalities, preterm delivery, fetal death, and low Apgar score, although the use of very potent topical corticosteroids, particularly in high doses, may be associated with low birthweight.[4] Proactive, twice weekly TCS application as maintenance therapy is regarded as safe, but caution is necessary if using potent TCS over large body surface areas, or sensitive areas as breast and thigh skin, on a more regular basis. Some experts suggest that class IV may be used as rescue therapy, or over longer periods on limited skin areas, but this is controversial. Fluticasone propionate should be avoided as it is the only TCS that is known not to be metabolized by the placenta.[1] There is experimental data that there is zero degradation of Fluticasone propionate at the placentar barrier, whereas the degradation of hydrocortisone is high and the degradation of betamethasone is low.[5, 6] Therefore, the use of fluticasone propionate in pregnant women is generally avoided.[1]

TCI. Reactive and proactive use of TCI may be preferable on the face and intertriginous areas, and on abdominal, breast and thigh skin, where the risk of striae formation increases with excessive use of TCS.

Antiseptics. Antiseptics, except triclosan, may be used by pregnant women if clinically needed to prevent recurring skin infections, but are not used as a general routine measure.

UV phototherapy. Therapy with narrow-band UVB (311 nm) and broad-spectrum UVB does not impose a risk to the fetus in pregnant woman. However, oral psoralen should not be used preconceptionally (3 months) or in pregnant women.

Second- and third-line treatments

Second- and third-line treatments are generally reserved for pregnant women with AE who remain inadequately controlled with TCS class II or III.

Systemic corticosteroids should not be used in the long-term in AE in general and even more so not during pregnancy, as it is associated with an increased risk of fetal complications, including gestational diabetes.[4] Only short courses of prednisolone (maximum 0.5 mg/kg/day) may be used with strict indication.

Ciclosporin may be used off-label in severe uncontrolled AE during pregnancy if topical anti-inflammatory treatment alone or in combination with UV treatment fails, and there is a clear need for better long-term disease control. However, extra attention should be given to the renal function and blood pressure of the mother. There is no evidence of teratogenicity. Ciclosporin crosses the placenta[7] and should not be used during pregnancy, unless the potential benefit to the mother justifies the potential risk to the fetus.

AZA may be used off-label in pregnant women with severe uncontrolled AE, who are already receiving this treatment at the time of conception (see also chapter 8.2). There is no evidence for teratogenicity from studies with patients with inflammatory bowel diseases. Close consultation with an experienced obstetrician is generally considered important when prescribing this in pregnant women.[1]

MTX and Alitretinoin are teratogenic and therefore strictly contra-indicated during pregnancy.

As for dupilumab, the guideline group suggests considering use during pregnancy if the potential benefits outweigh the potential risks to the fetus, and emphasizes that the decision to use or withhold the medication must be made on a case-by-case basis. This is in keeping with the label and mounting

evidence of the safety of dupilumab. The medication has been administered in well over 1,000 pregnant atopic eczema sufferers. [8-14] A propensity-matched cohort study, using data from the Collaborative Network of TriNetX, included 243 women treated with dupilumab before pregnancy, 293 treated during pregnancy and 300 treated during pregnancy and postpartum for type 2 chronic inflammatory diseases (atopic eczema, asthma, chronic rhinosinusitis with nasal polyps, prurigo nodularis, or eosinophilic esophagitis) and matched these patients with pregnant patients with type 2 chronic inflammatory diseases who were not exposed to dupilumab. Patients with outcomes occurring prior to the respective index events were excluded. Based on the data evaluated, the authors of the study conclude that there is no increased risk of adverse events for either the mother or the child. Of the 293 patients treated with dupilumab during pregnancy, 92 received the treatment for AD.[15] The authors of another retrospective multicenter case series, which reported on maternal and fetal outcomes in 85 cases of dupilumab exposure during pregnancy across 18 countries, also conclude that dupilumab is a good therapeutic option for the treatment of AD in women of childbearing potential.[16] On the other hand, an analysis examining reports documented between 1980 and 2023 in VigiBase that mentioned pregnancy- or fetus-related adverse reactions associated with drugs indicated for asthma, was published in 2025.[17]A total of 2,894 cases involving dupilumab were identified. The authors reported that, compared with medications other than biologics, the use of dupilumab during pregnancy was associated with a higher reporting odds ratio (ROR) for abortion or stillbirth (ROR 4.33; 95% CI, 3.16–5.94), spontaneous fetal death (ROR 5.34; 95% CI, 3.90–7.32), and spontaneous abortion (ROR 7.25; 95% CI, 5.26–9.99). Low ROR values were reported for pregnancy complications, gestational hypertension and related disorders, delivery complications, preterm birth and neonatal complications.[17] However, it is important to consider the limitations of the Vigibase database, including that reports do not prove causation. Reporting bias has been recognised as an important concern, as reporting is spontaneous and voluntary. In addition, the database lacks information on how many people in total were exposed to the medication, how often and how long, which means that it is not possible to calculate reliable incidence rates or risk probabilities from Vigibase alone.

For lebrikizumab, tralokinumab and nemolizumab the guideline group cannot recommend any of these medications, as there is currently no clinical data available to inform about any potential drug-associated risks.

Abrocitinib, baricitinib and upadacitinib are contraindicated during pregnancy according to label. There is no clinical data but single case reports supporting its safety in pregnant women. However, teratogenic effects have been described in animal models.[18]

Antihistamines are of limited efficacy in AE (see chapter antipruritic treatment). In case of need, loratadine or cetirizine should preferentially be used because of the broad experience with this drug in pregnant women. [19-21]

Due to lack of experience with crisaborole during pregnancy, this drug should not be used preconceptionally, in pregnancy or during lactation.

If antibiotic treatment is required for superinfected AE during pregnancy, all penicillins, cephalosporins, and erythromycin are considered safe and may be prescribed as needed.[22, 23]

Breastfeeding women

In breastfeeding women with AE, we **recommend** TCS II or III.	↑↑	**100%** Expert Consensus
In breastfeeding women with AE, we **suggest** prednisolone only as short-term rescue therapy for acute flares.	↑	
In breastfeeding women with AE, we **suggest against** abrocitinib, baricitinib, upadacitinib, ciclosporin and methotrexate.	↓	
In breastfeeding women with AE, we **cannot make a recommendation** regarding the use of dupilumab, lebrikizumab, nemolizumab and tralokinumab due to the current lack of clinical data.	0	

TCS and TCI: No studies have examined the safety of TCS and TCI use during lactation but no harmful effect is suspected. Nevertheless, topical treatment is generally applied to the nipple region immediately after nursing, allowing the drug to be absorbed into the skin before the next feeding.[1]

Systemic corticosteroids: Treatment with a short course of a systemic corticosteroids during lactation is safe, since <0.1% of the mother's ingested dosage is secreted into breastmilk.

With regard to biologics (dupilumab, lebrikizumab, nemolizumab and tralokinumab), current evidence is insufficient to make a clear recommendation for or against their use in breastfeeding mothers with AE. Limited data suggests that the concentration of biologics in general (not just IL4 and IL13 inhibitors) appears to be low in breast milk.[24] Being protein-based therapeutics, biologics are expected to be degraded by gastric acid and proteolytic enzymes in the infant's gastrointestinal tract, which may further limit systemic absorption. Nevertheless, given the very limited clinical experience, caution should be exercised, and the decision to use biologics during lactation should be made on a case-by-case basis by clinical experts.

MTX, AZA, ciclosporin, and JAK-Inhibitors are secreted in breastmilk and may induce immunosuppression in the neonate. MTX, AZA, ciclosporin, and JAK-Inhibitors are generally not suggested for lactating mothers.[1]

Family planning

Preconception recommendations for women

TCS and TCI: Although the literature on this subject is very sparse, all currently licensed topical AE therapies can be used without concern in women wishing to conceive.

MTX: Local labels in different countries suggest a contraindication range spanning from 1 month to 6 months before conception. European Medicines Agency (EMA) recommends 6 months as a means of precaution. The practice of the guideline group differs from this and we recommend stopping methotrexate 3 months before a planned conception.

Since JAK-inhibitors are contraindicated during pregnancy, the use of abrocitinib, baricitinib and upadacitinib should generally be avoided during periods of active family planning.

With regard to dupilumab, lebrikizumab, nemolizumab and tralokinumab, see chapter on pregnancy. Decisions regarding the administration of these drugs during active family planning, and potential exposure in early pregnancy, need to be made on a case-by-case basis, taking into account the respective half-lives of the drugs.

Preconception recommendations for men

TCS and TCI: Although the literature on this subject is extremely sparse, all topical AE therapies in men wishing to father a child can be used without concern.

Ciclosporin may be used in the treatment of AE in men at the time of conception, as there is no evidence for harm or decreased fertility.

MTX: Following the European S3-guideline on systemic treatment of psoriasis vulgaris a 3-month MTX pause prior to conception is recommended. However, (inadvertent) exposure beyond this time does not justify termination of pregnancy, because there is no scientific evidence of male teratogenicity.[1] Some data suggest that methotrexate (MTX) may potentially impair sperm quality, for example by altering sperm DNA or motility, although the evidence is contradictory.[25]

AZA and JAK-Inhibitors: there is no contraindication for the use of AZA and JAK-Inhibitors in men wishing to father a child.
Dupilumab, lebrikizumab, nemolizumab, tralokinumab: There is currently no evidence that men need to abstain from fathering a child while on therapy. Further data is awaited to clearly demonstrate evidence of no harm.

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