eTable 1. Recommendations for DMT Use Before and During Pregnancy, and During Lactation

DMT	Recommendations for use during pregnancy	Recommendations for contraceptive use	Pregnancy safety data	Breastfeeding safety data
Large molecules				
Interferon beta	The EMA advises that interferon beta can be considered during pregnancy, if clinically needed.[1] The FDA advises that data does not indicate a drug-associated risk of birth defects.[2] Contraindicated in pregnant patients (Health Canada)[3,4]	No need for contraception indicated (EMA and FDA).[1,2] Fertile women should take adequate contraception (Health Canada)[3,4]	European and global databases indicate no increased risk for fetal abnormalities[5,6]	The EMA advises that interferon beta can be used during breastfeeding.[1] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects.[2] A decision must be made whether to discontinue breastfeeding or discontinue interferon beta (Health Canada)[3,4] Potential exposure did not increase the risk of common adverse outcomes in the first 12 months. Negligible levels transfer to breast milk[7,8]
Glatiramer acetate	The EMA and Health Canada advise that glatiramer acetate can be continued only if potential benefit justifies potential	No need for contraception indicated (EMA, FDA and Health Canada)[9–11]	Teva's global database indicates no increased risk for fetal abnormalities[12]	The EMA advises that glatiramer acetate can be used during breastfeeding.[9] Negligible exposure to glatiramer acetate in breastfeeding infants and no increase in risk of

	risk to fetus.[9,10] The FDA concludes that there is currently not enough data to provide a recommendation[11]			common adverse outcomes in the first 12 months observed.[7,8,11] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects.[11] Health Canada advise caution when glatiramer acetate is administered during breastfeeding[10]
Small molecules				
Dimethyl fumarate	The EMA and Health Canada advise that dimethyl fumarate can be continued only if potential benefit justifies potential risk to fetus.[13,14] The FDA concludes that there is currently not enough data to provide a recommendation[15]	The EMA recommends use of contraception in women of childbearing potential,[13] but the need for contraception is not indicated by the FDA and Health Canada[14,15]	No risk of fetal abnormalities/adverse pregnancy outcomes from International registry trial[16]	The EMA advises that dimethyl fumarate should be discontinued when breastfeeding.[13] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effect.[15] Health Canada advises caution when dimethyl fumarate is administered when breastfeeding.[14] Low-level excretion in breast milk observed. More data are required[17]
Teriflunomide	Contraindicated during pregnancy (EMA, FDA and Health Canada)[18–20]	Both men and women should use effective	Contraindicated during pregnancy.[18–20] However, no elevated risk for CA observed	Animal studies have shown excretion of teriflunomide in breast milk, and it is therefore contraindicated for

		contraception during and after treatment, as long as teriflunomide blood plasma concentration is <0.02 mg/L (EMA and FDA).[14,15] Women must use reliable contraception (Health Canada)[20]	from exposure in first trimester[21,22]	breastfeeding (EMA and FDA)[18,19] A decision must be made whether to discontinue breastfeeding or discontinue teriflunomide, taking into account the importance of the drug to the mother (Health Canada)[20]
Oral cladribine	Contraindicated during pregnancy (EMA, FDA and Health Canada)[23–25]	Effective contraception must be used during treatment and for 6 months after treatment discontinuation (EMA, FDA and Health Canada)[23–25]	Contraindicated during pregnancy.[23–25] However, limited data indicate no elevated risk for SA or CA from exposure in first trimester[26]	Limited data indicate transfer in measurable quantities to breast milk.[27] Contraindicated during breastfeeding and for at least 1 week after treatment discontinuation (EMA and FDA).[23,24-] Contraindicated during breastfeeding and for 10 days after last dose (Health Canada)[25]

	Women using systemically acting hormone contraceptives should add a barrier method during treatment and for ≥4 weeks after last dose (Health Canada).[25] Male patients of reproductive potential should also take precautions to prevent pregnancy of their partner during treatment and for ≥6 months after treatment discontinuation[23–25]

S1P receptor modulators				
Fingolimod	Contraindicated during pregnancy by the EMA and Health Canada.[28,29] Patients are encouraged to avoid pregnancy by FDA.[30] Contraindicated in women of childbearing potential not using effective contraception by Health Canada[29]	Effective contraception must be used during treatment and for 2 months after treatment discontinuation (EMA, FDA and Health Canada)[28–30]	Limited data indicate moderate or 2-fold higher CA risk[28,31]	Limited human data are available; however, fingolimod is excreted in milk of treated animals during lactation and is therefore contraindicated during breastfeeding by EMA and Health Canada.[28,29] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects[30]
Ozanimod	Contraindicated during pregnancy by the EMA and Health Canada.[32,33] Patients encouraged to avoid pregnancy by the FDA.[34] Contraindicated in women of childbearing potential not using effective contraception by Health Canada[33]	Effective contraception must be used during treatment and for ≥3 months after treatment discontinuation (EMA, FDA and Health Canada)[32–34]	Contraindicated during pregnancy.[32,33] However, limited data indicate no elevated risk of SA, CA, or pregnancy outcomes from exposure in first trimester[35]	Animal studies have shown that ozanimod and its metabolites are excreted in breast milk and ozanimod is therefore contraindicated for breastfeeding (EMA).[32] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects.[34] Health Canada advises that women receiving ozanimod should not breastfeed[33]
Siponimod	Contraindicated during pregnancy (EMA, FDA	Effective contraception must	Limited data on exposure in utero, but safety is possibly	Limited human data available; however, siponimod is excreted in milk

	and Health Canada).[36–38] Contraindicated in women of childbearing potential not using effective contraception by Health Canada[37]	be used during treatment and for ≥10 days after treatment discontinuation (EMA, FDA and Health Canada)[36–38]	similar to fingolimod due to similar mechanism of action[36]	of treated animals during lactation and is therefore contraindicated during breastfeeding by the EMA.[36] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects.[38] Health Canada advises that women receiving siponimod should not breastfeed[37]
Ponesimod	Contraindicated during pregnancy (EMA and Health Canada)[39,40] and patients are encouraged to avoid pregnancy by the FDA[41]	Effective contraception must be used during treatment and for 1 week after treatment discontinuation (EMA, FDA and Health Canada)[39–41]	No data from the use of ponesimod in pregnant women, but safety is possibly similar to fingolimod due to similar mechanism of action[39]	Animal data suggests ponesimod or its metabolites may be excreted in breast milk, and ponesimod is therefore contraindicated during breastfeeding by the EMA.[39] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects.[41] A decision must be made whether to discontinue breastfeeding or discontinue ponesimod, considering the benefit of breastfeeding for the infant and the benefit of therapy for the mother (Health Canada)[40]
Monoclonal antibodies				

Alemtuzumab	The EMA advises that alemtuzumab can be continued only if potential benefit justifies potential risk to the fetus.[42] The FDA concludes that there is currently not enough data to provide a recommendation.[43] Health Canada does not recommend alemtuzumab use in pregnant women[44]	Effective contraception should be used during treatment and for 4 months after treatment discontinuation (EMA, FDA and Health Canada)[42–44]	SA on the higher end (22%) of the general population (17%-22%), but not associated with higher risk for CA or adverse pregnancy outcomes from exposure in the first trimester.[45] Exposure in the second or third trimester can result in fetal risks related to autoimmune thyroiditis, such as premature birth, neonatal Graves' disease, and neurocognitive impairment[45–47]	Animal studies have shown excretion of alemtuzumab in breast milk, and therefore alemtuzumab is contraindicated during breastfeeding and for 4 months following treatment discontinuation by the EMA and Health Canada.[42,44] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects[43]
Natalizumab	The EMA advises that natalizumab can be continued only if potential benefit justifies potential risk to fetus.[48] The FDA concludes that there is currently not enough data to provide a recommendation.[49]	No need for contraception indicated (EMA, FDA and Health Canada)[48–50]	Not associated with shorter mean birth length, lower mean birth weight, or lower mean gestational age[51] Exposure up to 12 weeks gestation is associated with slightly increased or normal risk of SA.[52,53] CA risk needs	The EMA advises that natalizumab be discontinued during breastfeeding.[48] Low levels detected in human breast milk, with increasing levels over time to 2.83 µg/mL.[54,55] However, after 1 year of exposure, no negative outcomes were observed in infant health or development.[54] The FDA advises parents/clinicians to consider the

	Health Canada advises that discontinuation should be considered if a patient becomes pregnant[50]		further studies. Exposure during third trimester resulted in lower birth weight, anemia, thrombocytopenia, and more hospitalizations for the first year[54,55]	mother's clinical needs alongside potential adverse effects.[49] Health Canada advise that a decision should be made whether to discontinue breastfeeding or discontinue natalizumab, taking into account the importance of the drug to the mother[50]
Rituximab	Continue only if potential benefit justifies potential risk to fetus (EMA, FDA and Health Canada)[56–58]	Effective contraception should be used during treatment and for 12 months after treatment discontinuation (EMA, FDA and Health Canada).[56–58] However, due to the drug's short half-life, many clinicians advise that pregnancy can be attempted 1 month after treatment	Reduced B-cell numbers in 39% of newborns, which returned to normal levels within 6 months. Exposure in utero was not associated with significantly higher SA or CA risk or adverse pregnancy outcomes[60,61]	The EMA and FDA advise that rituximab should be discontinued during breastfeeding and for 6 months after treatment discontinuation.[56,57] Health Canada advise women not to breastfeed during treatment and for 6 months after treatment discontinuation.[58] However, very low levels of rituximab are excreted into breast milk, with normal B-cell levels observed in breastfed babies exposed to rituximab[54,62]

		discontinuation with anti-CD20 therapies[59]		
Ocrelizumab	The EMA and Health Canada advise that ocrelizumab can be continued only if potential benefit justifies potential risk to fetus.[63,64] The FDA concludes that there is currently not enough data to provide a recommendation[65]	Effective contraception should be used during treatment and for 12 months (EMA)[63] or 6 months (FDA and Health Canada)[64,65] after treatment discontinuation. However, due to the drug's short half-life, many clinicians advise that pregnancy can be attempted 1 month after treatment discontinuation with anti-CD20 therapies[59]	No adverse pregnancy outcomes per the global safety database.[66] One report of reduced B-cell count observed in an infant exposed during second trimester, but levels normalized 79 days after delivery[54]	The EMA advises that ocrelizumab should be discontinued during breastfeeding,[63] whereas the FDA advises that patients/clinicians consider the mother's clinical needs alongside potential adverse effects.[65] The benefits of breastfeeding for the infant should be considered along with the mother's clinical need for ocrelizumab and any potential adverse effects from ocrelizumab or the mother's underlying condition (Health Canada).[64] However, a 2022 study of 57 pregnant women showed that infant exposure to ocrelizumab or rituximab during breastfeeding resulted in normal growth and development, with no severe or unexpected infections observed[67]

Ofatumumab	The EMA advises that ofatumumab can be continued only if potential benefit justifies potential risk to fetus.[68] The FDA concludes that there is currently not enough data to provide a recommendation.[69] Health Canada does not provide a recommendation[70]	Effective contraception should be used during treatment and for 6 months after treatment discontinuation (EMA, FDA and Health Canada)[68–70]	Limited studies performed, but data to date indicate no neonatal B-cell depletion or fetal abnormalities[71]	The EMA advises that breastfeeding should be stopped for the first few days postpartum if treated with ofatumumab, after which ofatumumab can be used during breastfeeding if clinically needed, or if the patient was treated with ofatumumab up to the last few months of pregnancy, breast-feeding can be started immediately after birth.[68] The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects.[69] Health Canada advises the benefits of breastfeeding for the infant should be considered along with the mother's clinical need for ocrelizumab and any potential adverse effects[70]
Ublituximab	The FDA advises that there are no data on the developmental risk associated with the use of ublituximab in pregnant women.[72] Ublituximab is	Effective contraception should be used during treatment and for 6 months after treatment	Due to its recent approval, there is currently no data on the safety of ublituximab during pregnancy	The FDA advises parents/clinicians to consider the mother's clinical needs alongside potential adverse effects[72]

	currently undergoing EMA approval, and Health Canada clinical evaluation/pre-registration	discontinuation (FDA)[72]

Abbreviations: CA = congenital abnormality; DMT = disease-modifying therapy; EMA = European Medicines Agency; FDA = US Food and Drug Administration; S1P = sphingosine-1-phosphate; SA = spontaneous abortion.

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