# Appendix 3: Standard phrases

 

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| **Evidence** | Considered safe for short-term useExtensive experience of safe use in breastfeeding**Evidence quantity**Only [very limited / limited] anecdotal evidence of safety which indicates no effects in a breastfed infantNo published evidence of safetyVery limited published evidence of safety *(e.g. when <5 subjects or only one report)*Limited published evidence of safety *(e.g. 6-20 subjects and >one report)*Moderate amount of published evidence of safety *(e.g. > 20 subjects and >3 reports)*Significant published evidence of safety *(e.g. > 50 subjects and >5 reports)*Specialist drug/complex disease area for which expert advice is recommended |
| **Pharmacokinetics** | Likely to be degraded in infant’s GI tract**Milk levels- anticipated**Low levels anticipated in milk due to the drug’s propertiesLow levels anticipated in milk due to the drug’s properties and likely to be degraded in infant’s GI tractLow levels anticipated in milk due to the drug’s properties and not absorbed from the infant’s GI tractLow levels anticipated in milk due to the drug’s properties and likely to be degraded in infant’s GI tract, although long half-life increases risk of accumulation in breastfed infantNegligible levels anticipated in milk due to the drug’s propertiesModerate milk levels anticipated due to the drug’s properties**Milk levels- actual**Only negligible amounts in breast milk Small amounts in breast milkSmall to moderate amounts in breast milkSignificant amounts in breast milkLong half-life increases risk of accumulation in breastfed infants**GI absorption**Not absorbed from the infant’s GI tractMinimal absorption from the infant’s GI tract Unlikely to enter milk and not absorbed from the infant’s GI tractNot absorbed from the mother’s GI tract |
| **Lactation and lactophysiology** | May interfere with lactationNormal component of breast-milk |
| **Adverse effects** | Although large protein molecules may appear in colostrum, risk to preterm infants and neonates is considered to be small and unproven *(use for all MABs etc unless evidence says different)*Minor adverse effect reported in breastfed infantNo adverse effects reported in breastfed infantsPossible risk of sedation in infantSerious adverse effect reported in breastfed infantSerious adverse effects reported in adultsTheoretical risk of hypersensitivity in breastfed infant |
| **Monitoring** | Avoid use unless infant monitoring can be undertakenMonitor infant for *…… [free text]*Monitor infant for bradycardiaMonitor infant for GI disturbancesMonitor infant for drowsiness and/or poor feedingMonitor infant for irritabilityMonitor infant for developmental milestones |
| **Infant use** | Avoid in neonatesUsed in full-term neonates from birthUsed in infants >1 month |
| **Other** | A potentially serious adverse effect has been found in animals, although not confirmed in human studies. This suggests teduglutide should be used with caution until more evidence is availableSpecialist drug/complex disease area for which expert advice is recommendedDiscontinued in the UKUnlicensed in the UKUnlicensed indication in the UK |

**Bibliography link:** <http://www.midlandsmedicines.nhs.uk/content.asp?ContentID=171&section=6&subsection=17&pageidx=6>

# Route

**Inhalation**

**Intranasal**

**Oral**

**Parenteral**

**Topical**

# Route notes

**for reversible airways obstruction**