# Appendix 3: Standard phrases

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| **Evidence** | Considered safe for short-term use  Extensive experience of safe use in breastfeeding  **Evidence quantity**  Only [very limited / limited] anecdotal evidence of safety which indicates no effects in a breastfed infant  No published evidence of safety  Very 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 properties  Low levels anticipated in milk due to the drug’s properties and likely to be degraded in infant’s GI tract  Low levels anticipated in milk due to the drug’s properties and not absorbed from the infant’s GI tract  Low 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 infant  Negligible levels anticipated in milk due to the drug’s properties  Moderate milk levels anticipated due to the drug’s properties  **Milk levels- actual**  Only negligible amounts in breast milk  Small amounts in breast milk  Small to moderate amounts in breast milk  Significant amounts in breast milk  Long half-life increases risk of accumulation in breastfed infants  **GI absorption**  Not absorbed from the infant’s GI tract  Minimal absorption from the infant’s GI tract  Unlikely to enter milk and not absorbed from the infant’s GI tract  Not absorbed from the mother’s GI tract |
| **Lactation and lactophysiology** | May interfere with lactation  Normal 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 infant  No adverse effects reported in breastfed infants  Possible risk of sedation in infant  Serious adverse effect reported in breastfed infant  Serious adverse effects reported in adults  Theoretical risk of hypersensitivity in breastfed infant |
| **Monitoring** | Avoid use unless infant monitoring can be undertaken  Monitor infant for *…… [free text]*  Monitor infant for bradycardia  Monitor infant for GI disturbances  Monitor infant for drowsiness and/or poor feeding  Monitor infant for irritability  Monitor infant for developmental milestones |
| **Infant use** | Avoid in neonates  Used in full-term neonates from birth  Used 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 available  Specialist drug/complex disease area for which expert advice is recommended  Discontinued in the UK  Unlicensed in the UK  Unlicensed 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**