

## Safety Alert

September 2023

### Synflorix

EDA performs label update to include the following:

#### Posology and method of administration :

##### *Paediatric population*

The safety and efficacy of Synflorix in children over 5 years of age have not been established

Use of Synflorix and other pneumococcal conjugate vaccines Limited clinical data are available on the use of both Synflorix and 13-valent pneumococcal conjugate vaccine (PCV13) in the immunisation course of an individual

#### Background:

##### Therapeutic indications

Active immunisation against invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to 5 years of age .

#### References:

EMA:

[https://www.ema.europa.eu/en/documents/product-information/synflorix-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/synflorix-epar-product-information_en.pdf)