

PREVENAR 13[®]

SPECIAL EDITION NEWSLETTER

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Background

Prevenar was introduced in 2006 and offered protection against seven strains of pneumococcal bacteria (4, 6B, 9V, 14, 18C, 19F and 23F). Since its introduction, there has been a fall in the number of cases of invasive pneumococcal disease in children aged 5 years and under caused by these 7 pneumococcal strains

What's different about the new Prevenar vaccine?

The new vaccine Prevenar 13[®] offers protection against the same 7 strains as Prevenar[®] plus an additional 6 pneumococcal strains (1, 3, 5, 6A, 7F and 19A).

Why is it being introduced?

The incidence of pneumococcal disease caused by these 6 additional strains has recently increased.

When will it be available?

Vaccine holding centres will be able to order Prevenar 13[®] from 1st March 2010.

When will GP practice staff start using the vaccine?

With an allowance of time for distribution across the country, all GP practices are expected to be using *only* Prevenar 13[®] in the routine childhood programme by 1st April 2010.

Will there be any changes to the schedule?

No. Prevenar 13[®] will be a direct replacement for the existing PCV vaccine (Prevenar[®]) and will follow the same three dose schedule, i.e. doses offered at 2, 4 and 13 months of age. This means that apart from using a replacement vaccine, the vaccination schedule remains unchanged.

What about infants who began the course with Prevenar[®]?

For infants who began their primary immunisation course with Prevenar[®], the course can be completed with Prevenar 13[®].

What about children in risk groups?

Children in risk groups (which are defined in the Pneumococcal Chapter (Chapter 25) of the Green Book) should be vaccinated according to the routine schedule as below. Clinicians may wish to consider offering one dose of Prevenar 13[®] opportunistically to those at risk children aged under 2 years who have already completed the course of 3 doses of Prevenar[®]. Children in these groups should also receive pneumococcal polysaccharide vaccine at the appropriate age as described in Chapter 25 of the Green Book. Advice on the immunisation of children under 5 years of age in risk groups who are unimmunised or have missed immunisations is also given in Chapter 25 of the Green Book.

How is the new vaccine presented?

The vaccine is in the same presentation as Prevenar[®]; each pack containing 10 single dose pre-filled syringes. A single dose of Prevenar 13[®] is 0.5ml. Needles are not included. The dimensions of a pack containing 10 doses of Prevenar 13[®] are: 100mm x 56mm x 44mm. A picture of the new pack and syringe design can be found at: www.wyethvaccines.co.uk/products.

How do GP practices order it?

Practices must place an order for Prevenar 13[®] with pharmacy distribution centre (PCD) in order to receive a delivery of the vaccine. The vaccine is not being distributed on automatic allocation.

What do practices do with existing stocks of Prevenar?

Existing stock should be used up before starting use of the new vaccine. Do not return unused stocks to the PCD.

Is there to be a new PGD?

A new PGD will be issued in March that covers Prevenar and Prevenar 13[®].

Will there be any changes to GP payments?

As this is a direct replacement for an existing vaccine, there will be no impact on payments to GPs from this change to the routine immunisation programme.

Why does Prevenar 13[®] carry a black triangle symbol▼?

This is a standard symbol added to the product information of a vaccine during the earlier stages of its introduction, to encourage reporting of all suspected adverse reactions.

Are there any safety concerns given it is a new vaccine?

The safety of the vaccine was assessed in controlled clinical studies and the safety profile of Prevenar 13[®] was similar to Prevenar[®]. For Prevenar[®], very common or common reactions reported included decreased appetite; pyrexia; irritability; any injection-site erythema; induration/swelling or pain/tenderness; somnolence; poor quality sleep.

Is there more information?

A new chapter of the Green Book has been produced by the Department of Health and can be accessed on-line. www.dh.gov.uk/en/PublicHealth/HealthProtection/Immunisation/Greenbook/dh_4097254

If you would like to comment on any aspect of this newsletter please contact Marie Laurie on 201 4933 or at marie.laurie@ggc.scot.nhs.uk

VACCINATION OF INDIVIDUALS WITH UNCERTAIN/INCOMPLETE IMMUNISATION STATUS

2 - 12 months of age	>12 months - 2 yrs of age	>2yrs - 10 yrs	10 yrs and over
<p style="text-align: center;">DTaP/IPV/Hib* + PCV**</p> <p style="text-align: center;">- 4 week gap -</p> <p style="text-align: center;">DTaP/IPV/Hib + MenC*</p> <p style="text-align: center;">- 4 week gap -</p> <p style="text-align: center;">DTaP/IPV/Hib + MenC + PCV</p> <p><small>*Where Hib and/or MenC not given as part of a primary course give:</small></p> <ul style="list-style-type: none"> • 3 doses of Hib-containing vaccine at monthly intervals • 2 doses (minimum) of Men C-containing vaccine at monthly intervals <li style="text-align: center;">or • 3 doses of MenC/Hib combined vaccine <p><small>**When PCV has not been given as part of a primary course give 2 doses at least 2 months apart (but can be given 1 month apart if necessary to ensure two doses before the age of 12 months)</small></p>	<p style="text-align: center;">DTaP/IPV/Hib* + PCV* + MMR + MenC*</p> <p style="text-align: center;">- 4 week gap -</p> <p style="text-align: center;">DTaP/IPV/Hib</p> <p style="text-align: center;">- 4 week gap -</p> <p style="text-align: center;">DTaP/IPV/Hib</p> <p style="text-align: center;">DTaP/IPV/Hib</p> <p><small>* All un- or incompletely immunised children require 1 dose of Hib, MenC, and PCV over the age of 1 year</small></p>	<p style="text-align: center;">DTaP/IPV/Hib* + MenC* + MMR</p> <p style="text-align: center;">- 4 week gap -</p> <p style="text-align: center;">DTaP/IPV/Hib + MMR</p> <p style="text-align: center;">- 4 week gap -</p> <p style="text-align: center;">DTaP/IPV/Hib</p> <p><small>* All un- or incompletely immunised children require 1 dose of Hib and MenC over the age of 1 year</small></p>	<p style="text-align: center;">Td/IPV + MenC* + MMR</p> <p style="text-align: center;">- 4 week gap -</p> <p style="text-align: center;">Td/IPV + MMR</p> <p style="text-align: center;">- 4 week gap -</p> <p style="text-align: center;">Td/IPV</p> <p><small>*1 dose of Men C for 24 yrs and under</small></p> <hr/> <p style="text-align: center;">HPV Girls 12 - 18 years of age</p> <ul style="list-style-type: none"> • 3 doses of HPV at 0, 1-2 and 6 months * • Where significant challenges in scheduling occur, a minimum interval of 3 months may be left between the 2nd and 3rd dose of Cervarix. • Where the 2nd dose is given late and there is a high likelihood that the individual may not complete the course, a minimum of 1 month can be left between the 2nd and 3rd doses. <p><small>* If course interrupted - continue where left off</small></p>
Booster	Booster	Booster	Booster
As per UK schedule	<p>As per UK schedule</p> <p><small>An additional dose of DTap/IPV/Hib given under 3yrs of age does not count as a booster to the primary course and should be disregarded</small></p>	<p><small>1st dTap/IPV or DTaP/IPV booster can be given as early as 1 year after completion of primary course to re-establish on routine schedule</small></p>	<p>1st Td/IPV booster <small>preferably 5 yrs following completion of primary course</small></p> <p>2nd Td/IPV booster <small>5-10 yrs after 1st booster</small></p>
	MMR	MMR	MMR
	<ul style="list-style-type: none"> • Doses of MMR/measles given prior to 12 months of age should not be counted • For individuals <18 months of age a minimum interval of 3 months should be left between 1st and 2nd dose of MMR • For individuals >18 months of age a minimum of 1 month should be left between 1st and 2nd doses of MMR • 2 doses of MMR should be given irrespective of history of measles, rubella or mumps infection and/or age. 		

General Principles

- Unless reliable vaccine history, individuals should be assumed to be **unimmunised**, and a full course of immunisations planned
- Individuals coming to UK part way through their immunisation schedule should be transferred onto the UK schedule and immunised as appropriate for age
- If primary course has been started but not completed, continue where left off - **NO NEED TO REPEAT DOSES OR RESTART COURSE**
- **IPV** should be used to complete a vaccination course which may have been started with OPV
- **aP** should be used to complete a primary course which may have been started with whole cell pertussis vaccine
- **MenC/Hib** combined vaccine can be used when Hib alone or Hib/Men C is required
- A minimum of 1 year should be left between DTP/IPV primary course and 1st booster and a minimum of 5 years should be left between the 1st and 2nd boosters

Note: BCG and Hep B vaccine are not included in this algorithm