Product: Comvac® 5

1. NAME AND DESCRIPTION OF THE MEDICINAL PRODUCT

Comvac® 5 is a five-component prophylactic and therapeutic vaccine indicated for the primary immunization of infants from six weeks of age up to school going age of 6 years for the prevention of Diphtheria, Tetanus, Pertussis, Hepatitis B, and Haemophilus influenzae type b (Hib) by subcutaneous injection into the arm of infants who require the major primary antigens of the infantile tetanus vaccine as well as the Hib conjugate vaccine.

2. PHARMADEUTICAL FORM

3. CLINICAL PARTICULARS

3.1. General Advice

The vaccine should be administered according to the recommended schedule of day 0,30,60.

3.2. Contraindications

The vaccine should not be administered to children or adults who are hypersensitive to any of the components.

3.3. Precautions

3.3.1. Pregnancy

3.3.2. Breastfeeding

3.4. Adverse Effects

3.5. Immunogenicity

3.6. Pharmacokinetics

3.7. Stability

3.8. Administration

4. CLINICAL TRIAL EXPERIENCE

5. INFANT IMMUNIZATION

6. PACKAGING AND STORAGE

7. PRESENTATION

8. MARKETING AUTHORITY

9. LEGAL CATEGORY

10. PATIENT INFORMATION

11. PACKAGING AND LABELLING

12. COMPLAINTS AND SUGGESTIONS

13. DATA SHEET

14. ARTWORK APPROVAL

15. CHANGE CONTROL

16. SIGNATURE

For complaints and suggestions about the product, and any adverse event, Bharat Biotech International Ltd.

Date: 29-06-2019

Comvac® 5 Package Insert for Domestic

Specs

Product

Convac® 5

50%, 25%, 10% of the total

4510

Front/Back

Print

V-3

W-7.5x9.23.12

Color

90% Black C

QA - RA

Corp comm

Packaging

 Hod - QC

HOD - MED

HOD - QAO

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