* these reactions usually disappear within 1-2 days without treatment

Adverse reactions reported from post-marketing surveillance
Adverse reactions reported from post marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:
Blood and lymphatic system disorders:
Transient thrombocytopenia, transient lymphadenopathy
Immune system disorders:
Allergic reactions, in rare cases leading to shock, angioedema
Nervous system disorders:
Neuralgia, paraesthesia, febril convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome
Vascular disorders:
Vasculitis associated in very rare cases with transient renal involvement
Skin and subcutaneous tissue disorders:
Generalised skin reactions including pruritus, urticaria or non-specific rash
This medicinal product contains thiomersal (an organomercuric compound) as a preservative and therefore it is possible that sensitisation reactions may occur (see section 4.3).

4.9. Overdose
Overdosage is unlikely to have any untoward effect.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02
Seroprotection is generally obtained within 2 to 3 weeks. The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

5.2. Pharmacokinetic properties
Not applicable

5.3. Preclinical safety data
Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Buffer solution:
Potassium dihydrogenphosphate
Disodium hydrogenphosphate
Sodium chloride
Water for injection.

6.2. Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3. Shelf life
1 year.

6.4. Special precautions for storage
Store at +2°C to +8°C (in a refrigerator). Do not freeze. Keep container in the original carton.

6.5. Nature and contents of container
0.5 ml in pre-filled syringe (glass, type I) with stopper (rubber), fitted with a stainless steel needle, pack sizes of 1 and 10 syringes.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling
Unused vaccine and other waste material should be disposed of in compliance with local rules for the disposal of products of this nature.
The vaccine should be allowed to reach room temperature before use.
Shake before use.

7. MARKETING AUTHORISATION HOLDER

Novartis Vaccines and Diagnostics Limited
Gaskill Road
Speke
Liverpool
L24 9GR
UK.

8. MARKETING AUTHORISATION NUMBER

PL 18532/0038.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 7 June 2006

10. DATE OF REVISION OF THE TEXT

June 2008