

# GenHevac B PASTEUR VACCINE

20 micrograms/0.5 ml

RECOMBINANT HEPATITIS B VACCINE

suspension for injection in pre-filled syringes



## Please read all this package insert carefully before vaccination.

Keep this package insert until you have completed the vaccination schedule, you may need to read it again.

You must follow the advice of your doctor or nurse carefully. If you need more information and advice, ask your doctor or your nurse.

Make sure that you complete the vaccination schedule. Otherwise, your protection may not be complete.

This medicinal product has been prescribed to you personally. Do not give it to anyone else.

## COMPOSITION

The active ingredient is: Recombinant hepatitis B virus surface antigen\*

(S and pre-S<sub>2</sub> proteins) . . . . . 20 micrograms  
for one 0.5 ml dose

\* produced on CHO cell line

The other ingredients are: aluminium hydroxide, formaldehyde, sodium chloride, polysorbate 80, monopotassium phosphate, disodium phosphate dodecahydrate and water for injections.

## MARKETING AUTHORIZATION HOLDER

Aventis Pasteur S.A.  
2, avenue Pont Pasteur - 69007 Lyon - France

## 1. WHAT IS GenHevac B PASTEUR 20 micrograms/0.5 ml AND WHEN IS IT USED?

This medicinal product is a vaccine which protects against hepatitis B virus infection. It does not protect against hepatitis A, C or E virus infections or against other known pathogenic agents in the liver.

It is presented in the form of a suspension for injection in pre-filled syringes (0.5 ml in boxes of 1 or 20).

## 2. INFORMATION REQUIRED BEFORE USING GenHevac B PASTEUR 20 micrograms/0.5 ml

Do not use GenHevac B PASTEUR 20 micrograms/0.5 ml:

- in the event of hypersensitivity (allergy) to any of the vaccine's ingredients, or occurring after an injection of this vaccine,
- if you are suffering from severe febrile infection.

## Take special precautions with GenHevac B PASTEUR 20 micrograms/0.5 ml:

If you suffer from multiple sclerosis. Inform your doctor so that he/she can assess the potential benefit offered by vaccination.

## Pregnancy and lactation:

It is not recommended to use this medicinal product during pregnancy, unless advised otherwise by your doctor. If you find out that you are pregnant, consult your doctor, who will be able to adapt the treatment to your condition.

Ask your doctor or your pharmacist for advice before taking any medicinal product.

## List of excipients with a known effect:

Formaldehyde (0.02%), sodium (in chloride and disodium phosphate dodecahydrate form), potassium (in monopotassium phosphate form).

## Use of other medicinal products:

This vaccine may be administered at the same time as specific hepatitis B immunoglobulins, provided a separate injection site is used.

Vaccination should ideally be continued with the same vaccine. However, if required, this vaccine may complete vaccination in subjects having previously received another hepatitis B vaccine.

Inform your doctor or your pharmacist if you are taking or have recently taken any other medicinal product, even in the case of non-prescription medicinal products.

## 3. HOW TO USE GenHevac B PASTEUR 20 micrograms/0.5 ml?

### Posology

The recommended dose for each injection is 20 micrograms, irrespective of the subject's age.

Two injections at a monthly interval followed by a third injection administered 5 to 12 months after the second injection.

If rapid immunisation is required (children born to mothers with a risk of hepatitis B transmission, victims of recent contamination), the first dose of vaccine and a suitable dose of anti-HBs immunoglobulins should be administered simultaneously.

In exceptional circumstances, when faster immunisation is required, a schedule of 3 injections administered intramuscularly at days 0-10-21 may be suggested. If this schedule is used, a booster dose is recommended 12 months after the first injection.

### Administration method

Shake well before use to suspend the vaccine.

This vaccine must be injected by the intramuscular route in the deltoid muscle in adults. In newborns, infants and toddlers, the injection should be administered in the anterolateral part of the thigh.

In exceptional cases, the vaccine may be administered by the subcutaneous route in patients subject to severe haemorrhaging.

This vaccine must never be injected by the intravenous route.

### If you forget to take GenHevac B PASTEUR 20 micrograms/0.5 ml:

Your doctor will decide when to administer the omitted dose.

## 4. WHAT ARE THE POSSIBLE UNDESIRABLE EFFECTS?

Like all medicinal products, GenHevac B PASTEUR 20 micrograms/0.5 ml is liable to have undesirable effects.

The undesirable effects below have been reported after wide use of the vaccine. As with other hepatitis B vaccines, in many cases, the causal relationship with the vaccine has not been established.

The most frequently reported reactions are locally: transient pain, redness, induration, nodules associated with the presence of adjuvant which may persist for several weeks.

Rare cases of the following have been reported:

- tiredness, fever, faintness,
- dizziness, headaches, sensitivity disorders,
- nausea, vomiting, abdominal pains,
- transient increase in liver enzymes,
- joint and muscle pains,
- itching, urticaria, rash.

Very rare cases of the following have been reported:

- Severe allergic reactions,
- various peripheral or central nervous system disorders: peripheral neuropathy: [polyradiculoneuritis (diffuse peripheral nerve root disorder frequently of inflammatory origin), facial paralysis]; optical neuritis (lesion of optical nerve); demyelinating central nervous system disorders (multiple sclerosis flare-up) occurring in the weeks following vaccination, without a certain causal relationship having been established at the present time (see section 2 "Information required before using GenHevac B PASTEUR 20 micrograms/0.5 ml"),
- arthritis (joint inflammation),
- vasculitis (vessel wall inflammation).

If you notice undesirable effects not mentioned in this package insert, inform your doctor or pharmacist.

## 5. HOW TO STORE GenHevac B PASTEUR 20 micrograms/0.5 ml?

Keep out of the reach and sight of children.

Store between + 2°C and + 8°C (in a refrigerator), protected from light.

Do not freeze.

Do not use after the expiry date marked on the box.

**This package insert was last approved on:**  
02-2002

Aventis Pasteur

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