B. PACKAGE LEAFLET

Package leaflet: Information for the user

HBVAXPRO 5 micrograms, suspension for injection
Hepatitis B vaccine (rDNA)

Read all of this leaflet carefully before you or your child is vaccinated because it contains important information.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What HBVAXPRO 5 micrograms is and what it is used for

This vaccine is indicated for active immunisation against hepatitis B virus infection caused by all known subtypes in individuals from birth through 15 years of age considered at risk of exposure to hepatitis B virus.

It can be expected that hepatitis D will also be prevented by immunisation with HBVAXPRO as hepatitis D does not occur in the absence of hepatitis B infection.

The vaccine will not prevent infection caused by other agents such as hepatitis A, hepatitis C and hepatitis E and other pathogens known to infect the liver.

2. What you need to know before you or your child receive HBVAXPRO 5 micrograms

Do not use HBVAXPRO 5 micrograms
- if you or your child is allergic to hepatitis B surface antigen or to any of the other ingredients of HBVAXPRO (see section 6.)
- if you or your child has a severe illness with fever

Warnings and precautions

The container of this vaccine contains latex rubber. Latex rubber may cause severe allergic reactions.

Talk to your doctor, pharmacist or nurse before you or your child receives HBVAXPRO 5 micrograms.

Others vaccines and HBVAXPRO 5 micrograms
HBVAXPRO can be administered at the same time as with hepatitis B immunoglobulin, at a separate injection site.
HBVAXPRO can be used to complete a primary immunisation course or as a booster dose in subjects who have previously received another hepatitis B vaccine.

HBVAXPRO may be administered at the same time as with some other vaccines, using separate sites and syringes.

Tell your doctor, pharmacist or nurse if you or your child is taking, or has recently taken, any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Caution should be exercised when prescribing the vaccine to pregnant or breast-feeding women.
Ask your doctor, pharmacist or nurse for advice before taking any medicine.

Driving and using machines
HBVAXPRO is expected to have no, or negligible, influence on the ability to drive and use machines.

HBVAXPRO 5 micrograms contains sodium: This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium- free'.

3. How HBVAXPRO 5 micrograms is given

Dosage

The recommended dose for each injection (0.5 ml) is 5 micrograms for individuals from birth through 15 years of age.

A course of vaccination should include at least three injections.

Two immunisation schedules can be recommended:
- two injections with an interval of one month followed by a third injection 6 months after the first administration (0,1,6 months).
- if immunity is needed quickly: three injections with an interval of one month and a fourth dose 1 year later (0,1,2,12 months).

In case of a recent exposure to the hepatitis B virus, a first dose of HBVAXPRO together with the appropriate dose of immunoglobulin can be given.

Some local vaccination schedules currently include recommendations for a booster dose. Your doctor, pharmacist or nurse will inform you if a booster dose should be given.

Method of administration

The vial should be well shaken until a slightly opaque white suspension is obtained.
Once the vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial must be discarded.
The doctor or nurse will give the vaccine as an injection into muscle. The upper side of the thigh is the preferred site for injection in neonates and infants. The upper arm muscle is the preferred site for injection in children and adolescents.

This vaccine should never be given into a blood vessel.

Exceptionally, the vaccine may be administered subcutaneously in patients with thrombocytopoenia (diminution of blood platelets) or to persons at risk of haemorrhage.

If you or your child forget one dose of HBVAXPRO 5 micrograms

If you or your child miss a scheduled injection, talk to your doctor, pharmacist or nurse. Your doctor or nurse will decide when to give the missed dose.

If you or your child have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

As with other hepatitis B vaccines, in many instances, the causal relationship of side effects to the vaccine has not been established.

The most common side effects seen are injection-site reactions: soreness, redness and hardening.

Other side effects are reported very rarely:

- Low platelet count, Lymph node disease
- Allergic reactions
- Nervous system disorders such as pins and needles, Facial paralysis, Nerve inflammations including Guillain-Barre Syndrome, Inflammation of the nerve of the eye that leads to impaired vision, Brain inflammation, Exacerbation of multiple sclerosis, Multiple sclerosis, Convulsions, Headache, Dizziness and Fainting
- Low blood pressure, Blood vessel inflammation
- Asthma-like symptoms
- Vomiting, Nausea, Diarrhoea, Abdominal pain
- Skin reactions such as eczema, Rash, Itching, Hives and Skin blistering, Hair loss
- Joint pain, Arthritis, Muscle pain, Pain in extremity
- Fatigue, Fever, Vague illness, Flu-like symptoms
- Elevation of liver enzymes
- Inflammation of the eye which causes pain and redness

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store HBVAXPRO 5 micrograms

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the label.

Store in a refrigerator between 2°C and 8°C.
Do not freeze.

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What HBVAXPRO 5 micrograms contains

The active substance is :
Hepatitis B virus surface antigen, recombinant (HBsAg) * ..... 5 micrograms
Adsorbed on amorphous aluminium hydroxyphosphate sulfate (0.25 milligram Al^{+})

* produced in *Saccharomyces cerevisiae* (strain 2150-2-3) yeast by recombinant DNA technology.

The other ingredients are sodium chloride, borax and water for injections.

What HBVAXPRO 5 micrograms looks like and contents of the pack

HBVAXPRO 5 micrograms is a suspension for injection in a vial.
Pack sizes of 1 and 10 vials without syringe/needle.
Pack size of 1 vial with syringe and needle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
MSD VACCINS
162 avenue Jean Jaurès
69007 Lyon
France

Manufacturer Responsible for Batch Release:
Merck Sharp and Dohme, B.V.
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For any information about this vaccine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved in {MM/YYYY}.

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

The following information is intended for medical or health care professionals only:

Instructions

The vaccine should be inspected visually prior to administration for any foreign particulate matter and/or abnormal physical appearance. The vial should be well shaken until a slightly opaque white suspension is obtained.