Package leaflet: Information for the user

HBVAXPRO® 40 micrograms, suspension for injection
Hepatitis B vaccine (rDNA)

Read all of this leaflet carefully before you are vaccinated because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you 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 40 micrograms is and what it is used for
2. What you need to know before you receive HBVAXPRO 40 micrograms
3. How HBVAXPRO 40 micrograms is given
4. Possible side effects
5. How to store HBVAXPRO 40 micrograms
6. Contents of the pack and other information

1. What HBVAXPRO 40 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 predialysis and dialysis adult patients.

It can be expected that hepatitis D will also be prevented by immunisation with HBVAXPRO as hepatitis D (caused by the delta agent) 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 use HBVAXPRO 40 micrograms

Do not use HBVAXPRO 40 micrograms
- if you are allergic to hepatitis B surface antigen or to any of the other ingredients of HBVAXPRO (see section 6.)
- if you have 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 receive HBVAXPRO 40 micrograms.

Other vaccines and HBVAXPRO 40 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 can be administered at the same time as with other vaccines, using separate sites and syringes.

Tell your doctor, pharmacist or nurse if you are taking or have 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 40 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 40 micrograms is given

Dosage

The recommended dose for each injection (1 ml) is 40 micrograms for predialysis and dialysis adult patients

A course of vaccination should include three injections.

The schedule is two injections with an interval of one month followed by a third injection 6 months after the first administration (0, 1, 6 months).

A booster dose must be considered in these vaccinees if the antibody level against hepatitis B virus surface antigen is less than 10 IU/l.

Method of administration

The vial should be well shaken until a slightly opaque white suspension is obtained.
The doctor or nurse will give the vaccine as an injection into muscle. The upper arm muscle is the preferred site for injection in adults.

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 forget one dose of HBVAXPRO 40 micrograms

If you 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 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

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store HBVAXPRO 40 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 40 micrograms contains

The active substance is:
Hepatitis B virus surface antigen, recombinant (HBsAg) * ..... 40 micrograms
Adsorbed on amorphous aluminium hydroxyphosphate sulfate (0.50 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 40 micrograms looks like and contents of the pack

HBVAXPRO 40 micrograms is a suspension for injection in a vial.
Pack size of 1 vial.

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.
Waarderweg, 39
2031 BN Haarlem
The Netherlands

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 January 2019.

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

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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.