TWINRIX

Patient Information Leaflet

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

TWINRIX

Hepatitis A (inactivated) virus and recombinant-DNA hepatitis B virus surface antigen.

Suspension for injection.

Sugar-free.

Read all of this leaflet carefully before you or your child are vaccinated.

TWINRIX is not for self-medication and must be administered by a healthcare professional.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- TWINRIX has been prescribed for you or your child only and should not be shared with other people. It may harm them, even if their symptoms are the same as yours.

This leaflet has been written assuming the person receiving TWINRIX is reading it, but it can be given to adolescents and children so you may be reading it for your child.

WHAT TWINRIX CONTAINS:

Each 1,0 mL dose of vaccine contains 720 ELISA units of hepatitis A virus antigen and 20 µg of r-DNA hepatitis B virus surface antigen.

The other ingredients are: aluminium hydroxide, aluminium phosphate, sodium chloride and water for injections.

Aminoacids for injection, formaldehyde, neomycin sulphate, polysorbate 20, residual tris and phosphate buffer are all present in tiny amounts.

WHAT TWINRIX IS USED FOR:

TWINRIX is a vaccine used to prevent hepatitis A and hepatitis B disease in adults and children aged from 1 year upwards. The vaccine works by causing the body to make its own protection (antibodies) which protect against these diseases. This vaccine can also protect against hepatitis D, as hepatitis D does not occur in the absence of hepatitis B infection.

People with a weakened immune system (such as due to HIV infection) may not get the full benefit from TWINRIX.

BEFORE YOU ARE GIVEN TWINRIX:

You should not be given TWINRIX:

- if you have previously had an allergic reaction to TWINRIX, or any ingredient contained in this vaccine. The active substance and other ingredients in TWINRIX are listed at the beginning of this leaflet
- if you have previously had an allergic reaction to any vaccine against hepatitis A and hepatitis B
- if you have a severe infection with a high temperature. In these cases, the vaccination will be postponed until after recovery. A minor infection such as a cold should not be a problem but talk to your doctor first.

Take special care with TWINRIX:

- if you are on dialysis for kidney disease

- if you have an illness which may affect the immune system
- if you have a bleeding problem or bruise(s) easily.

Fainting can occur following, or even before, any needle injection, therefore, tell a doctor or the nurse if you fainted with a previous injection.

If you have problems with your immune system, you may be given TWINRIX, but the vaccine may not protect you as well as those with normal immune systems. You may therefore need more doses of TWINRIX.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving this medicine.

Taking other medicines with TWINRIX:

Always tell your healthcare professional if you or your child are taking any other medicines. (This includes complementary or traditional medicines.)

TWINRIX can be given at the same time as other childhood vaccines. A different place for the injection will be used for each vaccine.

HOW TO RECEIVE TWINRIX:

Do not share medicines prescribed for you with any other person.

TWINRIX is used to vaccinate people from 1 year upwards. The dose is 1,0 mL.

The doctor or nurse will inject the recommended dose of vaccine.

TWINRIX is usually injected into the upper arm muscle in adults and older children or into the thigh muscle in young children. However, TWINRIX may be injected under the skin for patients with blood disorders.

The vaccine must never be injected into a vein.

If you missed a dose of TWINRIX:

It is important to follow the instructions from the doctor/nurse regarding return visits for further injections. If an additional (booster) dose is necessary, the doctor will tell you. If you forget to go back to the doctor at the scheduled time, ask the doctor for advice.

POSSIBLE SIDE EFFECTS:

TWINRIX can have side effects.

Very rarely, some people can have a serious allergic reaction to the vaccine. Contact your doctor or nurse immediately if you have any of the following side effects:

- itchy rash of the hands and feet
- swelling of the eyes and face
- difficulty in breathing or swallowing
- a sudden drop in blood pressure and loss of consciousness.

These reactions will usually occur before leaving the doctor's surgery. However, if any of the above happens, tell your doctor immediately or go to the nearest casualty department at your nearest hospital.

➔ These are all very serious side effects. If you have them, you may have had a very serious allergic reaction to TWINRIX.

Tell your doctor if you notice any of the following:

- **Frequent side effects**:
  - headache
  - pain and redness at the injection site
  - tiredness
  - feeling irritable
  - feeling drowsy

- diarrhoea, nausea and vomiting
- swelling at the injection site
- generally feeling unwell.

- **Less frequent side effects**:
  - upper respiratory tract infection
  - dizziness
  - aching muscles
  - fever more than 37,5 °C.

- **The following side effects can also occur:**
  - swollen glands in the neck, armpit or groin
  - loss of appetite
  - pins and needles
  - low blood pressure
  - rash, itching
  - joint pain
  - flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
  - allergic reactions: rashes that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing
  - severe headache with stiff neck and sensitivity to light
  - bleeding or bruising more easily than normal, purple or red brown spots visible through the skin

- paralysis, fits or seizures, loss of skin sensitivity to pain or touch, swelling or infection of the brain, numbness or weakness of the arms and legs, inflammation of nerves
- inflammation of some blood vessels
- purple or reddish-purple bumps on the skin, serious skin rashes, hives
- joint swelling, muscular weakness.

If any of these side effects get serious, please tell your doctor or pharmacist.

Not all side effects reported for TWINRIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using TWINRIX, please consult your doctor, pharmacist or other healthcare professional for advice.

STORING AND DISPOSING OF TWINRIX:

Store all medicines out of reach of children.

Store at +2 °C to +8 °C (in a refrigerator).

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

Do not freeze. Discard if vaccine has been frozen.

Do not use after the expiry date stated on the label and packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRESENTATION OF TWINRIX:

Available as a single dose of 1,0 mL suspension in a pre-filled syringe (type I glass) with a plunger stopper (bromobutyl rubber) and with a rubber tip cap.

The tip cap and rubber plunger stopper of the pre-filled syringe are not made with natural rubber latex.

IDENTIFICATION OF TWINRIX:

A clear glass syringe containing a turbid liquid after shaking with a slow settling white deposit. The supernatant is colourless. The precipitate is easily brought into suspension when shaken.

REGISTRATION NUMBER:

32/30.1/0244

NAME AND ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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