

PACKAGE LEAFLET

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Read all of this leaflet carefully before your child starts receiving this vaccine.

- Keep this leaflet until your child has finished the complete vaccination course. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This vaccine has been prescribed for your child and should not be passed on to others.

In this leaflet:

1. What Tritanrix HepB is and what it is used for
2. Before your child receives Tritanrix HepB
3. How Tritanrix HepB is given
4. Possible side effects
5. Storing Tritanrix HepB
6. Further information

Tritanrix HepB, Suspension for injection

Diphtheria, tetanus, inactivated whole cell pertussis (whooping cough) and hepatitis B recombinant, adsorbed vaccine.

- The active substances contained in 1 dose (0.5 ml) of Tritanrix HepB are:

Diphtheria toxoid*	≥ 30 IU
Tetanus toxoid*	≥ 60 IU
Inactivated <i>Bordetella pertussis</i> strain**	≥ 4 IU
Hepatitis B virus surface Antigen recombinant **(S protein)***	10 micrograms

* adsorbed on aluminium oxide hydrated Total: 0.26 milligrams Al³⁺

** adsorbed on aluminium phosphate Total: 0.37 milligrams Al³⁺

*** produced on genetically-engineered yeast cells (*Saccharomyces cerevisiae*)

- The other ingredients in the vaccine are: aluminium oxide hydrated, aluminium phosphate, phenoxyethanol, sodium chloride, thiomersal and water for injections.

Marketing authorisation holder and Manufacturer: GlaxoSmithKline Biologicals s.a.
Rue de l'Institut 89
B-1330 Rixensart
Belgium

1. WHAT TRITANRIX HepB IS AND WHAT IT IS USED FOR

Tritanrix HepB is presented as a suspension for injection in a monodose vial (0.5 ml) – pack size of 1. The suspension is white and milky.

Tritanrix HepB is a vaccine used in children to prevent four diseases: diphtheria, tetanus (lockjaw), pertussis (whooping cough) and hepatitis B. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

- **Diphtheria:** Diphtheria mainly affects the airways and sometimes the skin. Generally the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The

bacteria also release a toxin (poison), which can cause nerve damage, heart problems, and even death.

- **Tetanus** (Lockjaw): Tetanus bacteria enter the body through cuts, scratches or wounds in the skin. Wounds that are especially prone to infection are burns, fractures, deep wounds or wounds contaminated with soil, dust, horse manure/dung or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and even death. The muscle spasms can be strong enough to cause bone fractures of the spine.
- **Pertussis** (Whooping cough): Pertussis is a highly infectious illness. The disease affects the airways causing severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a “whooping” sound, hence the common name “whooping cough”. The cough may last for 1-2 months or longer. Pertussis can also cause ear infections, bronchitis which may last a long time, pneumonia, fits, brain damage and even death.
- **Hepatitis B**: Hepatitis B is caused by the hepatitis B virus. It causes the liver to become swollen (inflamed). The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva (spit) of infected people.

Vaccination is the best way to protect against these diseases. None of the components in the vaccine are infectious.

2. BEFORE YOUR CHILD RECEIVES TRITANRIX HepB

You must tell your doctor:

- if your child has experienced any health problems after previous administration of a vaccine.
- if your child has previously had any allergic reaction to Tritanrix HepB, or any ingredient contained in this vaccine. The active substances and other ingredients in Tritanrix HepB are listed at the beginning of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- if your child has previously had an allergic reaction to any vaccine against diphtheria, tetanus, pertussis (whooping cough) or hepatitis B diseases.
- if your child experienced problems of the nervous system within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.
- if your child has a severe infection with a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.
- if your child has any known allergies.

IN THE ABOVE CASES, TRITANRIX HepB SHOULD NOT BE GIVEN TO YOUR CHILD.

Also, tell your doctor:

- if after previously having Tritanrix HepB or another vaccine against pertussis (whooping cough) disease, your child had any problems, especially:
 - ◆ A high temperature (over 40°C) within 48 hours of vaccination
 - ◆ A collapse or shock-like state within 48 hours of vaccination
 - ◆ Persistent crying lasting 3 hours or more within 48 hours of vaccination
 - ◆ Seizures/fits with or without a high temperature within 3 days of vaccination
- if your child has a bleeding problem or bruises easily
- if your child has a tendency to seizures/fits due to a fever, or if there is a history in the family of this
- if your child is taking any other medicine or has recently received any other vaccine.

In these cases, your doctor can determine the right time and scheme of vaccination for your child.

3. HOW TRITANRIX HepB IS GIVEN

Your child will receive a total of three injections with an interval of at least one month between each one. Each injection is given on a separate visit. You will be informed by the doctor or nurse when you should come back for subsequent injections.

If additional injections are necessary, the doctor will tell you.

If your child misses a scheduled injection, talk to your doctor and arrange another visit.

Make sure your child finishes the complete vaccination course of three injections. If not, your child may not be fully protected against the diseases.

The doctor will give Tritanrix HepB as an injection into the muscle.

The vaccine should never be given into a vein.

4. POSSIBLE SIDE EFFECTS

Any vaccine may have some side effects.

Your child may feel:

- ◆ pain or discomfort at the injection site

or you may see some:

- ◆ redness or swelling at the injection site.

However, these effects usually clear up within a few days.

Other side effects which can occur are:

- ◆ feeding problems, gastrointestinal symptoms such as vomiting, diarrhoea
- ◆ Fever (more than 38°C)
- ◆ Drowsiness, irritability, unusual crying

If these events continue or become severe, tell your doctor.

As with all injectable vaccines, there is an extremely small risk of allergic reactions. These can be recognised by:

- ◆ Itchy rash of the hands and feet
 - ◆ Swelling of the eyes and face
 - ◆ Difficulty in breathing or swallowing
- Such reactions will usually occur before leaving the doctor's surgery. However, you should seek immediate treatment in any event.

Tritanrix HepB contains a hepatitis B component, to provide protection against disease caused by hepatitis B virus. The following undesirable events have occurred very rarely following the administration of hepatitis B containing vaccines :

- ◆ seizures or fits
- ◆ bleeding or bruising more easily than normal

This medicinal product contains thiomersal as a preservative and it is possible that your child may experience an allergic reaction.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. It is possible that your child will have no side effects from vaccination.

5. STORING TRITANRIX HepB

Store at 2°C and 8°C (in a refrigerator)
Store in the original package in order to protect from light.
Do not freeze. Freezing destroys the vaccine.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the pack. The date for last use corresponds to the last day of the month mentioned.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation holder.

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This leaflet was last approved on

The following information is intended for medical or healthcare professionals only:

Tritanrix HepB can be mixed with the lyophilised Hib vaccine (Hiberix).

Upon storage, a white deposit and clear supernatant can be observed. This does not constitute a sign of deterioration.

The vaccine should be well shaken in order to obtain a homogeneous turbid white suspension and be inspected visually for any foreign particulate matter and/or variation of physical aspect. In the event of either being observed, discard the container.

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6. Further information

Tritanrix HepB, Suspension for injection, multidose

Diphtheria, tetanus, inactivated whole cell pertussis (whooping cough) and hepatitis B recombinant, adsorbed vaccine.

- The active substances contained in 1 ml (2 doses) of Tritanrix HepB are:

Diphtheria toxoid*	≥ 30 IU
Tetanus toxoid*	≥ 60 IU
Inactivated <i>Bordetella pertussis</i> strain**	≥ 4 IU
Hepatitis B virus surface Antigen recombinant **(S protein)***	10 micrograms

* adsorbed on aluminium oxide hydrated Total: 0.26 milligrams Al³⁺

** adsorbed on aluminium phosphate Total: 0.37 milligrams Al³⁺

*** produced on genetically-engineered yeast cells (*Saccharomyces cerevisiae*)

per 0.5 ml

- The other ingredients in the vaccine are: aluminium oxide hydrated, aluminium phosphate, phenoxyethanol, sodium chloride, thiomersal and water for injections.

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B-1330 Rixensart
Belgium

1. WHAT TRITANRIX HepB IS AND WHAT IT IS USED FOR

Tritanrix HepB is presented as a suspension for injection in a multidose vial (2 x 0.5 ml) – pack size of 1.

The suspension is white and milky.

Tritanrix HepB is a vaccine used in children to prevent four diseases: diphtheria, tetanus (lockjaw), pertussis (whooping cough) and hepatitis B. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

- **Diphtheria:** Diphtheria mainly affects the airways and sometimes the skin. Generally the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The bacteria also release a toxin (poison), which can cause nerve damage, heart problems, and even death.
- **Tetanus (Lockjaw):** Tetanus bacteria enter the body through cuts, scratches or wounds in the skin. Wounds that are especially prone to infection are burns, fractures, deep wounds or wounds contaminated with soil, dust, horse manure/dung or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and even death. The muscle spasms can be strong enough to cause bone fractures of the spine.
- **Pertussis (Whooping cough):** Pertussis is a highly infectious illness. The disease affects the airways causing severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a “whooping” sound, hence the common name “whooping cough”. The cough may last for 1-2 months or longer. Pertussis can also cause ear infections, bronchitis which may last a long time, pneumonia, fits, brain damage and even death.
- **Hepatitis B:** Hepatitis B is caused by the hepatitis B virus. It causes the liver to become swollen (inflamed). The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva (spit) of infected people.

Vaccination is the best way to protect against these diseases. None of the components in the vaccine are infectious.

2. BEFORE YOUR CHILD RECEIVES TRITANRIX HepB

You must tell your doctor:

- if your child has experienced any health problems after previous administration of a vaccine.
- if your child has previously had any allergic reaction to Tritanrix HepB, or any ingredient contained in this vaccine. The active substances and other ingredients in Tritanrix HepB are listed at the beginning of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- if your child has previously had an allergic reaction to any vaccine against diphtheria, tetanus, pertussis (whooping cough) or hepatitis B diseases.
- if your child experienced problems of the nervous system within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.
- if your child has a severe infection with a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.
- if your child has any known allergies.

IN THE ABOVE CASES, TRITANRIX HepB SHOULD NOT BE GIVEN TO YOUR CHILD.

Also, tell your doctor:

- if after previously having Tritanrix HepB or another vaccine against pertussis (whooping cough) disease, your child had any problems, especially:
 - ◆ A high temperature (over 40°C) within 48 hours of vaccination
 - ◆ A collapse or shock-like state within 48 hours of vaccination
 - ◆ Persistent crying lasting 3 hours or more within 48 hours of vaccination
 - ◆ Seizures/fits with or without a high temperature within 3 days of vaccination
- if your child has a bleeding problem or bruises easily
- if your child has a tendency to seizures/fits due to a fever, or if there is a history in the family of this
- if your child is taking any other medicine or has recently received any other vaccine.

In these cases, your doctor can determine the right time and scheme of vaccination for your child.

3. HOW TRITANRIX HepB IS GIVEN

Your child will receive a total of three injections with an interval of at least one month between each one. Each injection is given on a separate visit. You will be informed by the doctor or nurse when you should come back for subsequent injections.

If additional injections are necessary, the doctor will tell you.

If your child misses a scheduled injection, talk to your doctor and arrange another visit.

Make sure your child finishes the complete vaccination course of three injections. If not, your child may not be fully protected against the diseases.

The doctor will give Tritanrix HepB as an injection into the muscle.

The vaccine should never be given into a vein.

4. POSSIBLE SIDE EFFECTS

Any vaccine may have some side effects.

Your child may feel:

- ◆ pain or discomfort at the injection site

or you may see some:

- ◆ redness or swelling at the injection site.

However, these effects usually clear up within a few days.

Other side effects which can occur are:

- ◆ feeding problems, gastrointestinal symptoms such as vomiting, diarrhoea
- ◆ Fever (more than 38°C)
- ◆ Drowsiness, irritability, unusual crying

If these events continue or become severe, tell your doctor.

As with all injectable vaccines, there is an extremely small risk of allergic reactions. These can be recognised by:

- ◆ Itchy rash of the hands and feet
 - ◆ Swelling of the eyes and face
 - ◆ Difficulty in breathing or swallowing
- Such reactions will usually occur before leaving the doctor's surgery. However, you should seek immediate treatment in any event.

Tritanrix HepB contains a hepatitis B component, to provide protection against disease caused by hepatitis B virus. The following undesirable events have occurred very rarely following the administration of hepatitis B containing vaccines :

- ◆ seizures or fits
- ◆ bleeding or bruising more easily than normal

This medicinal product contains thiomersal as a preservative and it is possible that your child may experience an allergic reaction.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. It is possible that your child will have no side effects from vaccination.

5. STORING TRITANRIX HepB

Store at 2°C and 8°C (in a refrigerator)

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

Do not freeze. Freezing destroys the vaccine.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the pack. The date for last use corresponds to the last day of the month mentioned.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation holder.

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The following information is intended for medical or healthcare professionals only:

Tritanrix HepB can be mixed with the lyophilised Hib vaccine (Hiberix).

Upon storage, a white deposit and clear supernatant can be observed. This does not constitute a sign of deterioration.

The vaccine should be well shaken in order to obtain a homogeneous turbid white suspension and be inspected visually for any foreign particulate matter and/or variation of physical aspect. In the event of either being observed, discard the container.

When using a multidose vial, each dose should be taken with a sterile needle and syringe. As with other vaccines, a dose of vaccine should be withdrawn under strict aseptic conditions and precautions taken to avoid contamination of the contents.

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- If you have further questions, please ask your doctor or your pharmacist.
- This vaccine has been prescribed for your child and should not be passed on to others.

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3. How Tritanrix HepB is given
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5. Storing Tritanrix HepB
6. Further information

Tritanrix HepB, Suspension for injection, multidose

Diphtheria, tetanus, inactivated whole cell pertussis (whooping cough) and hepatitis B recombinant, adsorbed vaccine.

- The active substances contained in 5 ml (10 doses) of Tritanrix HepB are:

Diphtheria toxoid*	≥ 30 IU
Tetanus toxoid*	≥ 60 IU
Inactivated <i>Bordetella pertussis</i> strain**	≥ 4 IU
Hepatitis B virus surface Antigen recombinant **(S protein)***	10 micrograms

* adsorbed on aluminium oxide hydrated Total: 0.26 milligrams Al³⁺

** adsorbed on aluminium phosphate Total: 0.37 milligrams Al³⁺

*** produced on genetically-engineered yeast cells (*Saccharomyces cerevisiae*)

per 0.5 ml

- The other ingredients in the vaccine are: aluminium oxide hydrated, aluminium phosphate, phenoxyethanol, sodium chloride, thiomersal and water for injections.

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Belgium

1. WHAT TRITANRIX HepB IS AND WHAT IT IS USED FOR

Tritanrix HepB is presented as a suspension for injection in a multidose vial (10 x 0.5 ml) – pack size of 1.

The suspension is white and milky.

Tritanrix HepB is a vaccine used in children to prevent four diseases: diphtheria, tetanus (lockjaw), pertussis (whooping cough) and hepatitis B. The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

- **Diphtheria:** Diphtheria mainly affects the airways and sometimes the skin. Generally the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The bacteria also release a toxin (poison), which can cause nerve damage, heart problems, and even death.
- **Tetanus (Lockjaw):** Tetanus bacteria enter the body through cuts, scratches or wounds in the skin. Wounds that are especially prone to infection are burns, fractures, deep wounds or wounds contaminated with soil, dust, horse manure/dung or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and even death. The muscle spasms can be strong enough to cause bone fractures of the spine.
- **Pertussis (Whooping cough):** Pertussis is a highly infectious illness. The disease affects the airways causing severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a “whooping” sound, hence the common name “whooping cough”. The cough may last for 1-2 months or longer. Pertussis can also cause ear infections, bronchitis which may last a long time, pneumonia, fits, brain damage and even death.
- **Hepatitis B:** Hepatitis B is caused by the hepatitis B virus. It causes the liver to become swollen (inflamed). The virus is found in body fluids such as blood, semen, vaginal secretions, or saliva (spit) of infected people.

Vaccination is the best way to protect against these diseases. None of the components in the vaccine are infectious.

2. BEFORE YOUR CHILD RECEIVES TRITANRIX HepB

You must tell your doctor:

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- if your child experienced problems of the nervous system within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease.
- if your child has a severe infection with a high temperature (over 38°C). A minor infection such as a cold should not be a problem, but talk to your doctor first.
- if your child has any known allergies.

IN THE ABOVE CASES, TRITANRIX HepB SHOULD NOT BE GIVEN TO YOUR CHILD.

Also, tell your doctor:

- if after previously having Tritanrix HepB or another vaccine against pertussis (whooping cough) disease, your child had any problems, especially:
 - ◆ A high temperature (over 40°C) within 48 hours of vaccination
 - ◆ A collapse or shock-like state within 48 hours of vaccination
 - ◆ Persistent crying lasting 3 hours or more within 48 hours of vaccination
 - ◆ Seizures/fits with or without a high temperature within 3 days of vaccination
- if your child has a bleeding problem or bruises easily
- if your child has a tendency to seizures/fits due to a fever, or if there is a history in the family of this
- if your child is taking any other medicine or has recently received any other vaccine.

In these cases, your doctor can determine the right time and scheme of vaccination for your child.

3. HOW TRITANRIX HepB IS GIVEN

Your child will receive a total of three injections with an interval of at least one month between each one. Each injection is given on a separate visit. You will be informed by the doctor or nurse when you should come back for subsequent injections.

If additional injections are necessary, the doctor will tell you.

If your child misses a scheduled injection, talk to your doctor and arrange another visit.

Make sure your child finishes the complete vaccination course of three injections. If not, your child may not be fully protected against the diseases.

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The vaccine should never be given into a vein.

4. POSSIBLE SIDE EFFECTS

Any vaccine may have some side effects.

Your child may feel:

- ◆ pain or discomfort at the injection site

or you may see some:

- ◆ redness or swelling at the injection site.

However, these effects usually clear up within a few days.

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- ◆ feeding problems, gastrointestinal symptoms such as vomiting, diarrhoea
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If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. It is possible that your child will have no side effects from vaccination.

5. STORING TRITANRIX HepB

Store at 2°C and 8°C (in a refrigerator)

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

Do not freeze. Freezing destroys the vaccine.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the pack. The date for last use corresponds to the last day of the month mentioned.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation holder.

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The following information is intended for medical or healthcare professionals only:

Tritanrix HepB can be mixed with the lyophilised Hib vaccine (Hiberix).

Upon storage, a white deposit and clear supernatant can be observed. This does not constitute a sign of deterioration.

The vaccine should be well shaken in order to obtain a homogeneous turbid white suspension and be inspected visually for any foreign particulate matter and/or variation of physical aspect. In the event of either being observed, discard the container.

When using a multidose vial, each dose should be taken with a sterile needle and syringe. As with other vaccines, a dose of vaccine should be withdrawn under strict aseptic conditions and precautions taken to avoid contamination of the contents.