

PACKAGE LEAFLET: INFORMATION FOR THE USER**Rotarix®, powder and solvent for oral suspension**

Rotavirus vaccine, live

Read all of this leaflet carefully before your child receives this vaccine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for your child. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Rotarix® is and what it is used for
2. Before your child receives Rotarix®
3. How Rotarix® is given
4. Possible side effects
5. How to store Rotarix®
6. Further information

1. WHAT ROTARIX® IS AND WHAT IT IS USED FOR

Pharmaco-therapeutic group: viral vaccines, ATC code: J07BH01

Rotarix® is a viral vaccine, containing live, attenuated human rotavirus, that helps to protect your child against gastro-enteritis (diarrhoea and vomiting) caused by rotavirus infection.

Rotavirus infection is the most common cause of severe diarrhoea in infants and young children. Rotavirus is easily spread from hand-to-mouth due to contact with stools from an infected person. Most children with rotavirus diarrhoea recover on their own. However, some children become very ill with severe vomiting, diarrhoea and life-threatening loss of fluids that requires hospitalisation. Rotavirus infections are responsible for hundreds of thousands of deaths worldwide every year especially in developing countries, where nutrition and health care are not optimal.

When a person is given the vaccine, the immune system (the body's natural defences) will make antibodies against the most commonly occurring types of rotavirus. These antibodies protect against disease caused by these types of rotavirus.

As with all vaccines, Rotarix® may not completely protect all people who are vaccinated against the rotavirus infections it is intended to prevent.

2. BEFORE YOUR CHILD RECEIVES ROTARIX®**Rotarix® should not be given:**

- if your child has previously had any allergic reaction to rotavirus vaccines or any component contained in Rotarix®. The active substances and other ingredients in Rotarix® are listed at the end 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 intussusception (a bowel obstruction in which one segment of bowel becomes enfolded within another segment).
- if your child was born with a malformation of the gastrointestinal system that would predispose for intussusception.
- if your child has any disease which reduces his/her resistance to infection.
- if your child has a severe infection with a high temperature. It might be necessary to postpone the vaccination until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- if your child has diarrhoea or is vomiting. It might be necessary to postpone the vaccination until recovery.

Take special care with Rotarix®

Excretion of the live vaccine virus in the stools of vaccinated children is known to occur after vaccination, especially around the 7th day. Persons in contact with recent vaccinated children should wash their hands after changing the child's nappies.

Rotarix® should be given with caution to children in close contacts with individuals having any disease or receiving any medicine which may reduce his/her resistance to infection.

A lower immune response (reduced ability of the body to respond to the vaccine) may be observed when Rotarix® is given to premature children.

Rotarix® should be given with caution to children with disorders of the stomach or intestines or children with growth retardation.

Using other vaccines

Please tell your doctor if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription or has recently received any other vaccine.

Rotarix® may be given at the same time your child receives other normally recommended vaccinations, such as diphtheria, tetanus, pertussis (whooping cough), *Haemophilus influenzae* type b, oral or inactivated polio, hepatitis B and pneumococcal vaccines.

Using Rotarix® with food and drink

There are no restrictions on your child's consumption of food or liquids, either before or after vaccination.

Breast-feeding

There is no evidence available to suggest that breast-feeding would reduce the protection against rotavirus gastro-enteritis afforded by Rotarix®. Therefore, breast-feeding may be continued during the vaccination schedule.

Important information about some of the ingredients of Rotarix®

If you have been told by your doctor that the child being vaccinated

has an intolerance to some sugars, contact your doctor before using this vaccine.

3. HOW ROTARIX® IS GIVEN

The doctor or nurse will administer the recommended dose of Rotarix® to your child. The vaccine (1 ml liquid) will be given orally. Under no circumstance should this vaccine be administered by injection.

Your child will receive two doses of the vaccine. Each dose will be given on a separate occasion with an interval of at least 4 weeks between the two doses. The first dose may be given from the age of 6 weeks. The two doses of the vaccine must have been given by the age of 24 weeks, although they should preferably have been given before 16 weeks of age.

In case your child spits out or regurgitates most of the vaccine dose, a single replacement dose may be given at the same vaccination visit.

When Rotarix® is given to your child for the first dose, it is recommended that your child also receives Rotarix® (and not another rotavirus vaccine) for the second dose.

It is important that you follow the instructions of your doctor or nurse regarding return visits. If you forget to go back to your doctor at the scheduled time, ask your doctor for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rotarix® can cause side effects, although not everybody gets them.

Side effects that occurred during clinical trials with Rotarix® were as follows:

- ◆ Very common (side effects which may occur in equal or more than 1 per 10 doses of vaccine):
 - loss of appetite
 - irritability
- ◆ Common (side effects which may occur in less than 1 per 10 but equal or more than 1 per 100 doses of vaccine):
 - fever, fatigue
 - diarrhoea, vomiting, regurgitation of food, flatulence, abdominal pain
- ◆ Uncommon (side effects which may occur in less than 1 per 100 but equal or more than 1 per 1,000 doses of vaccine):
 - crying
 - sleep disorder, sleepiness
 - constipation
- ◆ Rare (side effects which may occur in less than 1 per 1,000 but equal or more than 1 per 10,000 doses of vaccine):
 - upper respiratory tract infection, hoarseness, runny nose
 - dermatitis, rash
 - muscle cramp

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ROTARIX®

Keep out of the reach and sight of children.

Do not use Rotarix® after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Do not freeze.

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

After reconstitution, the vaccine contained in the syringe should be administered promptly. If the reconstituted vaccine is not used within 24 hours, it should be discarded.

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.

6. FURTHER INFORMATION**What Rotarix® contains**

- The active substances are:

Human rotavirus RIX4414 strain (live attenuated)*
not less than 10^{6.0} CCID₅₀

*Produced on Vero cells

- The other ingredients in Rotarix® are:

Powder: sucrose, dextran, sorbitol, amino acids, Dulbecco's Modified Eagle Medium (DMEM)

Solvent: calcium carbonate, xanthan gum, sterile water

What Rotarix® looks like and contents of the pack

Powder and solvent for oral suspension

Rotarix® is supplied as a whitish powder in a single dose glass vial and a separate pre-filled syringe of solvent which contains a slow settling white deposit and a colourless supernatant. There is also a transfer adapter which allows easy transfer of the solvent into the vial containing the powder for mixing the different components of the vaccine.

Both components must be mixed together before your child receives the vaccine. The mixed vaccine will appear more turbid than the solvent alone.

Rotarix® is available in a pack of 1, 5, 10 or 25.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

GlaxoSmithKline Biologicals s.a.

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This leaflet was last approved in March 2006

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.eu.int/>

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

A white deposit and clear supernatant is observed upon storage of the syringe containing the solvent. The solvent should be inspected visually both before and after shaking for any foreign particulate matter and/or abnormal physical appearance prior to reconstitution.

The reconstituted vaccine is slightly more turbid than the solvent and is milky white in appearance.

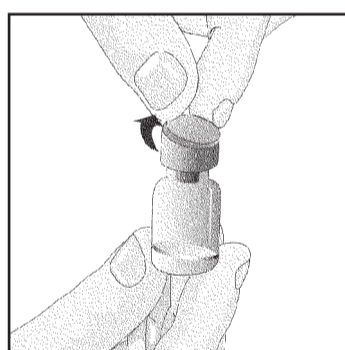
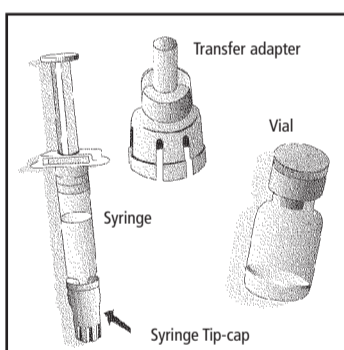
The reconstituted vaccine should also be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, discard the vaccine. Any unused vaccine or waste material should be disposed of in accordance with local requirements.

Instructions for reconstitution and administration of the vaccine:

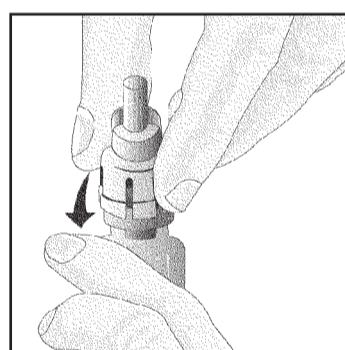
1. Remove the plastic cover from the vial containing the powder.
2. Connect the transfer adapter onto the vial by pushing it downwards until the transfer adapter is properly and securely placed.
3. Shake the syringe containing the solvent vigorously. The shaken suspension will appear as a turbid liquid with a slow settling white deposit.

4. Remove the protective tip cap from the syringe.
5. Connect the syringe into the transfer adapter by pushing it firmly on this device.
6. Inject the entire content of the syringe into the vial containing the powder.
7. With the syringe still attached, shake the vial and examine it for complete suspension of the powder. The reconstituted vaccine will appear more turbid than the solvent alone. This appearance is normal.
8. Withdraw the entire mixture back into the syringe.
9. Remove the syringe from the transfer adapter.
10. This vaccine is for **oral administration only**. The child should be seated in a reclining position. Administer the entire content of the syringe **ORALLY** (by administering the entire content of the syringe on the inside of the cheek). **Do not inject**.

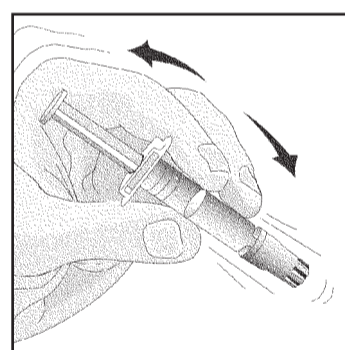
If the reconstituted vaccine is to be stored temporarily before administration, replace the protective tip cap on the syringe. The syringe containing the reconstituted vaccine should be shaken gently again before **ORAL** administration. **Do not inject**.



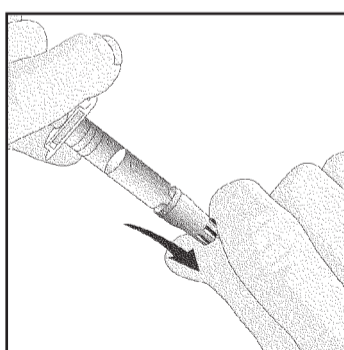
1. Remove the plastic cover from the vial containing the lyophilised powder.



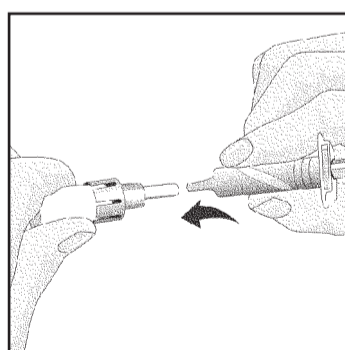
2. Connect the transfer adapter onto the vial by pushing it downwards until the transfer adapter is positioned securely on the top of the vial.



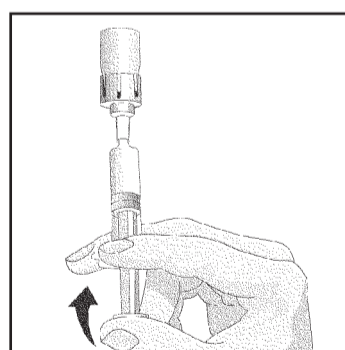
3. Shake the syringe containing the suspension vigorously. The shaken suspension will appear as a turbid liquid with a slow settling white deposit.



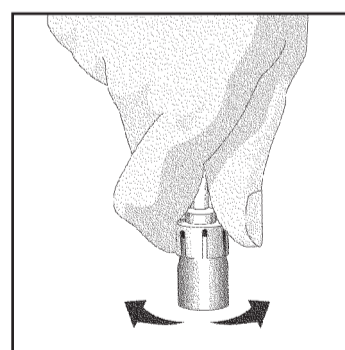
4. Remove the protective tip cap from the syringe.



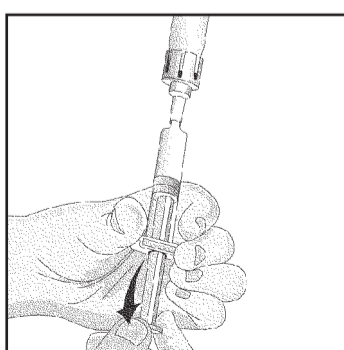
5. Connect the syringe into the transfer adapter by pushing it firmly on this device.



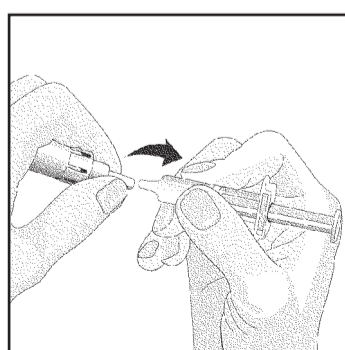
6. Inject the entire content of the syringe into the vial containing the lyophilised powder.



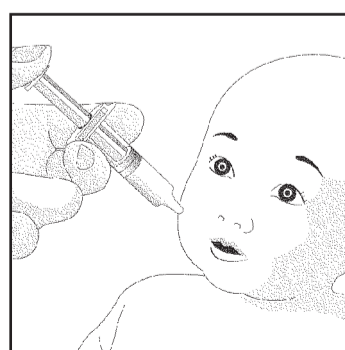
7. With the syringe still attached, shake the vial and examine it for complete suspension of the powder. The reconstituted vaccine will appear turbid. This appearance is normal.



8. Withdraw the entire mixture back into the syringe.



9. Remove the syringe from the transfer adapter.



10. Administer the entire content of the syringe orally (on the inside of the cheek). The child should be seated in a reclining position. **Do not inject**.