ROTARIX

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about your child receiving this vaccine, speak to your doctor or nurse.

1. Why is my child receiving ROTARIX?

ROTARIX is a live vaccine used to protect your child against gastroenteritis (diarrhoea and vomiting) caused by rotavirus RIX4414 strain. The vaccine works by causing the body to produce its own protection (antibodies) against this disease.

For more information, see Section 1. Why is my child receiving ROTARIX? in the full CMI.

2. What should I know before my child receives ROTARIX?

Your child should not receive ROTARIX if they have had a previous allergic reaction to ROTARIX or to any of the ingredients listed at the end of the CMI.

Talk to your doctor or nurse if your child has any other medical conditions including a history of chronic gastrointestinal disease, a rare illness affecting their immune system known as Severe Combined Immunodeficiency (SCID) or has a severe infection.

For more information, see Section 2. What should I know before my child receives ROTARIX? in the full CMI.

3. What if my child is taking other medicines?

Some medicines may interfere with ROTARIX and affect how it works.

A list of these medicines is in Section 3. What if my child is taking other medicines? in the full CMI.

4. How does my child receive ROTARIX?

- Your doctor or nurse will administer ROTARIX to your child.
- The dose is 1.5 mL given into your child's mouth.
- Your child will receive 2 doses of ROTARIX. Each dose is given on a separate day with an interval of at least 4 weeks between them.

More instructions can be found in Section 4. How does my child receive ROTARIX? in the full CMI.

5. What should I know after my child receives ROTARIX?

Things you should do	• Keep a record of your child's vaccination history. • Wash your hands immediately after changing nappies and before you prepare and eat food. • Continue to feed your child as normal. There are no restrictions on feeding your child, including breast milk, before or after vaccination with ROTARIX.
Looking after your vaccine	• ROTARIX will usually be kept at the doctor's clinic or in the pharmacy. • If you need to store it, keep it in the refrigerator between 2°C and 8°C. Do not freeze. Protect from light.

For more information, see Section 5. What should I know after my child receives ROTARIX? in the full CMI.

6. Are there any side effects?

Side effects which have been reported following administration of ROTARIX include diarrhoea, vomiting, abdominal pain, constipation, regurgitation of food, flatulence, fever, chest infection, hoarseness, runny nose, a loss of appetite, dehydration, muscle cramps, feeling tired increased crying, irritability, dermatitis and rash.

If your child develops any symptoms suggestive of a blocked or twisted intestine such as severe abdominal pain, persistent vomiting, bloody stools, an abdominal mass you can feel, abdominal bloating or a high fever seek medical attention immediately.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ROTARIX

Active ingredient: *human rotavirus RIX4414 strain (live attenuated)*

Consumer Medicine Information (CMI)

This leaflet provides important information about receiving ROTARIX. **You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about your child receiving ROTARIX.**

Where to find information in this leaflet:

1. Why is my child receiving ROTARIX?
2. What should I know before my child receives ROTARIX?
3. What if my child is taking other medicines?
4. How does my child receive ROTARIX?
5. What should I know after my child receives ROTARIX?
6. Are there any side effects?
7. Product details

1. Why is my child receiving ROTARIX?

ROTARIX is a vaccine used to protect your child against rotavirus infection.

Rotavirus infection is the most common cause of severe diarrhoea and vomiting in infants and young children.

Rotavirus is easily spread by hand-to-mouth contact with the stool of an infected person.

Most children with rotavirus diarrhoea recover on their own. Some children may become very unwell with severe vomiting, diarrhoea and life-threatening loss of fluids that requires hospitalisation.

ROTARIX is a live vaccine that contains the human rotavirus RIX4414 strain which is used to protect against rotavirus gastroenteritis (diarrhoea and vomiting).

The vaccine works by causing your body's natural defences (immune system) to produce its own protection (antibodies) against the most commonly occurring types of rotaviruses.

As with all vaccines, ROTARIX may not completely protect all people who are vaccinated against the disease it is intended to prevent. ROTARIX will not protect against other types of gastroenteritis caused by other types of viruses or organisms.

2. What should I know before my child receives ROTARIX?

Warnings

Your child should not receive ROTARIX if:

- they have had a previous allergic reaction to ROTARIX or any of the ingredients listed at the end of this leaflet. Signs of an allergic reaction include itchy skin rash, shortness of breath and swelling of the face or tongue. Always check the ingredients to make sure your child can receive this vaccine
- they have a history of chronic gastrointestinal disease or were born with a defect in the gastrointestinal system
- they have a rare inherited illness which affects their immune system called Severe Combined Immunodeficiency (SCID).

Check with your doctor or nurse if your child:

- has any other medical conditions
- has a severe infection with a high fever. In this case, vaccination with ROTARIX may be postponed. A minor infection such as a cold should not be a problem however talk to your doctor or nurse before vaccination
- currently has severe diarrhoea or is vomiting. In this case, vaccination may be postponed until your child has recovered. Talk to your doctor or nurse before vaccination
- takes any medicines for any other condition
- has previously had a part of their intestine blocked or has been twisted (intussusception).

If your child develops any symptoms suggestive of a blocked or twisted intestine such as severe abdominal pain, persistent vomiting, bloody stools, an abdominal mass you can feel, abdominal bloating or a high fever seek medical attention immediately.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

ROTARIX is not intended to be used in adolescents or adults, therefore use in pregnancy and when breastfeeding is unlikely.

3. What if my child is taking other medicines?

Tell your doctor or nurse if your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ROTARIX and affect how it works.

4. How does my child receive ROTARIX?

Your doctor or nurse will give your child the vaccine.

How much is given

- The dose of ROTARIX is 1.5 mL.

How is it given

- ROTARIX is given into the mouth.
- Under no circumstances should ROTARIX be injected.

When is ROTARIX given

- Your child will receive 2 doses of ROTARIX.
- Each dose is given on a separate day with an interval of at least 4 weeks between them.
- The first dose is usually given between 6 and 14 weeks of age. The second dose must be given by 24 weeks of age.

If you think your child has been given too much ROTARIX

As this vaccine is given by a doctor or nurse it is unlikely that your child will receive too much.

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

However, if you feel that your child has been given too much ROTARIX, you should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If your child misses a dose of ROTARIX

It is important that you follow the instructions from your doctor or nurse regarding return visits for the second dose.

If you forget to take your child for their second dose, talk to your doctor for advice.

5. What should I know after my child receives ROTARIX?

Things you should do

- Keep a record of your child's vaccination history.
- Wash your hands immediately after changing nappies and before you prepare and eat food.
- Continue to feed your child as normal. There are no restrictions on feeding your child, including breast milk, before or after vaccination with ROTARIX.

Call your doctor straight away if:

- your child experiences severe abdominal pain, persistent vomiting, bloody stools, an abdominal mass that you can feel, abdominal bloating or a high fever
- experiences wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash (hives) or faints. These could be symptoms of an allergic reaction.

Remind any doctor, nurse or pharmacist that you see for your child that they have recently been vaccinated with ROTARIX.

Looking after your vaccine

- ROTARIX will usually be stored at the doctor's clinic or at the pharmacy.
- If you need to store ROTARIX, it is important to keep it in the refrigerator between 2°C and 8°C.
- Keep ROTARIX in the carton to protect it from light.
- Do not freeze ROTARIX.

Follow the instructions in the carton on how to take care of your vaccine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

If your child no longer needs to receive this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not receive this vaccine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If your child does experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or nurse if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal disorders: • diarrhoea • vomiting • abdominal pain • constipation • regurgitation of food • flatulence **General disorders and administration site conditions:** • fever **Respiratory, thoracic and mediastinal disorders:** • chest infection • hoarseness • runny nose **Metabolism and nutrition disorders:** • loss of appetite • dehydration **Musculoskeletal disorders:** • muscle cramp **Nervous system disorders:** • feeling tired • increased crying • irritability **Skin and subcutaneous tissue disorders:** • dermatitis • rash	**Speak to your doctor if your child has any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Gastrointestinal disorders: • blockage and twisting of the intestines with signs such as severe stomach pain, persistent vomiting, blood in the stool, a swollen belly or a high fever **Immune system disorders:** • allergic reaction Symptoms of an allergic reaction include: • swelling of the limbs, face, eyes, inside of the nose, mouth or throat • shortness of breath, breathing or swallowing difficulties • hives, itching (especially of the hands or feet), reddening of the skin (especially around the ears) or severe skin reactions • unusual tiredness or weakness that is sudden and severe	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or nurse if you notice anything else that may be making your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

7. Product details

What ROTARIX contains

Active ingredient (main ingredient)	live attenuated human rotavirus strain RIX4414
Other ingredients (inactive ingredients)	• adipic acid • Dulbecco's modified eagle medium (contains phenylalanine) • sodium hydroxide • sucrose • water for injections

Your child should not receive this vaccine if they are allergic to any of these ingredients.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine

spongiform encephalopathy) has resulted from the administration of any vaccine product.

What ROTARIX looks like

ROTARIX is a clear, colourless liquid, free of visible particles.

ROTARIX is available in a squeezable tube in packs of 1 or 10 (AUST R 326141).

Not all pack sizes and container types may be distributed in Australia.

Who distributes ROTARIX

GlaxoSmithKline Australia Pty Ltd

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Abbotsford, Victoria, 3067

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www.gsk.com.au

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