

Applicant name: The Biovac Institute (Pty) Ltd

1.3.2

08 October 2024

Product name: ROTAVAC 5D Liquid for oral
Dosage form and strength: administration
Each 0,5 ml of vaccine contains:
10^{5,0} Focus Forming Units (FFU) of
live attenuated Rotavirus 116E

PATIENT INFORMATION LEAFLET

ROTAVAC 5D

Rotavirus vaccine

This vaccine is not for self-administration and should be administered by a HealthCare Professional.

SCHEDULING STATUS

S2

PRODUCT NAME

ROTAVAC 5D. Oral liquid. Rotavirus vaccine (live).

One dose 0,5 ml or 5 drops contains:

Rotavirus 116E strain* (live attenuated) not less than 10^{5,0} FFU* produced in Vero cells.

Contains sucrose 0,25 g and trehalose 2,5 mg per dose.

Read all of this leaflet carefully because it contains important information for you.

ROTAVAC 5D is available without a doctor's prescription, to protect against gastroenteritis (diarrhoea and vomiting) caused by rotavirus infection. Nevertheless, you still need to use **ROTAVAC 5D** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **ROTAVAC 5D** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What ROTAVAC 5D is and what it is used for

ROTAVAC 5D is a rotavirus vaccine used to protect your child against gastroenteritis (gut infection causing diarrhoea and vomiting) caused by rotavirus infection. It is given to infants from the age of 6 weeks as a 3-dose series.

2. What you need to know before you are vaccinated with ROTAVAC 5D

ROTAVAC 5D should not be given:

- If your child has had a previous allergic reaction to rotavirus vaccine or any other ingredient in **ROTAVAC 5D**. Including neomycin and kanamycin which are antibiotics.
- If your child has a rare inherited illness called Severe Combined Immunodeficiency Disease (SCID) which affects his/her immunity.
- If your child has previously had intussusception (IS) (a bowel obstruction in which one part of the bowel becomes enfolded within another part); or has a history of gut malformation that could lead to IS.
- If your child has a history of inherited or genetic gut disorders.
- If your child has ongoing diarrhoea and vomiting.
- If your child has a severe infection with a high fever the vaccination must be postponed.

Warnings and precautions

Tell your doctor or healthcare provider before your child receives **ROTAVAC 5D**:

- If your child has any disease or is taking any medicine which reduces his/her resistance to infection or if his/her mother has taken any medicine during pregnancy that may weaken the immune system.
- If your baby has been diagnosed with human immunodeficiency virus (HIV) infection.
- If your child has any disorder of the gastrointestinal system.
- If your child has not been gaining weight and growing as expected.
- If your baby has any infection, including chest infections, or severe or mild fever.

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- If your child has a close contact such as a household member who has a weakened immune system, e.g., a person with cancer or who is taking medicines that may weaken the immune system.

Take special care with ROTAVAC 5D:

After your child has received **ROTAVAC 5D**, contact your doctor or healthcare provider immediately if your child has persistent vomiting, blood in the stools, a swollen belly, or a lump in the belly. As always, please take care to wash your hands thoroughly with soap and water after changing soiled nappies. AS with all vaccines, **ROTAVAC 5D** may not completely protect all children who were vaccinated against gastroenteritis (diarrhoea and vomiting).

Other medicines and ROTAVAC 5D:

Always tell your health care provider if your child is taking any other medicine or has recently received any other vaccine. (This includes all complementary or traditional medicines.)

Your child may be given **ROTAVAC 5D** at the same time he/she receives other routine childhood vaccines such as the oral or inactivated polio, diphtheria-tetanus-pertussis (whooping cough), hepatitis B, and *Haemophilus influenzae* type B vaccines as well as pneumococcal vaccines.

ROTAVAC 5D with food and drink

There are no restrictions to your baby's liquid consumption including breast milk, either before or after vaccination with **ROTAVAC 5D**.

Pregnancy and breastfeeding

ROTAVAC 5D is a paediatric vaccine and should not be administered to adults, including pregnant women. Breast feeding may be continued during the immunisation schedule.

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ROTAVAC 5D contains:

- sucrose and trehalose.
- traces of human albumin.
- trace amounts of neomycin antibiotic and kanamycin antibiotic.

Tell your doctor or health care provider if your baby has any intolerance or allergy to these substances before receiving this vaccine.

3. How ROTAVAC 5D is given:

You will not be expected to give your child **ROTAVAC 5D**. Your doctor, nurse or healthcare provider will give the recommended dose of **ROTAVAC 5D** to your child. The vaccine is always given into the child's mouth. **ROTAVAC 5D should under no circumstances be injected.**

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Below is a representation for ROTAVAC 5D Vial.

Figure 1: Administration of ROTAVAC 5D vials



Your child will receive 3 doses of the vaccine. The first dose (0,5 ml or 5 drops) will be given at the age of 6 weeks followed by the second dose 4 weeks later then the third and final dose 4 weeks later. **ROTAVAC 5D** should be given to your child before the age of 34 weeks (8 months) If your child spits out or brings the vaccine dose back up, a single replacement dose may be given at the same vaccination visit. Your child may continue to receive the remaining doses according to the vaccination schedule. If **ROTAVAC 5D** is given to your child as the first dose, it is recommended that your child also receives. **ROTAVAC 5D** and not another rotavirus vaccine for the second and third doses.

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If your child is given more ROTAVAC 5D than they should:

Since a healthcare provider will administer **ROTAVAC 5D** he / she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take your child to receive ROTAVAC 5D:

If you forget to return according to the scheduled visits, ask your doctor or healthcare provider for advice.

4. Possible side effects

ROTAVAC 5D can have side effects.

Not all side effects reported for **ROTAVAC 5D** are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking **ROTAVAC5D**, please consult your healthcare provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following side effects:

Less frequent: Continuous vomiting, blood in stools and an

abdominal (belly) lump, or if the abdomen is bloated, swollen, or inflated.

These are all very serious side effects. Your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects: Cough, running nose, diarrhoea, fever, vomiting and irritability (crying).

Side effects with frequency unknown:

Tiredness, middle ear infection (otitis media), common cold (nasopharyngitis) and cough with wheezing (bronchospasm). If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects

If your child gets side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

or by reporting to the Holder of The Registration Certificate using the email address

DrugSafety@biovac.co.za

By reporting side effects, you can help provide more information on the safety of **ROTAVAC 5D**.

5. How to store-ROTAVAC 5D

Store all medicines out of reach of children. Store the vaccine between 2 °C to 8 °C (in a refrigerator). The multi-dose vial must be used in the same immunisation session or within a maximum of 6 hours.

DO NOT FREEZE.

Store in the original package and container. Do not use after the expiry date stated on the label
Return all unused vaccine to your pharmacist. Do not dispose of unused vaccine in drains or sewerage systems (e.g., toilets). Safely dispose of the empty vial, cap, and oral applicator in an approved biological waste container according to local regulations.

When not to use ROTAVAC 5D

ROTAVAC 5D contains a vaccine vial monitor (VVM). A VVM contains a heat-sensitive material that is printed on the label to register cumulative heat exposure over time. Healthcare providers must compare the colour of the heat sensitive square to a reference circle to determine whether or not the vaccine has been exposed to too much heat and should be discarded.

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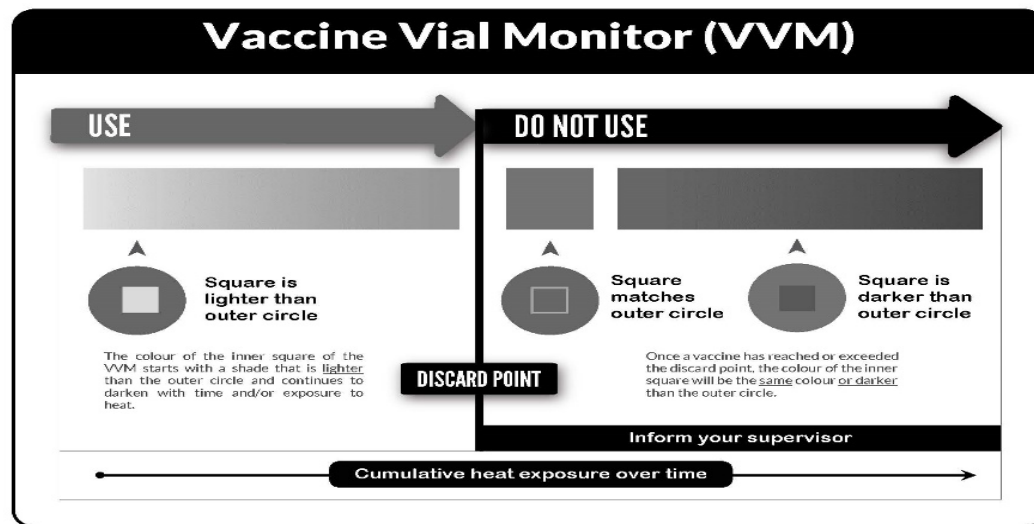
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Figure 1: Interpretation of the Vaccine Vial Monitor label



6. Contents of the pack and other information

What ROTAVAC 5D contains

The active substance is Rotavirus 116E strain (live attenuated) produced in Vero cells. Each dose (0,5 ml/5 drops) of vaccine contains not less than 10^{5.0} FFU live attenuated Rotavirus 116E.

The other ingredients are:

- Neomycin sulphate
- Kanamycin acid sulphate
- Sucrose
- Trehalose
- Lactalbumin hydrolysate
- Human albumin
- Potassium di-hydrogen orthophosphate
- Di-potassium hydrogen orthophosphate
- Tri-sodium citrate di-hydrate

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- Water for injection

What ROTAVAC 5D looks like and contents of the pack

Oral liquid. **ROTAVAC 5D** is a clear pinkish to pale yellow coloured liquid, free from particles.

ROTAVAC 5D is presented in:

- Single dose (0,5 ml) USP Type I glass vial with a grey bromo butyl rubber stopper and sealed with a Tear Lift Flip-down pink seal with a low-density polyethylene (LDPE) plastic dropper packed in a carton. 36 vials are packed into an outer carton.
- Multi-dose, 5 doses, (2,5 ml) USP Type I glass vial with a grey bromo butyl rubber stopper and sealed with a Tear Lift Flip-down pink seal with LDPE plastic dropper packed in a LDPE plastic dropper packed in a carton. 26 vials are packed into an outer carton.

Not all presentations may be marketed.

Holder of Certificate of Registration

The Biovac Institute (Pty) Ltd.

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7405, Cape Town

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This leaflet was last revised in

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Registration Application number

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