160 mm

195 mm

Rotavirus Vaccine, Live Attenuated (Oral) Liquid

ROTASIIL®- Liquid

DESCRIPTION
ROTASIIL™-Liquid [Rotavirus Vaccine, Live Attenuated (Oral)] supplied by Serum Institute of India Pvt. Ltd. is a Liquid Bovine Human Reassortant Rotavirus-Pentavalent Vaccine (LBRV-PV). The vaccine constitutes five viruses (Human and Bovine reassortant strains) of serotype G1, G2, G3, G4, and G9. All these strains constitute VP7 gene of respective serotype from human strains reassorted with bovine (UK) rotavirus. Each strain is propagated in VERO cells individually; and all five strains are blended before filling.
ROTASIIL™-Liquid is available as ready to use liquid formulation and the product has the appearance of yellowish translucent liquid with possible presence of inherent product aggregates. The vaccine contains no preservatives. ROTASIIL™-Liquid is for oral administration and not for injection. The vaccine conforms to I.P. and World Health Organization (W.H.O.) requirements.

COMPOSITION
Each dose of 2 ml contains:
Live Attenuated Bovine - Human Rotavirus Reassortant [G1, G2, G3, G4 and G9]* $\geq 10^{5.6}$ FFU / Serotype.
*Grown on vero cells.
Excipients: Citric acid, Potassium Phosphate Dibasic Anhydrous, Sucrose, Hydrolyzed Gelatin, Zinc Chloride, Calcium Chloride, Sodium citrate tribasic dihydrate, Eagle's MEM (Minimum Essential Medium) with Hank's Salts, Glutamine, Sodium Bicarbonate and Water for injection.
This vaccine contains no Preservatives.
Dose : 2 ml - 1 dose by oral administration.

INDICATION
ROTASIIL™-Liquid is indicated for active immunization of healthy infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered as a 3-dose series. The three dose regimen should be completed by one year of age.

CONTRAINDICATIONS
Hypersensitivity to any component of the vaccine is a contraindication to vaccine. Individuals who develop symptoms suggestive of hypersensitivity after receiving a dose of ROTASIIL™-Liquid should not receive further doses. Infants with a history of uncorrected congenital malformation of the gastrointestinal tract that would predispose the infant for intussusception should not receive vaccine. Individuals with Severe Combined Immunodeficiency Disease (SCID) should not receive vaccine as cases of gastroenteritis associated with other live rotavirus vaccines have been reported in infants with SCID. History of intussusception (IS) is a contraindication to vaccine administration.

WARNINGS and PRECAUTIONS
No safety or efficacy data of ROTASIIL™-Liquid is available in immunocompromised infants, infants infected with HIV or infants with chronic gastroenteritis. Administration of ROTASIIL™-Liquid may be considered with caution in immunocompromised infants and infants in close contact with immunodeficient persons if in the opinion of the physician the benefit far outweigh the risks of vaccine. Similarly, acute infection or febrile illness may be a reason for delaying the administration of ROTASIIL™-Liquid, if in the opinion of the physician the benefits far outweigh the risks of vaccine. Low-grade fever and mild upper respiratory tract infection are not contraindications to ROTASIIL™-Liquid.
Available published data shows a small increased incidence of intussusception (IS) following other live oral Rotavirus vaccines especially after the first dose. The safety data from the clinical trials of ROTASIIL (already licensed lyophilized formulation of BRV-PV) did not show any increased risk of IS when compared with placebo. In Phase III trial, no intussusception was reported in ROTASIIL™-Liquid and ROTASIIL groups. However, health care providers should carefully evaluate cases with symptoms suggestive of IS.
Similar to other rotavirus vaccines, vaccination with ROTASIIL™-Liquid may not protect all vaccine recipients against rotavirus infection. Also, ROTASIIL™-Liquid will not provide protection against gastroenteritis caused by the other pathogens.

Drug Interactions
Immunosuppressive therapies including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than minimal doses), may reduce the immune response to vaccines.
ROTASIIL™-Liquid can be administered concomitantly with other vaccines of the infant immunization programme, including combined diphtheria, tetanus toxoid and pertussis vaccine (DTP), inactivated poliovirus vaccine (IPV), oral polio vaccine (OPV), H. influenzae type b conjugate (Hib), hepatitis B vaccine. No interaction studies have been performed with ROTASIIL™-Liquid in infants with other medicinal products.
In phase 2/3 study of ROTASIIL™-Liquid, three doses of either ROTASIIL™-Liquid or ROTASIIL (Freeze-Dried) were administered 4 weeks apart (minimum interval of 4 weeks and maximum of 6 weeks). All subjects received concomitantly other UIP vaccines as per the national immunization schedule (DTwP-HepB-Hib, bOPV, IPV). Other than UIP, OPV was also administered during national / sub-national immunization days; BCG and Pneumococcal vaccines were also allowed during the study period.

Pregnancy
ROTASIIL™-Liquid is not indicated for adults, including women of child-bearing age and should not be administered to pregnant females. Animal reproduction studies have not been conducted with ROTASIIL™-Liquid.

ADVERSE REACTIONS
In the phase III trial of ROTASIIL, no differences were detected between ROTASIIL and placebo groups in the post vaccination rates of solicited adverse events within 7 days of each dose of vaccine. Similarly, in the phase III trial of ROTASIIL-Liquid, no differences were detected between ROTASIIL™-Liquid and ROTASIIL groups in the post-vaccination rates of solicited adverse events within 7 days of each dose of vaccine. These events in decreasing order of frequency were:
Fever (64.6% in ROTASIIL™-Liquid group and 66.8% in ROTASIIL group), irritability (51.5% in ROTASIIL™-Liquid group and 50.5% in ROTASIIL group), decreased appetite (31.9% in ROTASIIL™-Liquid group and 31.6 % in ROTASIIL group), decreased activity level (23.2% in ROTASIIL™-Liquid group and 22.3% in ROTASIIL group), vomiting (17.9% in ROTASIIL™-Liquid group and 13.8 % in ROTASIIL group) and diarrhea (12.1% in ROTASIIL™-Liquid group and 13.8% in ROTASIIL group). The incidence of all solicited events was similar in ROTASIIL™-Liquid and ROTASIIL groups. Most of these events were of short duration and predominately mild (74% of episodes) in severity. It should be noted that in the phase 3 study, ROTASIIL™-Liquid and ROTASIIL were administered to all children concomitantly with DTwP vaccine, which is known to cause a level of reactogenicity similar to that observed in this study.
The occurrence of unsolicited adverse events was monitored throughout the phase 3 trial and the incidence was similar in both the groups. The most frequent serious adverse events (SAE) observed included bronchiolitis, lower respiratory tract infection and gastroenteritis. Only one SAE of gastroenteritis that occurred within 7 days post-vaccination in ROTASIIL group was considered to be causally related.
No death as well as intussusception case was reported in this study.
Further, in Phase III trial of ROTASIIL, total thirteen cases of intussusception were diagnosed; 6 occurred in the ROTASIIL arm and 7 in the placebo arm. None occurred within 28 days of receiving a dose of ROTASIIL or placebo. None were related to study vaccination or led to discontinuations from the study.

Preclinical safety data
SIIPL conducted single- and repeated-dose toxicity studies of liquid rotavirus vaccine in rodents (Wistar rats) and non-rodents (New Zealand white rabbits) by oral gavage administrations. These studies were conducted with a hexavalent vaccine which included G1, G2, G3, G4, G8 and G9 reassortants. Single dose studies included 60 rats and 18 rabbits in three groups while repeated dose studies included 70 rats in four groups and 18 rabbits in three groups. The vaccine in single- and repeated-dose toxicity studies in both the species had no effects on their general health. There were no changes in body temperature, cumulative net body weight gains and hematological, clinical chemistry and urinalysis parameters in animals of either sex. No gross or microscopic histopathological changes were detected in all the organs studied.

Reason for issue: New		Specification: Printed on bible paper 40 gsm.		
Customer: Malaysia				
Product: Name **ROTASIIL-Liquid**		Colour: CMYK, Pantone 220 C and 072 C		
Item Code number: XXXXXXXX/XX	Specification No.:		Artwork made to: 100%	
Supercedes Item Code:		Dimensions: 160 x 195 mm		
Prepared By	Reviewed By	Approved By		Authorized By
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	CLINICAL RESEARCH & PHARMACOVIGILANCE	QUALITY ASSURANCE

File Name:E:\Artworks NL\Hadapsar\Insert\Export\Malaysia\ROTASIIL-Liquid English Insert - Malaysia - NL.cdr Date: 18.07.2026

160 mm

Pharmacodynamic properties
The immune response to natural rotavirus infection is not completely defined. It is known that prior exposure to rotavirus provides incomplete protection from the virus and therefore, infants and children can be reinfected from year to year. Natural infection, however, may provide some protection from severe diarrhea during subsequent infections. This may result from a virus specific immune response generated at the intestinal mucosal surface. ROTASIIL™-Liquid has been developed to mimic the immunologic responses stimulated by natural infection. It is assumed that vaccine virus replicates in the small intestine and induces immunity. The immunologic mechanism by which ROTASIIL™-Liquid protects against rotavirus gastroenteritis is not entirely understood. It is thought that IgA antibodies generated against ROTASIIL™-Liquid reflect a local immune response. A Phase III study with ROTASIIL assessed the immune response of ROTASIIL - Liquid in 1500 healthy infants. The seropositivity rates post dose 3 were 60.41% and 52.75% for ROTASIIL™-Liquid and ROTASIIL respectively. The seropositivity rates indicated that the vaccine is immunogenic in infants. These results are similar to those reported in India for other licensed rotavirus vaccines.

Pharmacokinetics
Evaluation of pharmacokinetic properties is not applicable for vaccines.

DOSAGE AND ADMINISTRATION
ROTASIIL™-Liquid is for ORAL ADMINISTRATION ONLY AND MUST NOT BE ADMINISTERED PARENTERALLY.

Dosage:
ROTASIIL™-Liquid should be administered as a 3-dose regimen, 4 weeks apart, beginning at 6 weeks of age. The three dose regimen should be completed by one year of age. ROTASIIL™-Liquid may be co-administered with other routine childhood immunizations (i.e., Diphtheria, Tetanus and Pertussis [DTwP], Hepatitis B vaccine, H. influenzae type b (Hib) vaccine, inactivated polio vaccine (IPV) and Oral Polio Vaccine [OPV]). Because of the typical age distribution of rotavirus gastroenteritis, rotavirus vaccination of children > 24 months of age is not recommended. Based on recommendations from the World Health Organization, if the routine childhood immunizations are initiated later than 6 weeks of age and/or at a longer dose interval than 4-weeks, ROTASIIL™-Liquid can still be administered, by itself or concomitantly with DTwP. There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after vaccination with ROTASIIL™-Liquid.

It is recommended that infants who receive ROTASIIL™-Liquid as the first dose should complete the three dose series with ROTASIIL™-Liquid. There is no data on safety, immunogenicity or efficacy of ROTASIIL™-Liquid when administered interchangeably with other available rotavirus vaccines. In case that an incomplete dose is administered (the baby spits up or regurgitates most of the vaccine), a single replacement dose may be administered at the same vaccination visit*. The baby may continue to receive the remaining doses as per schedule vaccines.

*Physician's discretion is advised.

ROTASIIL™-Liquid is for ORAL ADMINISTRATION ONLY AND MUST NOT BE ADMINISTERED PARENTERALLY.

Symptoms and treatment of overdose
No case of overdose has been reported

Effects on Ability to Drive and Use Machine
Not applicable

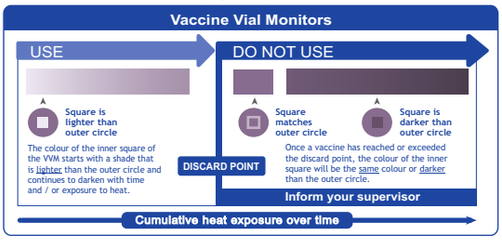
Dosage administration:
Each single oral dose of ROTASIIL™-Liquid is 2 ml in volume. The vaccine is available as ready to use either one plastic ampoule or a strip of five plastic ampoules of ROTASIIL™-Liquid. If the integrity of the vaccine ampoule has been compromised, that particular plastic ampoule must be discarded. The content of plastic ampoule should 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. The vaccine is dispensed as a single dose and is for one time use only. Any unused vaccine or waste material should be disposed-off in accordance with local requirements. The vaccine must not be mixed with other medicinal products.
For administration of vaccine orally refer section "Instructions for use".

STORAGE
ROTASIIL™-Liquid must be stored between +2°C to +8°C.
Protect from light. DO NOT FREEZE.

SHELF LIFE
24 months. Do not use after expiry date.

PRESENTATION
2 ml - 1 dose ampoule

THE VACCINE VIAL MONITOR (Optional)

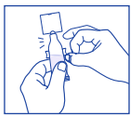


Vaccine Vial Monitors (VVMs) are part of the label on Rotavirus Vaccine, Live Attenuated (Oral) supplied through Serum Institute of India Pvt. Ltd. The colour dot which appears on the label of the ampoule is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the ampoule has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

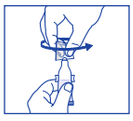
The interpretation of the VVM is simple. Focus on the inner square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the outer circle, then the vaccine can be used.

As soon as the colour of the inner square is the same colour as the outer circle or of a darker colour than the outer circle, then the ampoule should be discarded.

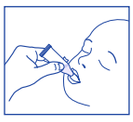
INSTRUCTIONS FOR USE
To administer the vaccine orally:



1) Clear the fluid from the dispensing tip by tapping the ampoule and holding it vertically.



2) Open the dosing ampoule by easy twist motion as shown in figure.



3) Administer the complete dose (2 ml) by gently squeezing the ampoule into infant's mouth toward the inner cheek until dosing ampoule is empty.

Revision date : 01.01.2026

Manufactured by:
SERUM INSTITUTE OF INDIA PVT. LTD.
S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 113-114, 168-170 (M), Hadapsar, Pune 411 028, INDIA
Protection from birth onwards

M.A. Holder:
SM Pharmaceuticals Sdn. Bhd.
Lot 88, Sungai Petani Industrial Estate, 08000, Sungai Petani, Kedah, Malaysia

(TM) Trademark under registration

XXXXXXXX/XX

195 mm

Reason for issue: New		Specification: Printed on bible paper 40 gsm.	
Customer: Malaysia			
Product Name: **ROTASIIL-Liquid**		Colour: CMYK, Pantone 220 C and 072 C	
Item Code number: XXXXXXXX/XX	Specification No.:	Artwork made to: 100%	
Supercedes Item Code:		Dimensions: 160 x 195 mm	

Prepared By	Reviewed By	Approved By		Authorized By
PACKAGING DEVELOPMENT	QUALITY CONTROL	REGULATORY AFFAIRS	CLINICAL RESEARCH & PHARMACOVIGILANCE	QUALITY ASSURANCE

File Name:E:\Artworks NL\Hadapsar\Insert\Export\Malaysia\ROTASIIL-Liquid English Insert - Malaysia - NL.cdr Date: 18.07.2026