For the vaccination of healthy pregnant swine, to provide passive protection to their nursing pigs against disease caused by eight pathogens: Rotavirus (2 modified live G serotypes 5 and 4 of serogroup A rotavirus), TGE (transmissible gastroenteritis), Colibacillosis (Escherichia coli pilus antigens K88, K99, F41 and 987P) and Enterotoxemia (Clostridium perfringens type C).

Advantages

- Safe and effective against neonatal rotaviral diarrhea, TGE, enterotoxemia and colibacillosis.
- Aids in the prevention of enterotoxemia to reduce death loss and scours
- 70–100% protection against *C. perfringens* type C challenged litters
- Four major *E. coli* pilus types; K88, K99, 987P and F41; for comprehensive protection against colibacillosis
- Unique modified live TGEV strain; acid-resistance selected for best gut-level protection
- First USDA-licensed vaccine with two serotypes of serogroup A rotavirus, G5 (*A*1) and G4 (*A*2), for best protection
- Up to 100% protection from mortality in rotavirus challenge of vaccinated sow litters
INTRODUCTION:
Porcine Rotavirus-Transmissible Gastroenteritis vaccine and Clostridium perfringens type C - Escherichia coli Bacterin-Toxoid are used for the vaccination of healthy pregnant swine, to provide passive protection to their nursing pigs against disease caused by eight pathogens:
1. Rotavirus (2 modified live G serotypes 5 and 4 of serogroup A rotavirus)
2. TGE (transmissible gastroenteritis)
3. Colibacillosis (Escherichia coli pilus antigens K88, K99, F41 and 987P)
4. Enterotoxemia (Clostridium perfringens type C).

These etiologic agents are important causes of neonatal porcine diarrhea. They often occur in combination with each other, causing increased morbidity and mortality losses. Furthermore, several of these diseases may produce similar clinical signs in baby pigs, therefore it is desirable to provide broad protection to nursing pigs. Laboratory confirmation of the cause of baby pig diarrhea is recommended since other viral, bacterial and coccidial agents also can cause similar disease signs.

PRODUCT DESCRIPTION:
The Rotavirus-TGE vaccine (ProSystem® TGE/Rota) contains 2 major serotypes of modified live Rotavirus and a modified live TGE virus in desiccated form. The bacterin-toxoid diluent (ProSystem® CE) is a purified, adjuvanted liquid product containing four major E. coli pilus antigens - K88, K99, F41 and 987P, and C. perfringens type C toxoid. Each serial of ProSystem® CE bacterin-toxoid is demonstrated to be compatible (non-viricidal) with ProSystem® TGE/Rota virus vaccine and therefore can be used as a diluent when packaged with the viral vaccine.

Safety and efficacy of the modified live rotaviruses and TGE has been demonstrated. The Rotavirus-TGE vaccine, rehydrated with the bacterin-toxoid, and the bacterin-toxoid alone have been evaluated for safety in pregnant swine as well as in laboratory animals. No adverse reactions were observed. Baby pigs are protected from disease caused by these agents by receiving colostral and milk antibodies from vaccinated dams. Therefore it is mandatory that sows and gilts are lactating and baby pigs are nursing adequately.

DOSAGE GUIDELINES:
Follow directions carefully. Two vaccination programs may be used.

Intramuscular (INJECTION) vaccination method: to be used for sows and gilts having significant virulent TGE exposure within the prior 12 months.
1. Reconstitute ProSystem® TGE/Rota virus vaccine with ProSystem® CE bacterin-toxoid diluent; shake bacterin-toxoid well before and after addition to the virus vaccine.
2. Inject pregnant sow or gilt with 2.0 ml intramuscularly at 5 weeks before farrowing and again at 2 weeks before each farrowing.

Oral and intramuscular (ORAL) vaccination method: to be used for sows and gilts not previously exposed to virulent TGE
1. For initial use, each pregnant sow or gilt must receive at least 2 oral and 1 intramuscular dosings of ProSystem® TGE/Rota virus vaccine and 2 doses of ProSystem® CE bacterin-toxoid before farrowing. Refer to the five-step method for oral vaccination, as shown on this package insert, using desiccated viral vaccine.
   a. 5 weeks before farrowing – 1 oral dose ProSystem® TGE/Rota and 1 intramuscular dose of ProSystem® CE bacterin-toxoid
   b. 3 weeks before farrowing – 1 oral dose ProSystem® TGE/Rota
   c. 1 week before farrowing – 1 intramuscular dose of ProSystem® TGE/Rota rehydrated with ProSystem® CE bacterin-toxoid

2. Subsequent farrowings – 2 weeks before farrowing, administer 1 oral dose of ProSystem® TGE/Rota and 1 intramuscular dose of ProSystem® TGE/Rota rehydrated with ProSystem® CE bacterin-toxoid.
   For combination injection, reconstitute ProSystem® TGE/Rota dried vaccine with the accompanying ProSystem® CE bacterin-toxoid diluent. Shake well before use. If the bacterin-toxoid is given separately (e.g., at the time of oral vaccination with ProSystem® TGE/Rota), the 2.0 ml dose can be injected either intramuscularly or subcutaneously.
   For best TGE protection, sows and gilts which have never been exposed to virulent TGE virus should be vaccinated following the ORAL vaccination guidelines (above) and their baby pigs should be orally vaccinated with ProSystem® TGE (Transmissible Gastroenteritis vaccine) following package insert guidelines. 762708-01

CAUTION:
1. Do not use hot water—it will destroy the vaccine!
2. Use vaccine immediately after reconstitution. Do not use oral TGE vaccination program.
3. Use in healthy pregnant swine only, and do not vaccinate within 21 days of slaughter.
4. Conditions which interfere with lactation adversely affect immunity in baby pigs.
5. If allergic reaction follows use of this product, treat with epinephrine.
6. Although this product has been shown to be efficacious, some animals may be unable to develop or maintain an adequate immune response following vaccination if they are incubating any infectious disease, are malnourished or parasitized, or stressed due to shipment or adverse environmental conditions.
7. For highly TGE-susceptible (seronegative) sows and gilts, always use oral TGE vaccination program.
8. Contains gentamicin, polymyxin B and thimerosal as preservatives.

RECOMMENDED METHODS FOR ORAL VACCINATION OF SWINE
Step 1. Pour approximately 2 to 2½ gallons of cool water into a large plastic bucket. Add 5–10 cups of dry milk (any type of dry milk for human consumption is acceptable). Do not use hot water—it will destroy the vaccine!
Step 2. Stir milk mixture well. Drywall paddles (as shown in steps 1 and 2) attached to 1/2” drill make mixing easier.
Step 3. Remove metal ring and stopper. Reconstitute vaccine with milk mixture; add reconstituted vaccine to milk, and stir. (The bacterin-toxoid packaged in combination with viral vaccine must always be injected.)
Step 4. Slowly add 40 lbs. of clean ground corn to the milk/vaccine mixture. Stir continuously, using an electric 1/2” drill and drywall paddle, until mixture thickens and drill pulls down. There should be no run-off seen. Mixing procedure takes approximately 3 minutes.
Step 5. Feed to pregnant sows and gilts in one of two ways: 1. Feed sows individually with approximately 4 lbs. of milk/vaccine/corn mixture. 2. Spread milk/vaccine/corn mixture in a row onto concrete, feeding 10 sows at a time.