

EMA/153444/2019 EMEA/V/C/004858

# ReproCyc ParvoFLEX (inactivated porcine parvovirosis vaccine)

An overview of ReproCyc ParvoFLEX and why it is authorised in the EU

# What is ReproCyc ParvoFLEX and what is it used for?

ReproCyc ParvoFLEX is a veterinary vaccine given to female pigs to protect their unborn piglets from porcine parvovirus infection via the placenta. Porcine parvovirus causes infertility, still births and small litters in female pigs. ReproCyc ParvoFLEX contains inactivated (killed) porcine parvovirus strain 27a viral protein 2.

# How is ReproCyc ParvoFLEX used?

ReproCyc ParvoFLEX can only be obtained with a prescription and is available as an injection. It is given into the muscle of female pigs from 5 months of age. The initial vaccination course is two injections given 3 weeks apart, with the second injection given at least 3 weeks before mating. Protection starts at the beginning of pregnancy and lasts for 6 months. A single booster injection can be given every 6 months to maintain immunity.

For more information about using ReproCyc ParvoFLEX, see the package leaflet or contact your veterinarian or pharmacist.

#### How does ReproCyc ParvoFLEX work?

ReproCyc ParvoFLEX is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The vaccine contains a porcine parvovirus protein that does not cause disease. When ReproCyc ParvoFLEX is given to female pigs the animals' immune system recognises the viral protein as 'foreign' and makes antibodies against it. If the animals come into contact with the virus the immune system will be able to respond quickly. This will help protect the unborn piglets against porcine parvovirus infections during pregnancy.

ReproCyc ParvoFLEX also contains the adjuvant (ingredient that strengthens the immune response) carbomer.



# What benefits of ReproCyc ParvoFLEX have been shown in studies?

Three laboratory studies showed that ReproCyc ParvoFLEX protects against transplacental porcine parvovirus infection, since more than 95% of piglets from vaccinated female pigs were protected from infection, as shown by absence of parvovirus.

A field study in Spain showed that ReproCyc ParvoFLEX, when given to female pigs, was as effective as an authorised porcine parvovirus vaccine, Parvoseng, as measured by the fertility of vaccinated animals, the number of still births and the size of the litters.

#### What are the risks associated with ReproCyc ParvoFLEX?

The most common side effect with ReproCyc ParvoFLEX (which may affect more than 1 in 10 animals) is short lived redness or swelling (up to 4 cm) at the injection site. These reactions resolve without treatment in 2 to 5 days.

An increase in body temperature can occur after vaccination (which may affect up to 1 in 10 animals) but this resolves within 24 to 48 hours.

# What are the precautions for the person who gives the medicine or comes into contact with the animal?

None.

# What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for meat from pigs treated with ReproCyc ParvoFLEX is 'zero' days, which means that there is no mandatory waiting time.

#### Why is ReproCyc ParvoFLEX authorised in the EU?

The European Medicines Agency decided that ReproCyc ParvoFLEX's benefits are greater than its risks and it can be authorised for use in the EU.

#### Other information about ReproCyc ParvoFLEX

ReproCyc ParvoFLEX received a marketing authorisation valid throughout the EU on 26 April 2019.

Further information on ReproCyc ParvoFLEX can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/reprocyc-parvoflex.

This overview was last updated in February 2019.