

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIGEN PUPPY 2b

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains

Active substance:

Live attenuated canine Parvovirus 2b Strain CPV39: $10^{5.6}$ to $10^{7.5}$ CCID₅₀*

* Cell culture infectious dose.

Exipients:

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Colourless suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Dog (puppy)

4.2 Indications for use, specifying the target species

For active immunisation of dogs against canine parvovirus, to reduce virus excretion, to prevent mortality and typical signs (enteric form) from the age of 5 weeks.

The onset of protection occurs two weeks after vaccination. The duration of protection has been demonstrated until the age of 11 weeks.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The vaccinal strain can spread. It has been demonstrated that this spread did not cause adverse effects on pregnant or lactating females or cats.

4.5 Special precautions for use

Special precautions for use in animals

The vaccine should be administered in accordance with the usual aseptic conditions for vaccination. Animals have to be treated for intestinal endoparasites prior to vaccination. Vaccinate only healthy puppies.

In the case of high levels of maternal derived antibodies ($>1/80$) the seroconversion rate is reduced from 94% to 42%.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

The active ingredient of the vaccine is non-pathogenic for man but normal precautions should be taken to avoid contact with the skin and mucosa and self-injection. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A slight transitory (lasting less than 1 minute) pruritus at the point of injection which may be associated with slight pain may be observed for up to 30 minutes after vaccination. Slight transitory swelling could also be observed at the injection site, disappearing spontaneously within 2-3 hours after occurrence.

Occasional hypersensitivity reactions may be observed in some animals. In case of anaphylactic reactions, administer immediately corticoidotherapy or antihistamines associated with the usual treatment against anaphylactic reactions/shocks.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other.

4.9 Amounts to be administered and administration route

Administer one dose of 1ml of the product subcutaneously to 5 week old puppies.

Due to the heterogeneous distribution of maternal antibodies among puppies a second injection of a 1 ml dose two weeks later is recommended. To ensure a long term protection, a conventional vaccination scheme with a vaccine containing a parvovirus valence should be carried out starting before the age of 11 weeks.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

A ten-fold overdose of CANIGEN Puppy 2b at the maximal authorized release titre showed no other reactions than those mentioned in section 4.6 "Adverse reactions".

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: canine parvovirus vaccine

ATCvet code: QI07AD01

The active substance of the vaccine is an attenuated live canine parvovirus type 2b strain to stimulate active immunity against enteric form of parvovirus in puppies from 5 weeks of age. It induces the development of specific antibodies against CPV serotypes -2b, -2a, -2.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate anhydrous
Water for injection

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4. Special precautions for storage

Store and transport refrigerated between 2°C and 8°C.
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Vial (glass, type I) of 3 ml for injectable preparations with elastomer stopper containing 1 ml of vaccine. The product is presented in boxes of 10 or 50 vials.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements. Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBERS

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/05/2003.

10 DATE OF REVISION OF THE TEXT

010/2017