SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CASTOMIX
Lyophilisate and suspension for injection for rabbits.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of vaccine (0,5 ml) contains:
Lyophilisate:
Active substance:
Attenuated virus of myxomatosis strain MAV …….. $\geq 10^3$ $TCID_{50}$
Excipients:
Protective medium for lyophilisation

Suspension:
Active substance:
Inactivated rabbit haemorrhagic disease virus strain PHB 98 ≥ 1280 HAU
Adjuvant:
Aluminium hydroxide gel ≤ 1,50 mg
Excipients:
Thiomersal ≤ 0,06 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for injection.
Lyophilisate of light yellow to light pink colour, good soluble in liquid part of the vaccine, without rest of abrasive non soluble particles.
Suspension of red-brown colour with easily shakeable sediment.

4. CLINICAL PARTICULARS

4.1 Target species
Rabbits from 10 weeks of age.

4.2 Indications for use, specifying the target species
For active immunization of rabbits to prevent clinical signs and mortality caused by RHD virus and virus of myxomatosis.

Onset of immunity: 7 to 14 day
Duration of immunity: 9 months for MXT virus 12 months for RHDV.

According to the trials results, the progeny of does immunized with CASTOMIX is well protected for at least 6 weeks of age against RHDV, but it remains fully sensitive to infection with myxoma virus.

4.3 Contraindications
None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

For live freeze-dried MXT component of the vaccine limited horizontal spread of vaccine strain was determined.
Do not vaccinate sick animals or animals suspected of any disease.

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

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)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.
The vaccination is not recommended during the last week of pregnancy.
No information is available on vaccination of lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

After reconstitution of the freeze-dried part with the liquid part of the product administer one dose (0,5 ml) by subcutaneous route preferably in the scapula region according to the following schedule:

Broiler rabbits
Basic vaccination: first injection: from 10 weeks of age.

Breeding rabbits
Basic vaccination: first injection: from 10 weeks of age
second injection: at the age of 6 months
Revaccination: one injection every 9 months

Emergency vaccination of rabbits under 10 weeks of age with respect to epizootic situation
Basic vaccination: first injection: minimum 6 weeks of age
second injection: one month later
Revaccination: every 9 months

Vaccinate only under aseptic conditions.
Use only sterile equipment (including needles and syringes).
The vaccine should be brought to room temperature prior to use.
Shake the vaccine before and during use.

Remark:
With respect to the seasonal disease incidence, it is recommended to perform the vaccination (revaccination) at least 14 days before the diseases could be expected.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
No adverse reactions have been observed after administration of an overdose of the vaccine.

4.11 Withdrawal period(s)
Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live and inactivated viral vaccine, ATCvet code: QI 08AH01

Vaccine contains inactivated rabbit haemorrhagic disease virus (RHDV) and live attenuated virus of myxomatosis (MXT).
Inactivated rabbit haemorrhagic disease virus (liquid component of the vaccine) induces specific humoral immune response. Mineral vehicle - aluminium hydroxide gel potentiates the immunogenic effect of the vaccine. Vaccination by live attenuated virus of myxomatosis (freeze-dried part of vaccine) induces cell-mediated immune response preferably.

Environmental properties
Rabbit haemorrhagic disease virus is inactivated - non infectious thus the spreading of immunizing antigen between susceptible animals is prevented. For live freeze-dried MXT component of the vaccine limited horizontal spread of vaccine strain was determined. Increase of virulence of vaccine strain was not determined.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lyophilisate:
Glutamic acid
Sucrose
Gelatin

Suspension:
Aluminium hydroxide gel
Thiomersal

6.2. Incompatibilities
Do not mix with any veterinary medicinal product except the liquid component supplied.

6.3 Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 12 months.
Shelf-life after reconstitution according to directions: 2 hours.

6.4. Special precautions for storage
Store at dark and dry place between +2°C to +8°C. Do not freeze.
It is important to minimize even short-term deviations from prescribed storage temperature.

6.5 Nature and composition of immediate packaging
Type I glass vial lyophilisate and suspension)
Chlorobutyl rubber stopper (vials of suspension)
Bromobutyl rubber stopper (vials of lyophilisate)
Aluminium cap

Box of 1 vial of 1 dose (lyophilisate) and 1 vial of 1 dose (liquid fraction)

Box of 1 vial of 5 doses (lyophilisate) and 1 vial of 5 doses (liquid fraction)
Box of 1 vial of 10 doses (lyophilisate) and 1 vial of 10 doses (liquid fraction)
Box of 1 vial of 20 doses (lyophilisate) and 1 vial of 20 doses (liquid fraction)
Box of 1 vial of 40 doses (lyophilisate) and 1 vial of 40 doses (liquid fraction)

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

PHARMAGAL BIO, s. r. o.
Murgašova 5
949 01 Nitra
Slovak Republic

8. MARKETING AUTHORISATION NUMBER(S)

SK: 97/045/06-S
PL: 1744/07

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8.9.2006 (SK); 05.04.2007 (PL)

10 DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.