Gallimune Se + St, water-in oil emulsion for injection

Authorised

- Salmonella enterica, subsp. enterica, serovar Typhimurium, strain DT104, Inactivated
- Salmonella enterica, subsp. enterica, serovar Enteritidis, strain PT4, Inactivated

Product identification

Medicine name:
Gallimune Se + St, water-in oil emulsion for injection
Gallimune Se + St Emulsja do wstrzykiwań

Active substance:
Salmonella enterica, subsp. enterica, serovar Typhimurium, strain DT104, Inactivated
Salmonella enterica, subsp. enterica, serovar Enteritidis, strain PT4, Inactivated

Target species:
Chicken (pullet)
Chicken

Route of administration:
Intramuscular use

Product details

Active substance and strength:

Salmonella enterica, subsp. enterica, serovar Typhimurium, strain DT104, Inactivated 149.00 antibody unit(s) / 0.30 millilitre(s)

Salmonella enterica, subsp. enterica, serovar Enteritidis, strain PT4, Inactivated 171.00 antibody unit(s) / 0.30 millilitre(s)

Pharmaceutical form:
Emulsion for injection

Withdrawal period by route of administration:
Intramuscular use:

- **Chicken (pullet)**
  - Meat and offal. 0 day
  - Egg. 0 day
- **Chicken**
  - Meat and offal. 0 day
  - Egg. 0 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QI01AB01

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Poland

Available in:
Poland

Package description:
(ID2) 3000 millilitre(s): Box with 10 Bottle (PolyPropylene) each with 300 millilitre(s), closed with Closure and Cap (Acrylnitril-Butadien-Kautschuk, Aluminium)

(ID1) 300 millilitre(s): Box with 1 Bottle (PolyPropylene) with 300 millilitre(s), closed with Closure and Cap (Acrylnitril-Butadien-Kautschuk, Aluminium)

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Immunological veterinary medicinal product application (Article 13d of Directive No 2001/82/EC)

Marketing authorisation holder:
Boehringer Ingelheim Animal Health France

Marketing authorisation date:
5/09/2007

Manufacturing sites for batch release:
Boehringer Ingelheim Animal Health Italia S.p.A. In Breve Boehringer Ingelheim Ah It S.p.A.

Responsible authority:
Office For Registration Of Medicinal Products Medical Devices And Biocidal Products

Authorisation number:
1751

Date of authorisation status change:
5/09/2007

Reference member state:
Germany

Procedure number:
DE/V/0282/001

Concerned member states:
Austria Belgium Cyprus Czechia Denmark France Greece Hungary Ireland

Italy Latvia Lithuania Luxembourg Netherlands Poland Portugal Slovakia Slovenia Spain United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.