

APSASOL AMOXICILINA 500 mg/g

Authorised

- Amoxicillin trihydrate

Product identification

Medicine name:

APSASOL AMOXICILINA 500 mg/g

Active substance:

Amoxicillin trihydrate

Target species:

Pig

Chicken (broiler)

Turkey (for meat production)

Duck (broiler)

Route of administration:

In drinking water use

Product details

Active substance and strength:

Amoxicillin trihydrate

500.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:

Powder for use in drinking water

Withdrawal period by route of administration:

In drinking water use:

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Pig

- Meat and offal. 6 day

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Chicken (broiler)

- Meat and offal. 1 day

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Turkey (for meat production)

- Meat and offal. 5 day

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Duck (broiler)

- Meat and offal. 9 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ01CA04

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Greece

Package description:

bag of 1 kg

bag of 400 g

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:

Andres Pinaluba S.A.

Marketing authorisation date:

10/08/2017

Manufacturing sites for batch release:

Andres Pinaluba S.A.

Responsible authority:

National Organization For Medicines

Authorisation number:

70291/28-06-2022/K-0224501

Date of authorisation status change:

27/06/2022

Reference member state:

Spain

Procedure number:

ES/V/0276/001

Concerned member states:

Bulgaria Croatia Cyprus Greece Hungary Italy Poland Portugal Romania

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

Documents

Summary of Product Characteristics

Package Leaflet

Combined File of all Documents

eu-PUAR-apsasol-amoxicilina-500-mg-g-powder-for-use-in-drinking-water-for-pigs--chickens--ducks-and-turkeys-en.pdf