6 December 2024
EMA/CVMP/536281/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Icthiovac ERM

Vaccine common name: inactivated vaccine against yersiniosis in Atlantic salmon

On 5 December 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product *Icthiovac ERM concentrate for dip suspension for Atlantic salmon*. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

Icthiovac ERM is an immunological veterinary medicinal product containing *Yersinia ruckeri*, serotype O1, biotype 1, strain 8363, inactivated; *Yersinia ruckeri*, serotype O2, biotype 1, strain 8365, inactivated; and *Yersinia ruckeri*, serotype O1, biotype 2, strain 8302, inactivated (ATCvet code QI10AB04) as active substances. The active substances act by stimulating active immunity against serotypes/biotypes O1BT1, O2BT1 and O1BT2 of *Yersinia ruckeri* in freshwater, to reduce mortality caused by them in Atlantic salmon fry.

The benefits of Icthiovac ERM are its ability to actively immunise Atlantic salmon fry against yersiniosis caused by serotypes/biotypes O1BT1, O2BT1 and O1BT2 of *Yersinia ruckeri* in freshwater. This is the first vaccine in the EU with three different serotypes/biotypes of *Yersinia ruckeri* for Atlantic salmon, and also the first vaccine intended for Atlantic salmon that contains serotype O2 of *Yersinia ruckeri*.

The full indication is:

"Active immunisation of Atlantic salmon fry to reduce mortality caused by serotype O1 (biotypes 1 and 2) and serotype O2 (biotype 1) of *Yersinia ruckeri* in freshwater.
Onset and duration of immunity after completion of the recommended vaccination scheme:
Onset of immunity: 294 degree days (3 weeks at 14 ± 1 ºC).
Duration of immunity: 2,129 degree days (5 months at 14 ± 1 ºC)".

There are no known side effects. Icthiovac ERM is generally well tolerated at the recommended dose. No adverse events from causes attributable to the product have been observed after administration of

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

a double concentration for twice the immersion time recommended.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC), which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Icthiovac ERM and therefore recommends the granting of the marketing authorisation.