Contents

• About Bova
• Cascade and legislation
• Countries exported to currently within EU
• Information needed to export
• Cost of medications
An emerging global company, Bova UK brings over fifteen years of experience from operating within the Australian veterinary market. A relatively new entrant in the UK and international with 6 years experience, Bova has been rapidly expanding its team with experienced professionals from the veterinary, pharmaceutical, and manufacturing fields.

- **2008**
  - Nick Bova took ownership of the family business, Bova Chemist (Sydney, Australia).

- **2010**
  - Bova Australia since emerged as the biggest compounding pharmacy to service the veterinary market.

- **2017**
  - The Bova UK facility was built and an Equine range was launched.

- **2018**
  - The Small Animal range has started its launch in the UK, with 50 more products to be released in 2019.

**Present Day**
- Continue to bring new formulations to the market. Invest in new equipment for manufacturing

**2021**
- Ground breaking research and launch of novel formulations to treat FIP and EMS
Dedicated manufacturing

Bova Specials is the first in the UK to hold a ManSA authorisation (Manufacturer ‘Specials’ Authorisation) to manufacture sterile and non-sterile products. Bova Specials UK Limited manufactures veterinary medicine under the ManSA authorisation number 3027, issued by The Veterinary Medicines Directorate, an Executive Agency of the United Kingdom government’s Department for Environment, Food and Rural Affairs.

The formulation pipeline is developed in conjunction with veterinarians to ensure that the right products are delivered to the market.

Dosage Forms Available

- Capsules
- Tablets
- Ophthalmic Preparations
- Cytotoxic Agents
- Oral Pastes
- Powders
- Topical gel
- Oral Suspensions
- Oral Solutions
- Micronized emulsions
- Sterile Injectable
- Sterile Infusions
- Reverse Thermodynamic Gel

Other Attributes

- Synthetic Flavouring Only
- pH Friendly Formulations
GMP and Product development

<table>
<thead>
<tr>
<th>REQUEST</th>
<th>SOURCING</th>
<th>FORMULATION DEVELOPMENT</th>
<th>PRODUCTION</th>
<th>QUALITY CONTROL</th>
<th>SUPPLY</th>
</tr>
</thead>
</table>
| • Expert panel  
• Literature review  
• Key opinion  
• Out of stocks  
• No available product | • All raw material and packaging approved  
• All suppliers undergo rigorous quality checks as per cGMP compliance  
• Raw material sampling and testing process confirm both the identity and integrity. | • Stability studies as per ICH guidelines to assign shelf life and data to back up.  
• Manufacturing processes have been validated as per good manufacturing practices.  
• Literature review  
• Sterility and Microbial testing | • Rigorous in-process testing is performed during manufacturing to ensure the quality of the product is maintained throughout the production process.  
• Operators are highly experienced and trained in the processes.  
• Product quality, consistency, and potency are met by following validated processes and continuous monitoring  
• Equipment Calibration | • Finished product testing  
• Validated analytical methods to perform release testing on all our products as per cGMP requirements.  
• The VMD approves the person responsible for the release and adds them on our ManSA authorisation.  
• The product that complies with the specifications is thoroughly reviewed by a trained and authorised quality assurance responsible person for the release.  
• After a satisfactory review, the product is released for distribution | • Cold chain validation  
• Pharmacovigilence  
• All territory managers and customer service teams trained on PV procedures and reporting. |
Feline Friendly Formulations

- Flavoured pastes and tablets
- Transdermal/paste/liquid options
- Accurate dosing
- Small tablet size
- Quad scoring
- Monohydrate formulations
Article 112

Use of medicinal products outside the terms of the marketing authorisation in non-food-producing animal species

1. By way of derogation from Article 106(1), where there is no authorised veterinary medicinal product in a Member State for an indication concerning a non-food-producing animal species, the veterinarian responsible may, under his or her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with the following medicinal product:

(a) a veterinary medicinal product authorised under this Regulation in the relevant Member State or in another Member State for use in the same species or another animal species for the same indication or for another indication;

(b) if there is no veterinary medicinal product as referred to in point (a) of this paragraph, a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004;

(c) if there is no medicinal product as referred to in point (a) or (b) of this paragraph, a veterinary medicinal product prepared extemporaneously in accordance with the terms of a veterinary prescription.

2. Except as regards immunological veterinary medicinal products, where there is no medicinal product available as referred to in paragraph 1, the veterinarian responsible may under his or her direct responsibility and in particular to avoid causing unacceptable suffering exceptionally treat a non-food-producing animal with a veterinary medicinal product authorised in a third country for the same animal species and same indication.

3. The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian’s responsibility, in accordance with national provisions.

4. This Article shall also apply to the treatment by a veterinarian of an animal of the equine species provided that it is declared as not being intended for slaughter for human consumption in the single lifetime identification document referred to in Article 8(4).

5. This Article shall apply also when an authorised veterinary medicinal product is not available in the relevant Member State.
EU Countries Currently Approving Imports

- Sweden – Companion and equine formulations
- Netherlands – Equine formulations
- Czech Republic – FIP formulations
- Norway – FIP formulations
- Finland – FIP Formulations
- Germany – Companion animal study (FIP)
- Ireland – In discussion
- Greece – In discussion
- Cyprus – Just approved for FIP formulations
Retrospective study and outcome of 307 cats with feline infectious peritonitis treated with legally available veterinary compounded preparations of remdesivir and GS-441524 from 2020 to 2022

- **Locations of the multicentre study**
  - UK/Australia/Sweden/Switzerland/Japan

- **Number of Cats**
  - 307 cats details submitted

- **Conclusions**
  - Regulated remdesivir and GS-441524 products, either alone or used sequentially, are very effective in the treatment of FIP. Variable protocols precluded statistical comparisons of different treatment regimens.
Long-term study of oral treatment with GS-441524 in cats with feline infectious peritonitis (FIP)

- locations of the multicenter study:
  - Munich and Zurich
- number of cats:
  - in total: 770
- contact:
  - Munich: fip@medizinische-kleintierklinik.de
  - Zurich: fiptx@vetlabor.ch
# Black market price comparison

Danièle Gunn-Moore, Emi Barker, Samantha Taylor, Séverine Tasker, Stephanie Sorrell (2022)

An update on treatment of FIP in the UK. Vet Times 51(49)p 8-11

<table>
<thead>
<tr>
<th>Weight</th>
<th>Effusive/Dry 10-12mg/kg</th>
<th>Tablets needed for 84 days</th>
<th>List Price @£14.75/tablet</th>
<th>Mutian Dose Rate</th>
<th>Wet 100mg/kg (5mg/kg active)</th>
<th>Mutian dose rate for 84 days</th>
<th>Mutian price difference</th>
<th>Mutian doses work out to be 5mg/kg effusive, 7.5mg/kg Ocular and 10mg/kg CNS as per their website</th>
</tr>
</thead>
<tbody>
<tr>
<td>2kg</td>
<td>1/2 tablet</td>
<td>42</td>
<td>£620</td>
<td>200mg capsule</td>
<td>£2,336</td>
<td>277%</td>
<td></td>
<td><strong>2.5mg of GS-441524 in every 50mg Mutian Capsule. Mutian advises much lower doses than feline medicine specialists.</strong></td>
</tr>
<tr>
<td>4kg</td>
<td>1 tablet</td>
<td>84</td>
<td>£1,239</td>
<td>2x200mg capsule</td>
<td>£6,072</td>
<td>277%</td>
<td></td>
<td><strong>Mutian doses work out to be 5mg/kg effusive, 7.5mg/kg Ocular and 10mg/kg CNS as per their website</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight</th>
<th>Ocular 15mg/kg</th>
<th>Tablets needed for 84 days</th>
<th>List Price @£14.75/tablet</th>
<th>Mutian Dose Rate</th>
<th>Ocular 150mg/kg (7.5mg/kg active)</th>
<th>Mutian dose rate for 84 days</th>
<th>Mutian price difference</th>
<th>Mutian doses work out to be 5mg/kg effusive, 7.5mg/kg Ocular and 10mg/kg CNS as per their website</th>
</tr>
</thead>
<tbody>
<tr>
<td>2kg</td>
<td>3/4 tablet</td>
<td>63</td>
<td>£990</td>
<td>200mg+100mg capsule</td>
<td>£3,530</td>
<td>280%</td>
<td></td>
<td><strong>Mutian doses work out to be 5mg/kg effusive, 7.5mg/kg Ocular and 10mg/kg CNS as per their website</strong></td>
</tr>
<tr>
<td>4kg</td>
<td>1 1/4 tablet</td>
<td>105</td>
<td>£1,549</td>
<td>3x200mg capsule</td>
<td>£7,008</td>
<td>352%</td>
<td></td>
<td><strong>Mutian doses work out to be 5mg/kg effusive, 7.5mg/kg Ocular and 10mg/kg CNS as per their website</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight</th>
<th>CNS 20mg/kg</th>
<th>Tablets needed for 84 days</th>
<th>List Price @£14.75/tablet</th>
<th>Mutian Dose Rate</th>
<th>CNS 200mg/kg (10mg/kg active)</th>
<th>Mutian dose rate for 84 days</th>
<th>Mutian price difference</th>
<th>Mutian doses work out to be 5mg/kg effusive, 7.5mg/kg Ocular and 10mg/kg CNS as per their website</th>
</tr>
</thead>
<tbody>
<tr>
<td>2kg</td>
<td>1/2 tablet BID (1 tablet)</td>
<td>84</td>
<td>£1,239</td>
<td>2x200mg capsule</td>
<td>£6,072</td>
<td>277%</td>
<td></td>
<td><strong>Mutian doses work out to be 5mg/kg effusive, 7.5mg/kg Ocular and 10mg/kg CNS as per their website</strong></td>
</tr>
<tr>
<td>4kg</td>
<td>1 tablet BID (2 tablets)</td>
<td>168</td>
<td>£2,478</td>
<td>4x200mg capsule</td>
<td>£9,344</td>
<td>277%</td>
<td></td>
<td><strong>Mutian doses work out to be 5mg/kg effusive, 7.5mg/kg Ocular and 10mg/kg CNS as per their website</strong></td>
</tr>
</tbody>
</table>
Veterinary Support

Practice Support
Contact Details

• **Emma Jones**
  • Companion Animal and Equine Business manager
  • [emma@bova.co.uk](mailto:emma@bova.co.uk)
  • +447780 443731

• **Export Team**
  • [export.orders@bova.co.uk](mailto:export.orders@bova.co.uk)