

Zolvix 25 mg/ml Oral Solution for Sheep (EU/2/09/101/001-010)

Change of distribution category from POM-V to POM-VPS

What is the VMD doing? What does it mean?

The VMD has agreed to a request to change the legal distribution category of an anthelmintic (i.e. wormer) for sheep from POM-V to POM-VPS. Zolvix 25 mg/ml Oral Solution is authorised for the treatment and control of gastro-intestinal nematode infections and associated diseases of sheep.

This means that this anthelmintic can now be prescribed by Pharmacists and Suitably Qualified Persons (SQPs) as well as vets.

Why are we doing it?

By expanding the categories of persons who can prescribe this anthelmintic, the VMD is making it more widely available. Increasing the availability of this product is intended to facilitate its incorporation into strategic worm control programmes on farm. Such strategic use of anthelmintics is in line with current guidance on best practice for worm control, from expert groups such as Sustainable Control of Parasites in Sheep (SCOPS). This could result in long term health benefits for sheep, for example by reducing the rate of development and spread of anthelmintic resistance in target parasites, thereby prolonging effective use of currently authorised anthelmintics.

Making sure anthelmintics are used properly to tackle resistance

Making sure anthelmintics continue to be effective is essential for the long term health, welfare and productivity of animals in the UK. The volume and appropriateness of use of all anthelmintics significantly influences the rate of development of anthelmintic resistance in the target parasites. It is therefore vital that anthelmintics are used appropriately to minimise further development of resistance.

In order to ensure that the new categories of prescribers are sufficiently familiar with Zolvix, and how to prescribe it effectively and responsibly, there will be a period of delay until 1st July 2017 before Zolvix can be prescribed by Pharmacists and SQPs. This delay will allow for additional training of these prescribers to take place.

A new compulsory training module will be implemented by AMTRA to augment the skills of all AMTRA registered SQPs permitted to prescribe farm animal products. New SQPs will be required to undertake a revised and extended module before gaining their farm animal registration. These training modules have been designed in line with current best practice recommendations from the SCOPS and Control of Worms Sustainably (COWS) groups and highlight the importance of a “one health” approach. In this way, sales of Zolvix will be accompanied by appropriate point-of-sales advice which will help ensure the product is used appropriately. Further details will be issued by AMTRA shortly - please visit www.amtra.org.uk where you will be able to get details on how to access this new training module which will be available both on-line and in the forthcoming AMTRA/AHDA CPD roadshows.

Monitoring anthelmintic resistance

It is important that farmers and prescribers report any suspected lack of efficacy to any anthelmintic to the [VMD](#). This is essential in order to understand the prevalence and nature of anthelmintic resistance and to inform prescribing decisions.

Additional technical content

Details of product

Zolvix is authorised for the treatment and control of mixed gastro-intestinal nematode infections and associated diseases in sheep. Zolvix contains monepantel (a class 4 anthelmintic).

Legal distribution categories:

In accordance with the Veterinary Medicines Regulations....

The distribution categories for authorised veterinary medicinal products are:

- Prescription Only Medicine – Veterinarian (POM-V)
- Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS)
- Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS)
- Authorised Veterinary Medicine – General Sales List (AVM-GSL).

POM-V medicines

- A POM-V medicine may only be supplied if it has been prescribed by a vet following a clinical assessment of the animal(s), which must be under their care.
- A client may ask for a written prescription if they want to buy the product from a supplier other than the prescribing vet.
- A vet or pharmacist may supply POM-V products or products for use under the [cascade](#) to non-clients but only against a written prescription from a vet.
- Products containing a new active substance will usually be categorised as POM-V.

POM-VPS medicines

- A POM-VPS medicine may be prescribed by any registered qualified persons (RQP).
- An RQP is a vet, pharmacist or Suitably Qualified Person (SQP).
- A clinical assessment of the animal(s) does not have to be carried out when prescribing POM-VPS medicines and the animal doesn't have to be under the RQP's care. However, the RQP must have sufficient information about the animal and the condition to be treated to enable them to prescribe and supply the most appropriate product.
- A customer may request a written prescription if they want to buy the product from a supplier other than the prescribing RQP. An RQP may supply POM-VPS medicines against a written prescription from another RQP.
- Pharmacists and SQPs may supply a POM-VPS medicine for use under the cascade if prescribed by a vet against a written prescription.

More information can be found here: <https://www.gov.uk/guidance/retail-of-veterinary-medicines>

The details and distribution categories for all medicines can be found on the VMD's [Product Information Database](http://www.vmd.defra.gov.uk/ProductInformationDatabase/) (<http://www.vmd.defra.gov.uk/ProductInformationDatabase/>).

Suitably Qualified Persons (SQPs)

A Suitably Qualified Person (SQP) is an animal medicines advisor, a legal category of professionally qualified persons who are entitled to prescribe and/or supply certain veterinary medicines under the Veterinary Medicines Regulations.

It is the duty of an SQP to ensure that the statutory requirements in respect of the prescription and/or supply of veterinary medicines are respected, advising on choice of medicine and their safe and effective use. The SQP is responsible for ensuring this irrespective of how the product is supplied, e.g. supply from a registered retail premises, postal supply, from a website, etc.

The Animal Medicines Training Regulatory Authority (AMTRA) is an independent regulatory body, appointed by the Secretary of State under the Veterinary Medicines Regulations to keep a register of SQPs. AMTRA's role is to ensure that the prescription and supply of VPS animal medicines in the UK is undertaken in a responsible manner by AMTRA qualified persons.

In 2016 Vet Skill Ltd was appointed by the Secretary of State as an additional body suitable to maintain a register of SQPs. Vet Skill Ltd has not yet begun to provide SQP training.

More information regarding AMTRA can be found here: <http://www.amtra.org.uk/>

More information regarding Vet Skill Ltd can be found here: <http://www.vetskill.com/>

Anthelmintics authorised for use in sheep in the UK:

There are five anthelmintic classes authorised in the UK for use against sheep helminths: the benzimidazoles (1-BZ); the imidazothiazole, levamisole (2-LV); the macrocyclic lactones (3-ML), which include the avermectins (ivermectin, doramectin, abamectin) and the milbemycins (moxidectin); the amino-acetonitrile derivatives (4-AAD); and the spiroindoles (5-SI).

Anthelmintic Resistance:

Definition:

Anthelmintic resistance is the ability of parasites to survive doses of drugs that would normally kill parasites of the same species and stage.¹ The development of anthelmintic resistance is a highly complex process influenced by the host, the parasite, environment and use of veterinary medicinal products (VMPs).

Anthelmintic resistance in sheep nematodes in the UK and its economic impact:

The clinical impact of resistant worm populations is most widely recognised, in the UK, in sheep.

In 2011 the Parasitology Action Plan for Wales 2011 stated that 'triple resistance (i.e. to the 3 older classes [classes 1-3] of anthelmintic) has made sheep farming unsustainable on a number of farms in the UK'. A study conducted in Wales² in 2014-15 on 47 sheep farms demonstrated that 94% of farms had evidence of resistance to benzimidazoles (class 1), 68% to levamisole (class 2), 51% to ivermectin (class 3) and 19% to moxidectin (class 3). A study conducted in Northern Ireland³

¹ The World Association for the Advancement of Veterinary Parasitology

² 'Wales Against Anthelmintic Resistance Development' commissioned by Meat Promotion Wales

³ McMahan et al. (2013) Anthelmintic resistance in Northern Ireland (I): Prevalence of resistance in ovine gastrointestinal nematodes, as determined through faecal egg count reduction testing.

also found high levels of resistance, including 62% resistance to milbemycin (class 3). Resistance to the two newer classes of anthelmintic, (the amino-acetonitrile derivatives [class 4] and the spiroindoles [class 5]) is currently assumed to be low.

The annual cost of gastro-intestinal parasites to the British sheep industry was estimated to be £84 million in 2005, making parasitic gastroenteritis (PGE) the most costly disease affecting sheep. This cost is predominantly due to the effect of worms on production and is likely to be increasing as the level of anthelmintic resistance increases. Parasitic gastro-enteritis is consistently the most common APHA Veterinary Investigation Diagnosis Analysis (VIDA) finding for sheep. PGE was also the most common diagnosis for lambs in a survey of fallen stock in north-east England.⁴

Changes in understanding of impact of anthelmintic use and environmental factors on rate of development of anthelmintic resistance:

Anthelmintic resistance to the 'older' anthelmintic classes (classes 1-3) has developed in the UK. However, to put this in context, when these products were authorised, key opinion leaders were recommending attempts to eliminate parasite burdens by strict interval dosing of anthelmintics alongside management practices such as 'dose and move'. These practices exerted significant selection pressure for resistance in the target parasite population. Subsequently, there have been considerable advances in understanding the interaction between anthelmintic use, farm management practices, selection pressure and the development of anthelmintic resistance. This in turn has prompted development of evidence-based recommendations regarding sustainable use of anthelmintics. Indeed, SCOPS was founded in 2003 in the UK with this main aim. The newer anthelmintics, including Zolvix [monepantel] and Startect [derquantel/abamectin], have been authorised alongside new anthelmintic guidance principles which are predicted to help safeguard their efficacy in the longer term (www.scops.org.uk). Modelling studies suggest that strategic anthelmintic regimens alongside maintenance of parasites *in refugia* will slow the rate of development of resistance (Leathwick and Hosking 2009; Learmount *et al.* 2012; Leathwick 2012).

References:

- Leathwick DM and Hosking BC (2009) Managing anthelmintic resistance: Modelling strategic use of a new anthelmintic class to slow the development of resistance to existing classes. *NZ Vet J* 57(4) 203-207.
- Learmount J, Taylor MA, Bartram DJ (2012) A computer simulation study to evaluate resistance delaying control strategies with a derquantel–abamectin combination on UK sheep farms. *Vet. Parasitol.* 187, 244-253.
- Leathwick DM (2012) Modelling the benefits of a new class of anthelmintic in a combination. *Vet Para* 186, 93-100.

Use of newer anthelmintics (e.g. Zolvix) in sheep:

This change in legal distribution category will facilitate wider availability of Zolvix, by permitting supply through additional prescriber routes.

⁴ SHAWG report 2016/2017.

Strategic use of the newer anthelmintics could:

- reduce the spread of parasites conferring anthelmintic resistance between premises via appropriate quarantine treatment (both Startect [derquantel/abamectin] and Zolvix [monepantel] have demonstrated efficacy against strains of parasites resistant to benzimidazoles, levamisole, and macrocyclic lactones) (Little et al., 2001);
- slow the rate of development of resistance to the older anthelmintic classes (classes 1-3) (in particular the macrocyclic lactones (class 3), which are essential for control of sheep scab in the UK) (Leathwick and Hosking, 2009);
- and enable better control of parasite populations that are already resistant to the older anthelmintic classes (Bartram et al., 2012).

References:

- Bartram DJ, Leathwick DM, Taylor MA, Geurden T, Maeder SJ (2012) The role of combination anthelmintic formulations in the sustainable control of sheep nematodes. *Vet Para* 186, 151-158.
- Leathwick DM and Hosking BC (2009) Managing anthelmintic resistance: Modelling strategic use of a new anthelmintic class to slow the development of resistance to existing classes. *NZ Vet J* 57(4) 203-207.
- Little PR, Hodge A, Maeder SJ, Wirtherle NC, Nicholas DR, Cox GG, Conder GA (2011) Efficacy of a combined oral formulation of derquantel-abamectin against the adult and larval stages of nematodes in sheep, including anthelmintic-resistant strains. *Vet Para* 181, 180-193.

Links:

Sustainable Control of Parasites in Sheep (SCOPS)

A steering group was founded in the UK in 2003, comprising experts from industry and research. The group aims are to “develop sustainable strategies for parasite control in sheep, facilitate and oversee the delivery of these recommendations to the industry and ensure that new research and development is incorporated to refine and improve advice given to the sheep industry”. These SCOPS principles are conveyed to industry and farmers through a variety of media: SCOPS website; farmer publications; promotional material at trade shows and conferences; and CPD training.

Web link: <http://www.scops.org.uk/>

Control of Worms Sustainably (COWS)

An industry stakeholder group which aims to promote best practice in the control of cattle parasites.

Web link: <http://www.cattleparasites.org.uk/>