Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Systamex 2.265 %w/v Worm Drench

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	
Oxfendazole	2.265 % w/v
Excipients	
Sorbic Acid (E200)	0.150 % w/v
Methyl Parahydroxybenzoate (E218)	0.150 % w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
A white to off-white smooth, uniform suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the target species

Indications: A worm drench for cattle and sheep for the control of mature and immature gastro-intestinal roundworms and lungworms and also tapeworms. It is also ovicidal.
It controls the following:

Gastrointestinal worms: *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus* including *N. battus, Cooperia, Bunostomum, Capillaria, Oesphagostomum, Chabertia* and *Trichuris* spp.

Lungworms: *Dictyocaulus viviparous*.

Tapeworms: *Monieza* (heads and segments).

At the recommended dose in cattle, oxfendazole is effective against inhibited larvae of *Cooperia* and usually effective against inhibited/arrested larvae of *Ostertagia.*

In sheep, it is effective against inhibited/arrested stages of *Nematodirus* and benzimidazole susceptible *Haemonchus* and *Ostertagia.*

4.3 Contraindications

Do not use in animals with known sensitivity to the active ingredient.

4.4 Special warnings for each target species

As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of anthelmintic resistance developing. If the product does not achieve the desired clinical effect, other diseases, nutritional disturbances or anthelmintic resistance may be involved.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Direct contact with the skin should be kept to a minimum. Wear suitable protective clothing including impervious rubber gloves.
Wash concentrate from the skin immediately with plenty of water. In the case of contact with eyes, wash immediately with plenty of water and seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

None at the recommended dosage.

4.7 Use during pregnancy, lactation or lay

Studies have shown that oxfendazole produces no adverse maternal or foetal effects when administered to pregnant cattle or sheep. When administered to lactating cattle and sheep, less than 1 % of the administered dose is excreted in the milk. Therefore, there is little risk to suckling animals when the product is administered to lactating females.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

Cattle:
Dose according to bodyweight at the rate of 4.5 mg of oxfendazole per kg bodyweight, e.g.

Bodyweight	*Dose*
100 kg (2 cwt)	20 ml
150 kg (3 cwt)	30 ml
200 kg (4 cwt)	40 ml
250 kg (5 cwt)	50 ml
300 kg (6 cwt)	60 ml

Above 300 kg, give 10 ml per 50 kg

Sheep: Dose according to bodyweight at the rate of 5 mg oxfendazole per kg bodyweight equivalent to 1 ml per 4.5 kg, e.g.

Bodyweight	Dose
9 kg (approx 20 lb)	2 ml
13.5 kg (approx 30 lb)	3 ml
18 kg (approx 40 lb)	4 ml
22.5 kg (approx 50 lb)	5 ml
27 kg (approx 60 lb)	6 ml
31.5 kg (approx 70 lb)	7 ml
36 kg (approx 80 lb)	8 ml
40 .5 kg (approx 90 lb)	9 ml
45 kg (approx 100 lb)	10 ml

Above 45 kg, give 1 ml per 4.5 kg.

Give the recommended dose by mouth using standard dosing equipment. The suspension should be well shaken before use. Dosing equipment should be cleaned thoroughly before and after use. Dosing may be repeated at required intervals.

When to dose: General: Dosing may be repeated at required intervals because in the British climate, sheep and cattle are almost continually exposed to reinfection and regular dosing to prevent worm population build up is essential. The following are guidelines to regular dosing:

Cattle: Lungworm: Where lungworm (husk) is a problem, dose at the first sign of coughing. Treat all animals in the group and repeat at 3 - 4 week intervals as necessary

Ostertagiasis: For the prevention of Type II ostertagiasis dose stock in the late autumn. If animals are not housed immediately, a further treatment should be given in January/ February.

Young Cattle: Dose about 1 month after turning out to pasture. Repeat treatment at intervals of 1 - 2 months.

Bought in cattle: Dose on arrival.
After dosing, stock should ideally be held for at least 8 hours, or longer if practical, before putting out to pasture, in order that the worm eggs in the gut may be sterilised.

Dairy Cattle: Dose cows shortly before or immediately after calving.

Sheep: Ewes: Dose ewes before lambing and/or 4 - 6 weeks after lambing. Dose again before the rams are turned out.

Lambs: For routine roundworm control, give a first treatment at about 6 weeks of age. Repeat at monthly intervals.

Nematodiriasis: Give the first treatment when an outbreak is expected or during the first two weeks of May. Give two further treatments at an interval of 3 weeks.

Bought in sheep: Dose on arrival.
Ideally, sheep and lambs should be held for at least 8 hours after dosing before moving to clean pasture. Where it is inconvenient to hold them for this time, sheep
treated with Systamex Worm Drench can be turned on to infested pasture overnight and moved to clean pasture within 24 hours of dosing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

There are no specific recommendations in the case of overdosage.

4.11 Withdrawal Period(s)

Animals intended for human consumption must not be slaughtered during treatment.

Cattle:
Meat and offal: 28 days.
Cattle intended for human consumption may only be slaughtered from 28 days after the last treatment.
Milk: 5 days.
Milk for human consumption must not be taken during treatment. Milk intended for human consumption may be taken from cows after 5 days from the last treatment.

Sheep:
Meat and offal: 10 days.
Sheep intended for human consumption may only be slaughtered from 10 days after the last treatment.
Milk: Not for use in sheep producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; Benzimidazoles and related substances; Oxfendazole.
ATCvet Code: QP52AC02.

5.1 Pharmacodynamic properties

Oxfendazole is an anthelmintic of the benzimidazole group. It is effective in the treatment and control of adult and immature gastro-intestinal roundworms and lungworms (including *Ostertagia, Haemonchus, Trichostrongylus, Nematodirus* (including *N. battus*), *Cooperia, Capillaria, Oesphagostomum, Chabertia, Trichuris and Dictyocaulus* spp.). It is also effective against roundworm eggs and tapeworms (*Moniezia* spp.).
Oxfendazole acts on helminth parasites by inhibiting the fumarate reductase system and glycogen metabolism.

5.2 Pharmacokinetic properties

Absorption
Studies in cattle showed that the organic extractable portion of the radioactivity present in the plasma ranged from 99% at 0.25 hours to 88 % at 8 to 12 hours after oral administration of 14-C oxfendazole. Approximately 77 % of the orally administered oxfendazole was absorbed. Orally administered 14 C-oxfendazole studies in sheep showed that an average of 85 % of the administered compound was absorbed. Organic extractable portion of the plasma levels ranged from 75 to 90 % up
to 24 hours after dosing. The maximum plasma levels were seen at 8 hours and the half-life was found to be 28 hours.

Distribution
In oral 14C-oxfendazole studies in sheep and cattle, the liver was found to be the site of highest concentration and slowest depletion of the drug-related residue. Total residues depleted with half-lives of 7 and 3 days in cattle and sheep respectively. In cattle, liver protein-bound residue was shown to be only 13 % bioavailable as oxfendazole and in sheep only 8 %.

Biotransformation
Oxfendazole is metabolised into the thioether and the sulfone.

Elimination
In radiolabelled studies in cattle and sheep, about 21 % of the orally administered 14-C was recovered from the urine and 65 % from the faeces. Less than 1 % of oxfendazole is excreted in the milk, with the half-life being 18 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyl 40 stearate
Macrogol 8000
Sodium citrate
Citric acid monohydrate
Xanthan gum
Colloidal anhydrous silica
Sorbic acid (E200)
Methyl parahydroxybenzoate (E218)
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

6.4 Special precautions for storage

Keep the container in the outer carton.
Protect from direct sunlight.
Do not freeze.
Do not store above 25°C.

6.5 Nature and composition of immediate packaging

1 litre and 2.5 litre flexipacks.

0.5, 1, 2.5, 5, 10 and 20 litre rigid polyethylene packs.

1, 2.5 and 5 litre HDPE back-packs.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Do not contaminate ponds, waterways or ditches with product or used container. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Ltd.
Shire Park
Welwyn Garden City
Hertfordshire
AL7 1TW
England

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/038/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT