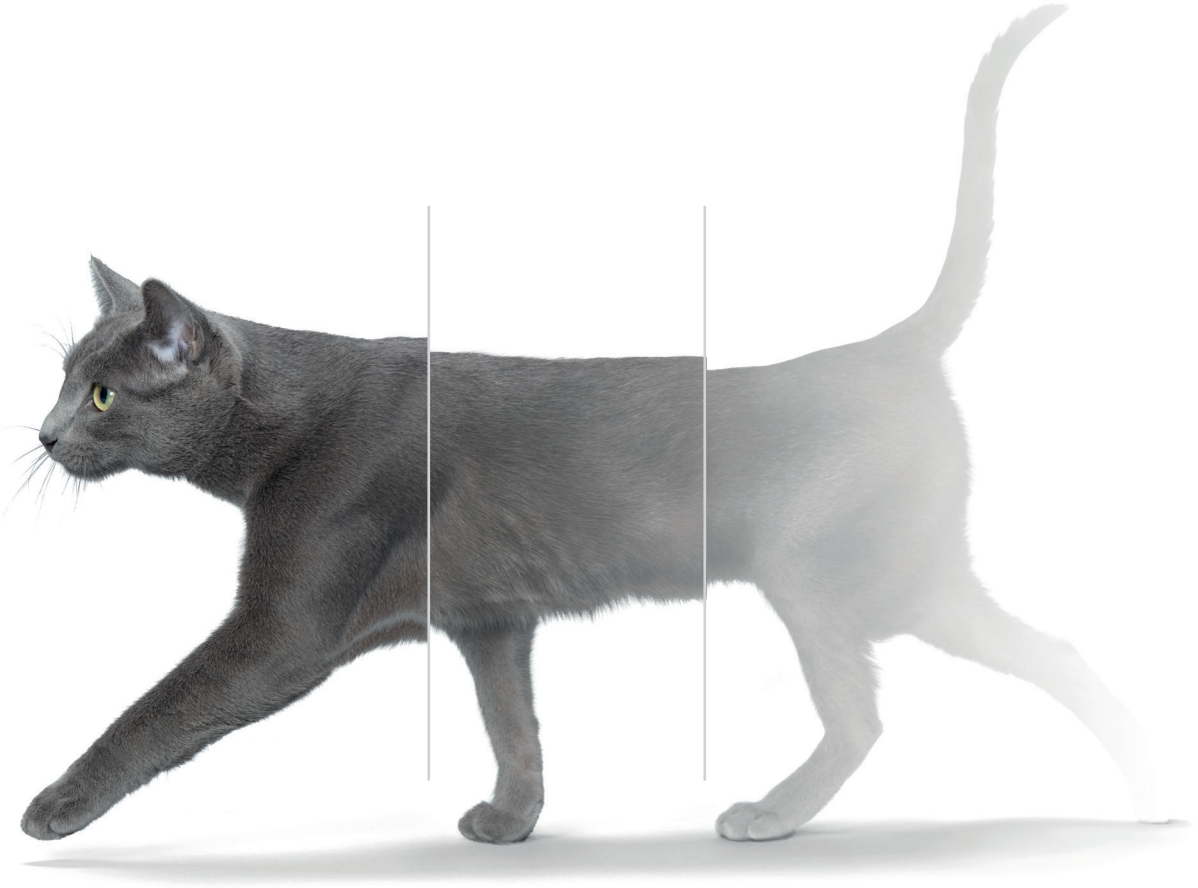
Dechra
Veterinary Products

With unintended weight loss, you can't afford to wait.



The first and only veterinary licensed transdermal medication for the management of weight loss in cats.

Mirataz®

Take control with Mirataz

The importance of treating poor appetite and weight loss resulting from chronic medical conditions in cats

Unintended feline weight loss may be associated with serious consequences;

- A Low Body Condition Score (BCS) is linked to **reduced survival** across many disease states[1-4]
- Prolonged inadequate nutrition may be **more detrimental** to the patient than the primary disease process[5]
- In diseased cats a change in production of inflammatory cytokines, catecholamines, cortisol, insulin and glucagon can trigger a **hyper-metabolic state**, characterised by protein catabolism, cachexia, insulin resistance, lipolysis and increased energy expenditure[6-8]
- Patients with cachexia may get into a negative nitrogen and energy balance, lose lean body mass and are at risk of developing **malnutrition**. Malnutrition can result in anaemia, hypoproteinaemia and reduced immune function, wound healing and organ function[6-7, 9-10]
- Poor appetite is **emotionally distressing to owners** and is perceived as an indication of poor quality-of-life[11-13]

Maintaining a strong appetite and ideal body condition in feline patients may improve their lifespan, quality of life and provide owners with peace of mind.

Poor appetite and weight loss needs to be treated swiftly

There's no time to waste when a cat's eating habits change and they start to lose weight.

- Cats can succumb quickly to the negative effects of anorexia and weight loss[14-16]
- **Early therapeutic intervention** is essential to minimise the impact of weight loss, allowing you time to diagnose the underlying cause[14-16]
- Cat owners may be more likely to comply with treatment recommendations (from diet changes to administering oral medications) if their cat is eating[17]

Identifying weight loss early, and managing it long term, can help improve feline patients' overall health.

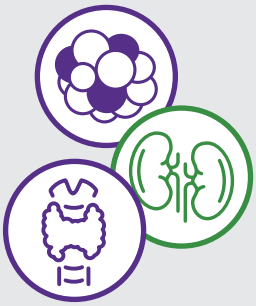
Did you know?

Weight loss can be the earliest indicator of disease in cats

A study found that cats lost a median of **8.9%** body weight in the 12 months before diagnosis of chronic kidney disease (CKD)

Weight loss was identified as early as **3 years** before diagnosis and accelerated following diagnosis of CKD[2]

Similar study results were seen in cats with cancer, renal failure, and thyroid disease, with weight loss beginning **> 2 years** prior to diagnosis[18]



On average, cats presenting with weight loss have been losing weight for about **a month**[19]

To **improve** patient **outcomes**, we can help cat owners understand that time is of the essence

A survey of EU vets indicated **weight loss** and **inappetence** is the **most common** reason for owners to bring their cat to the vet[20]

European vets see approximately **46 cases** of feline unintended weight loss due to underlying conditions per month[20]

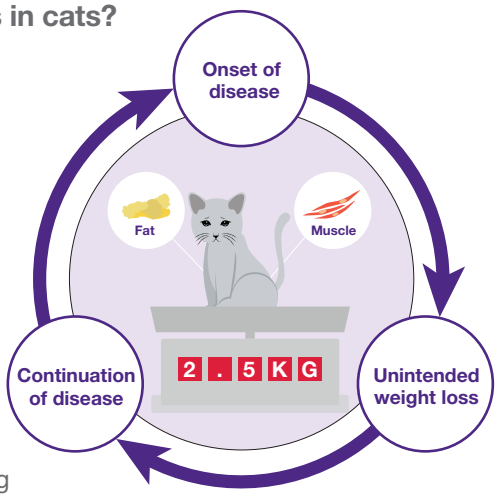
This equates to approximately **60 million** cases of feline unintended weight loss per year that may benefit from **Mirataz**

What causes poor appetite and weight loss in cats?

Some of the more common underlying diseases could be:[15, 21-22]

- hyperthyroidism
- chronic kidney disease
- inflammatory bowel disease
- neoplasia
- pancreatitis
- liver disease

Therefore, both identifying weight loss and diagnosing the underlying cause are important in successful treatment.



In summary

- Poor appetite and weight loss can have significant consequences to the survival time and quality-of-life of feline patients
- Treating weight loss and poor appetite before a definitive diagnosis is identified benefits the patient and allows you time for further investigation

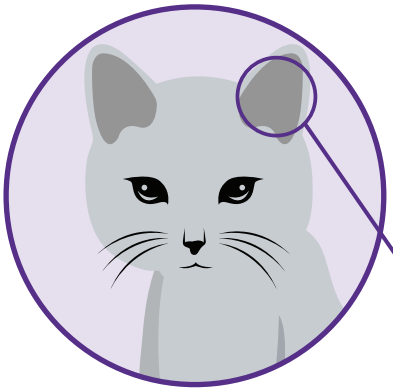
Introducing Mirataz

Mirataz is the first licensed veterinary medicinal product for **body weight gain** in cats experiencing poor appetite.

The active ingredient, **mirtazapine**, addresses reduced appetite and induces significant weight gain in as little as 14 days[23].

This can allow for a swift response to initial symptoms – **improving condition and wellbeing** before you have a definitive diagnosis, alongside providing support to patients already receiving long term treatment.

Mirataz is indicated for body weight gain in cats experiencing poor appetite and weight loss resulting from chronic medical conditions, so you will be able to address a symptom commonly displayed by a large number of your feline patients[16] and help to prolong lifespan[1-4]



Transdermal for easier application

Mirataz is a transdermal medication which may be easier for your clients to administer to cats that are unable to take oral medication due to poor appetite, nausea or vomiting. There is no need for the cat to eat in order to receive medication, so you can be assured of good patient compliance.

Mirataz is applied to the inside of the cat's ear.

Innovative new packaging

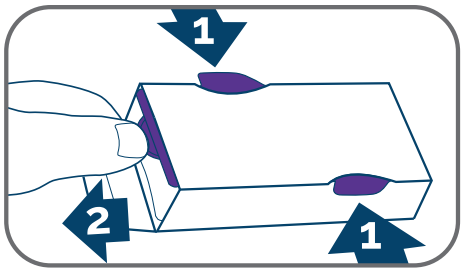
Innovative child-resistant packaging allows you to confidently prescribe Mirataz for owners to use at home, reducing the amount of time cats need to be hospitalised.

a) Open flap at end of carton

b) Press both tabs (arrow 1) simultaneously and pull on tab 2 to remove tray

c) Ensure you return the tube to the tray and place the tray back in the box

d) Push tray all way into the box, ensure it locks in place.



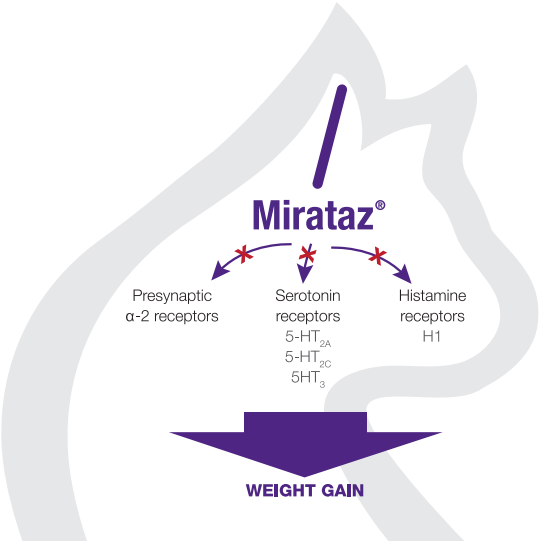
QR code

For an instruction video on using our new packaging, go to <<insert url>> or scan the QR code.

How does mirtazapine work?

The exact mechanism by which mirtazapine induces weight gain and addresses poor appetite appears to be multifactorial.
The pharmacodynamic action of mirtazapine involves interaction with several different receptors involved with appetite, nausea and emesis.

Specifically, antagonism of 5-HT2 and histamine H1 receptors may account for the orexigenic effects of the molecule[24]



QR code

For more information on how mirtazapine works, scan the QR code and watch the video

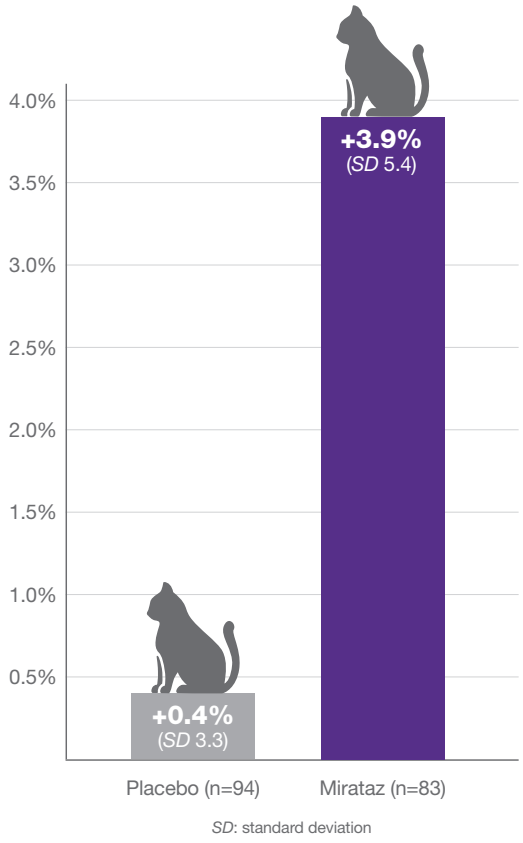
Mirataz: The evidence

Body weight gain

Mirataz treated cats demonstrated a **significant increase in body weight in as little as 14 days**[23].

Cats* with a documented history of ≥5% body weight loss were randomised to receive either Mirataz ointment or placebo once daily for 14 days. Changes in body weight between the two groups were evaluated from day 1 to day 14.

The mean percent change in body weight for cats receiving Mirataz was **+3.9%** compared to only +0.4% in the placebo group. This equated to a mean weight gain of **150 grams** in the Mirataz group versus only 10 grams in the placebo group. This change was considered **statistically significant** ($p < 0.0001$).



SD: standard deviation

Mirataz and underlying disease

Mirataz is indicated for weight gain in cats experiencing poor appetite and weight loss resulting from **chronic medical conditions**. Cats+ within the Mirataz field trial[23] were diagnosed with varying underlying diseases[25] (see below) and were receiving a range of medications alongside Mirataz including fluids, antibiotics, corticosteroids, antacids, anti-hypertensives, antiemetics and anti-thyroid medications[26].

Underlying diseases diagnosed in cats within the Mirataz field trial[25]

When analysing cats with suspect renal disease specifically[27] the mean percent change in body weight remained at +3.9% in the Mirataz treated group with **no significant difference in incidence of overall adverse reactions** in comparison to placebo.

These results were similar to a previously published study of cats with chronic kidney disease, which reported a mean weight gain of 180 grams in the mirtazapine treated group compared to an average 7 grams weight loss in the placebo group. In addition the treatment group saw significant increases in appetite and activity, and decreases in vomiting when compared to placebo[28].

Adverse reactions

Application of Mirataz has been found to be **well tolerated**. Application site erythema and behavioural changes were the most commonly reported adverse reactions during registration.[24] Vomiting was also described, however over a quarter of cats+ had pre-existing vomiting upon study enrolment due to underlying conditions [23].

In summary

Mirataz can be prescribed to a **wide variety** of feline patients seen within your practice. Mirataz addresses reduced appetite amongst cats, resulting in **significant** body weight gain whilst remaining **well tolerated**, regardless of underlying condition.

Mirataz has shown to **increase weight** in cats with many underlying diseases and is overall well tolerated.

*Per protocol population (Cats which completed the entire study through 14 days +/- 3 days)
+Safety population (Cats which received at least one dose of Mirataz/Placebo)

The benefits of a licensed transdermal

The use of mirtazapine in cats is not a new concept. **Human tablets and compounded versions of mirtazapine have been used off-label**, with a range of dosing regimens and rates described[5]. However:

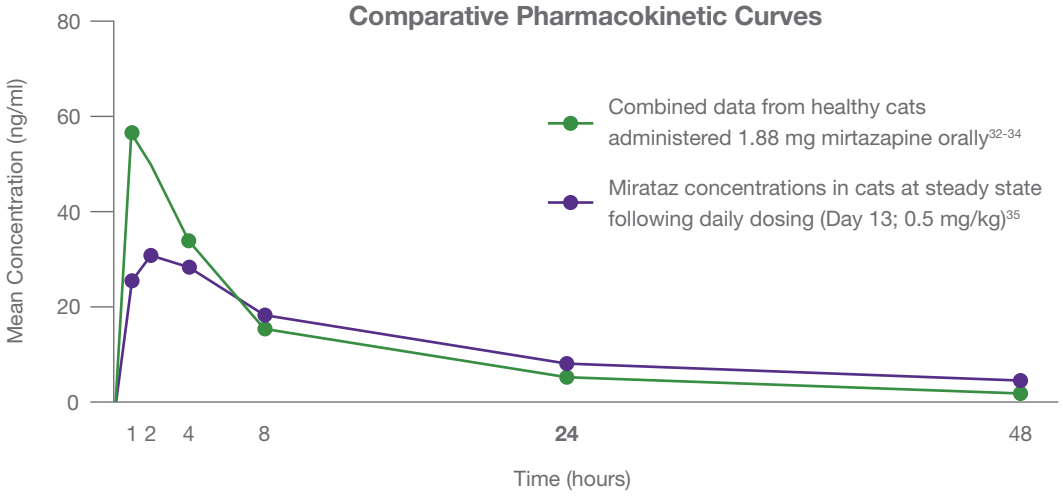
1. Human tablets must be split or broken, which may lead to **inaccurate dosing**. The impact on the user from handling cut or broken pills is also unknown[29]
2. **Compounded** transdermal mirtazapine preparations have been shown to have **inconsistent concentrations** achieved in respect to target dose[30]
3. Initial dosing was **based on human data** with no cat-specific pharmacokinetic support[31]

Why are pharmacokinetics important?

The pharmacokinetics (PK) of any medication can help to guide dosing regimen.

When the PK of **oral** mirtazapine were studied in healthy cats the data supported giving smaller doses, more frequently. In a pooled population (n=22), the mean peak concentration was 55.8 ng/ml (C_{max}) and the time taken to reach this was 1 hour (T_{max})[32-34].

With **Miratаz**, there is a lower mean C_{max} (39.6 ng/ml) and longer Tmax (2.1 hours)[35], **reducing serum peak concentration**. A lower mean C_{max} may help to **minimise adverse reactions**.



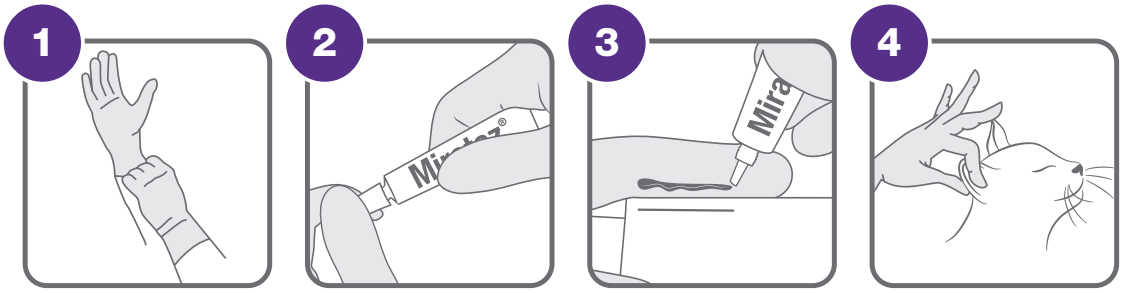
Overall, the PK data supports **daily administration** in cats with unintended weight loss caused by a range of **underlying diseases**.

The combination of documented pharmacokinetic data and a licensed formulation provides confidence. By using a licensed veterinary medicinal product, you can be assured that it has been subjected to rigorous European standards for the registration process ensuring only medicines that meet defined standard of quality, safety and efficacy are authorised.

Dosing and administration

Mirataz should be administered topically by applying a 3.8 cm ribbon of ointment (approximately 2 mg/cat, equal to 0.1 ml) with a gloved hand, onto the inner pinna of the cat's ear once daily for 14 days (see diagrams below).

We suggest that the first dose is applied in the consult room, enabling demonstration of correct application, before the owner continues use of Mirataz at home.



Step 1:

Wear impermeable gloves.

Step 2:

Twist cap on tube counterclockwise to open.

Step 3:

Apply even pressure on tube and squeeze a 3.8 cm line of ointment onto your index finger using the measured line on the carton.

Step 4:

Using your finger, gently rub ointment on inside surface of the cat's ear (pinna) spreading it evenly over the surface.

If contact with your skin occurs wash thoroughly with soap and water.

The line below coincides with the appropriate length of ointment to be applied:

QR code

To see how convenient Mirataz is to apply, go to <<insert url>> or scan the QR code.

Daily applications should be **alternated between the left and right ears**. If desired, the inner surface of the cat's ear may be cleaned by wiping with a dry tissue or cloth immediately prior to the next scheduled dose. We recommend **wearing gloves** and handling the pinnae with care.

Care should be taken to avoid contact with the treated cat for the **first 12 hours** after each daily application and until the application site is dry. It is therefore recommended to treat the cat in the evening. Treated cats should not be allowed to sleep with owners, especially children and pregnant women during all the period of the treatment.

Tailored nutrition from Dechra

Veterinary recovery diets play an important role in the management of unintended weight loss.

An 'ideal' recovery diet is: [6-7,9-10]

- High in protein: to support maintenance of lean body mass
- High in energy: Critical care patients are often anorectic or have a reduced appetite so small amounts of food need to meet energy needs. This is best achieved by providing high levels of dietary fat, as major source of energy in cachectic patients
- Low in carbohydrate: Critical care patients are often insulin resistant
- Highly digestible to compensate for reduced absorptive capacity
- Highly palatable to encourage eating even with poor appetite

Additional specific nutrients can also support unwell patients:

As well as a highly digestible, energy- and fat-dense, high-protein diet, specific nutrients can provide extra support to aid recovery.

- Marine sourced EPA and DHA Omega-3 fatty acids: [9-10, 36]
- Selected amino acids[6, 9-10]
  - Glutamine
  - Arginine
  - Branched-chain amino acids (valine, leucine, isoleucine)
- Zinc[10]
- Beta-1,3/1,6-glucans[37]
- L-carnitine[38]

Find out more about the SPECIFIC™ range here:

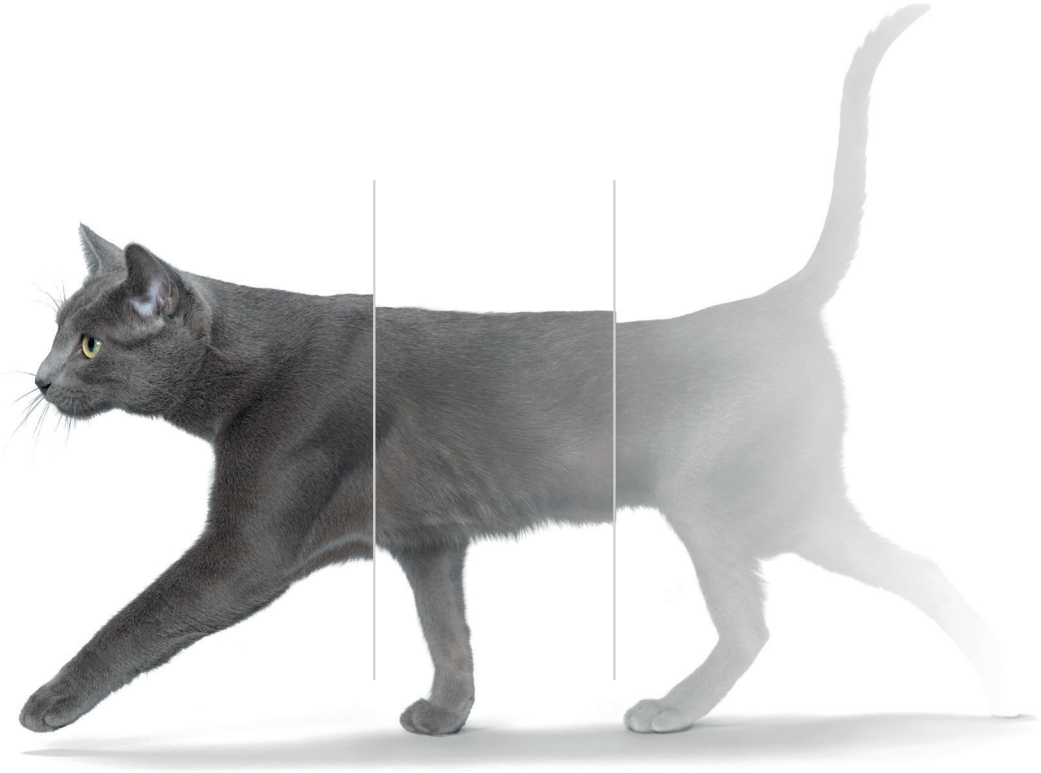
SPECIFIC F/C-IN-W and F/C-IN-L Intensive Support

To provide immediate and short term nutrition support SPECIFIC® Intensive Support are complete dietetic pet foods for cats and dogs for nutritional restoration, convalescence and feline hepatic lipidosis. The diets have a high energy density, high concentrations of essential nutrients and highly digestible ingredients. They have high levels of omega-3 fatty acids from fish oil and ß-1,3/1,6-glucans to support recovery and the immune system.

- High levels of energy, fat and protein to ensure sufficient nutrients and energy intake even with reduced appetite
- Beta-glucans, high levels of fish oil, zinc, selenium, arginine for immune support
- Highly digestible ingredients compensate for decreased digestion and ensure uptake of nutrients during periods of nutritional restoration
- L-carnitine to facilitate the ß-oxidation of fatty acids for energy generation, and support of lean body mass and cats with hepatic lipidosis
- F/C-IN-W Intensive Support is a wet diet with a special soft texture making it suitable for syringe and (when mixed with water) tube feeding
- F/C-IN-W Intensive Support has a very high palatability to stimulate voluntary food intake
- F/C-IN-L Intensive Support is a liquid diet, especially designed for tube feeding

Manage poor appetite and weight loss in cats with Mirataz

1. Reduced BCS and poor appetite are associated with reduced survival time and quality of life[1-4,11-13]
2. Mirataz is the first and only licensed transdermal medication for body weight gain in cats experiencing poor appetite and weight loss resulting from chronic medical conditions
3. Mirataz results in significant weight gain in cats in as little as 14 days following topical application[23]
4. Mirataz can be prescribed to a wide variety of feline patients seen within your practice, providing a way to quickly respond to initial symptoms, alongside providing support to those patients already receiving long term treatment



With unintended weight loss, you can't afford to wait.

Supporting you

There is an extensive range of resources to support you and your clients with using Mirataz

Resource

Resource

Resource

Resource

Resource

Resource

Resource

Resource

Resource

Did you know?

We have a dedicated in-house technical team who can help support you with individual cases.

In order for us to best advise on your case, you will need to provide us with all relevant information; current dosage, treatment duration, recent results and clinical assessment.

Get in touch via our website: **www.dechra.co.uk/contact** or call one of the team on **01939 211200.**

Mirataz®

Mirtazapine transdermal ointment

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Mirataz 20 mg/g transdermal ointment for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.1 g contains:

Active substance: Mirtazapine (as hemihydrate) 2 mg

Excipients: Butylhydroxytoluene (E321) 0.01 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Transdermal ointment.

Non-greasy, homogeneous, white to off-white ointment.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

For bodyweight gain in cats experiencing poor appetite and weight loss resulting from chronic medical conditions (see section 5.1).

4.3 Contraindications

Do not use in breeding, pregnant or lactating cats.

Do not use in animals less than 7.5 months of age or less than 2 kg body weight.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in cats treated with cyproheptadine, tramadol or monoamine oxidase inhibitors (MAOIs) or treated with an MAOI within 14 days prior to treatment with the veterinary medicinal product as there may be an increased risk of serotonin syndrome (see section 4.8).

4.4 Special warnings for each target species

The efficacy of the veterinary medicinal product has not been established in cats less than 3 years of age.

The efficacy and safety of the veterinary medicinal product has not been established in cats with severe renal disease and/or neoplasia.

Proper diagnosis and treatment of the underlying disease is key to managing weight loss, and treatment options are dependent on the severity of weight loss and underlying disease(s). The management of any chronic disease associated with weight loss should include providing appropriate nutrition and monitoring body weight and appetite.

The therapy with mirtazapine should not replace necessary diagnostics and/or treatment regimens needed to manage the underlying disease(s) causing unintended weight loss.

The efficacy of the product was only demonstrated with a 14-day administration corresponding to the current recommendations (see section 4.9). Repetition of the treatment has not been investigated and as such should only be done after benefit-risk balance assessment by the veterinarian.

The efficacy and safety of the veterinary medicinal product has not been established in cats weighing less than 2.1 kg or more than 7.0 kg (see also section 4.9).

4.5 Special precautions for use

Special precautions for use in animals

The veterinary medicinal product should not be applied on damaged skin. In the case of hepatic disease, elevated hepatic enzyme levels may be observed.

Kidney disease may cause reduced clearance of mirtazapine, which may result in higher drug exposure. In these special cases, biochemical hepatic and renal parameters should be regularly monitored during the treatment.

The effects of mirtazapine on glucose regulation have not been evaluated. In the case of use in cats with diabetes mellitus, glycaemia should be regularly monitored.

When used in hypovolemic cats, supportive treatment (fluid therapy) should be implemented.

Care should be taken that other animals in the household do not come in contact with the application site until it is dry.

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

The product can be absorbed via the cutaneous or oral route and can cause drowsiness or sedation.

Avoid direct contact with the product. Avoid contact with the treated animal for the first 12 hours after each daily application and until the application site is dry. It is therefore recommended to treat the animal in the evening. Treated animals should not be allowed to sleep with owners, especially children and pregnant women during all the period of the treatment.

Impermeable disposable protective gloves should be provided at the point of sale with the product and must be worn when handling and administering the veterinary medicinal product.

Thoroughly wash hands immediately after administration of the veterinary medicinal product or in case of skin contact with the product or the treated cat.

Limited data are available on the reproductive toxicity of mirtazapine. Given that pregnant women are considered a more sensitive population, it is recommended that pregnant women or women trying to conceive should avoid handling the product and avoid contact with treated animals throughout the treatment period.

The product may be harmful after ingestion.

Do not leave the tube out of its child-proof container except during the application phase. Children must not be present when applying the treatment to the cat.

The tube must be placed in the child-proof container after application, which must be closed immediately.

Do not eat, drink or smoke while handling the veterinary medicinal product.

The veterinary medicinal product is a skin sensitiser. People with known hypersensitivity to mirtazapine should not handle the veterinary medicinal product.

This veterinary medicinal product may cause eye and skin irritation. Avoid hand to mouth and hand to eye contact until hands have been thoroughly washed. In the case of contact with eyes, rinse the eyes thoroughly with clean water. In the case of contact with the skin, wash thoroughly with soap and warm water. If skin or eye irritation occurs or in case of accidental ingestion, seek immediately medical advice and show the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Application site reaction(s) (erythema, crust/scab, residue, scaling/dryness, flaking, head shaking, dermatitis or irritation, alopecia, and pruritus) and behavioural changes (increased vocalisation, hyperactivity, disoriented state or ataxia, lethargy/ weakness, attention seeking and aggression) occurred very commonly in safety and clinical studies.

Vomiting, polyuria associated with reduced urine specific gravity, elevated blood urea nitrogen (BUN) and dehydration were commonly observed in safety and clinical studies. Depending on the severity of vomiting, dehydration or behavioural changes, administration of the product may be discontinued according to the benefit-risk assessment of the veterinarian.

These adverse events, including local reactions, resolved at the end of treatment period with no specific treatment.

In rare occasions, hypersensitivity reactions can occur. In these cases, the treatment should be immediately withdrawn.

In case of oral ingestion, in addition to effects cited above (except local reactions), salivation and tremors may rarely occur.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Mirtazapine has been identified as potentially reprotoxic in rats and rabbits.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation: Do not use during pregnancy and lactation (see section 4.3).

Fertility: Do not use in breeding animals (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

Do not use in cats treated with cyproheptadine, tramadol or monoamine oxidase inhibitors (MAOIs) or treated with an MAOI within 14 days prior to treatment with the veterinary medicinal product as there may be an increased risk of serotonin syndrome (see section 4.3).

Mirtazapine may increase sedative properties of benzodiazepines and of other substances with sedative properties (antihistamines H1, opiates). The plasma concentrations of mirtazapine may be also increased when used concomitantly with ketoconazole or cimetidine.

4.9 Amounts to be administered and administration route

Transdermal use.

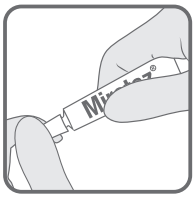
The veterinary medicinal product is applied topically to the inner pinna (inner surface of the ear) once daily for 14 days, at the dosage of 0.1 g ointment/cat (2 mg mirtazapine/cat). This corresponds to a 3.8 cm line of ointment (see below).

Alternate the daily application between the left and right ears. If desired, the inner surface of the cat's ear may be cleaned by wiping with a dry tissue or cloth immediately prior to the next scheduled dose. If a dose is missed, apply the veterinary medicinal product the following day and resume daily dosing.

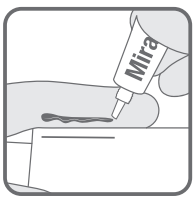
The recommended fixed dose has been tested in cats weighing between 2.1 kg and 7.0 kg

To apply the veterinary medicinal product:

Step 1: Put on impermeable gloves



Step 2: Twist cap on tube counter clockwise to open.



Step 3: Apply even pressure on tube and squeeze a 3.8 cm line of ointment onto your index finger using the measured line on the bottle or in this leaflet as a guide.

Step 4: Using your finger, gently rub ointment on inside surface of cat's ear (pinna) spreading it evenly over the surface. If contact with your skin occurs wash with soap and water.

The line below coincides with the appropriate length of ointment to be applied:

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

The known symptoms of a mirtazapine overdose of > 2.5 mg/kg in cats include: vocalization and behavioural changes, vomiting, ataxia, restlessness, and tremors. In case of an overdose, symptomatic/ supportive treatment should be instituted if needed.

In the case of overdose, the same effects as those observed at the recommended therapeutic dose were noted but with a higher incidence.

Transient increased hepatic alanine transferase can be observed uncommonly. It is not associated with clinical signs.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Psychoanaleptics, antidepressants

ATCvet code: QN06AX11

5.1 Pharmacodynamic properties

Mirtazapine is an α2-adrenergic receptor antagonist nor-adrenergic and serotonergic antidepressant drug. The exact mechanism by which mirtazapine induces weight gain appears to be multifactorial. Mirtazapine is a potent antagonist of 5-HT2 and 5-HT3 receptors in the central nervous system (CNS), and a potent inhibitor of histamine H1 receptors. Inhibition of 5-HT2 and histamine H1 receptors may account for the orexigenic effects of the molecule. Mirtazapine-induced weight gain may be secondary to changes in leptin and the tumour necrosis factor (TNF).

The product has an expected positive effect on feed intake by stimulating the appetite but this effect was not measured in the pivotal field trial. The only effect tested under field practice was on bodyweight: client-owned cats presented with a weight loss ≥ 5%, deemed clinically significant by the investigator, gained a statistically significant ($p<0.0001$) amount of weight, after 14 days of product administration (3.39% weight gain or average of 130 grams) compared to those cats administered placebo (0.09% weight gain or average of 10 grams).

5.2 Pharmacokinetic particulars

In a crossover study conducted with the product at 0.5 mg/kg in eight cats to determine the relative bioavailability of oral and transdermal 2% mirtazapine, the mean terminal half-life (25.6 ± 5.5 hours) with topical administration was over 2X longer than the mean terminal half-life (8.63 ±3.9 hours) with oral administration. Bioavailability following topical administration was 34% (6.5 to 89%) compared to oral administration during the first 24 hours and 65% (40.1 to 128.0%) based on AUC0-∞. After a single topical administration, the mean peak plasma concentration of 21.5 ng/ml (± 43.5) is reached in Tmax mean of 15.9 hours (1-48 hours). The mean AUC0-24 was 100 ng*h/ml (± 51.7).

After administration of the product to 8 cats at a dose of 0.5 mg/kg once daily for 14 days, mean peak plasma concentration of 39.6 ng/ml (± 9.72) is reached in Tmax mean of 2.13 hours (1-4 hours). The mean terminal half-life of mirtazapine was 19.9 h (± 3.70) and the mean AUC0-24 was 400 ng*h/ml (±100).

In the target animal safety study, where cats received a higher dose (2.8 to 5.4 mg) than the label dose (2 mg) once daily for 42 days, steady state was achieved within 14 days. The median accumulation between first and 35th dose was 3.71X (based on AUC ratio) and 3.90X (based on Cmax ratio).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 400

Macrogol 3350

Diethylene glycol monoethyl ether

Caprylocaproyl polyoxyglycerides

Oleyl alcohol

Butylhydroxytoluene (E321)

Dimethicone

Tapioca starch polymethylsilsesquioxane

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 30 days.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

The tube must be stored in the child resistant bottle with cap and returned to the bottle and capped immediately after every use.

6.5 Nature and composition of immediate packaging

5 gram coated aluminium tube (coat: lacquer (internal)/ enamel (external) with a low-density polyethylene (LDPE) screw cap and crimp sealant.

Each plastic bottle with a child resistant cap contains 1 tube (5 g) .

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Aniserve GmbH
Geyerspergerstr. 27
80689 Munich
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/247/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10/12/2019

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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