



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Mirataz (*mirtazapine*)

An overview of Mirataz and why it is authorised in the EU

### What is Mirataz and what is it used for?

Mirataz is a medicine used to produce an increase in bodyweight in cats with long-term conditions known to cause poor appetite and weight loss. It contains the active substance mirtazapine.

### How is Mirataz used?

The medicine is available as an ointment to be applied on the skin. It can only be obtained with a prescription.

The medicine is applied topically to the inner pinna (inner surface of the ear) once daily for 14 days. Only one ear is treated each day, so the left ear one day and the right ear the following day. If a dose is missed, the medicine can be applied the following day and daily dosing resumed.

For more information about using Mirataz, see the package leaflet or contact your veterinarian or pharmacist.

### How does Mirataz work?

Mirtazapine is absorbed through the skin of the ear into the bloodstream. The effects of mirtazapine on weight gain are complex and not fully understood. They include blocking some of the actions of serotonin and histamine, substances involved in the regulation of appetite, and an effect on levels of leptin, a hormone that controls hunger.

### What benefits of Mirataz have been shown in studies?

A clinical field trial performed in the US in cats who had at least 5% weight loss due to an underlying medical condition, showed that 14 days' treatment with Mirataz increased their bodyweight. The average weight gain after 14 days was approximately 130 g per cat and significantly higher than the average 10 g in the group receiving placebo (dummy treatment).

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## **What are the risks associated with Mirataz?**

The most common side effects with Mirataz (which may affect more than 1 in 10 cats) are signs of local irritation or inflammation at the site where the ointment is applied and behavioural changes (increased meowing, hyperactivity, disoriented state or inability to co-ordinate muscle movements, lack of energy/weakness, attention seeking and aggression). Local reactions resolve without treatment.

Mirataz must not be used in breeding, pregnant or lactating cats, in cats less than 7.5 months of age or less than 2 kg bodyweight.

Mirataz must not be used in cats treated with the medicines cyproheptadine, tramadol or monoamine oxidase inhibitors (MAOIs) or treated with an MAOI in the 14 days before treatment with Mirataz, as there may be an increased risk of serotonin syndrome. Serotonin syndrome is a potentially serious condition that may occur with medicines that raise serotonin levels in the body. The signs can range from mild to severe and include fever, agitation, increased reflexes, tremor, sweating, dilated pupils, diarrhoea, convulsions and seizures.

For the full list of side effects and restrictions of Mirataz, see the package leaflet.

## **What are the precautions for the person who gives the medicine or comes into contact with the animal?**

Direct contact with the medicine should be avoided. The medicine can be absorbed via the skin or mouth and can cause drowsiness or sedation. Impermeable disposable protective gloves should be provided when the medicine is purchased and these must be worn when handling and applying the medicine. Thoroughly wash hands immediately after application of the medicine or in case of skin contact with the medicine or the treated cat before the application site is dry.

Mirataz is a skin sensitiser and may cause eye and skin irritation. People who are hypersensitive (allergic) to mirtazapine should avoid contact with Mirataz. Hand to mouth and hand to eye contact should be avoided until hands have been thoroughly washed. In the case of contact with eyes, rinse the eyes thoroughly with clean water. If skin or eye irritation occurs, or in case of accidental ingestion, medical advice should be sought immediately and the label shown to the doctor.

It is recommended that pregnant women or women trying to conceive avoid handling the medicine and contact with treated animals throughout the treatment period.

The medicine may be harmful after ingestion and should be kept away from children, who should not be present when the cat is treated. The tube must not be left out of its child-proof container except while applying the medicine. The tube must be placed in the child-proof container after application, which must be closed immediately.

Contact should be avoided with the treated cat for the first 12 hours after each daily application. Therefore it is recommended to treat the cat in the evening. Treated cats should not be allowed to sleep with owners, especially children and pregnant women, during the entire treatment period.

People must not eat, drink or smoke while handling the medicine.

## **Why is Mirataz authorised in the EU?**

The European Medicines Agency decided that Mirataz's benefits are greater than its risks and it can be authorised for use in the EU.

## **Other information about Mirataz**

Mirataz received a marketing authorisation valid throughout the EU on 10 December 2019.

Further information on Mirataz can be found on the Agency's website:  
[ema.europa.eu/medicines/veterinary/EPAR/mirataz](http://ema.europa.eu/medicines/veterinary/EPAR/mirataz).

This overview was last updated in October 2019.