

Summary Public Assessment Report

Metronidazol EQL Pharma metronidazole

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metronidazole

Film-coated tablet, 200 mg, 400 mg

This is a summary of the public assessment report (PAR) for Metronidazol EQL Pharma. It explains how Metronidazol EQL Pharma was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Metronidazol EQL Pharma.

For practical information about using Metronidazol EQL Pharma, patients should read the package leaflet or contact their doctor or pharmacist.

What is Metronidazol EQL Pharma and what is it used for?

Metronidazol EQL Pharma is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Flagyl.

Metronidazol EQL Pharma is used in the treatment of is used to treat infections caused by certain types of bacteria that live without oxygen (anaerobic bacteria). Metronidazol EQL Pharma is also used to prevent infections associated with surgery and to treat infections caused by certain single-celled organisms (protozoans).

Examples of situations when Metronidazol EQL Pharma is used: In abdominal infections, Crohn's disease in the active stage, certain infections in the vagina and infections that starts from the teeth.

How does Metronidazol EQL Pharma work?

Metronidazol EQL Pharma works by killing certain types of bacteria that live without oxygen (anaerobic bacteria) and has also an effect on infections caused by single-celled organisms (protozoans).

How is Metronidazol EQL Pharma used?

The pharmaceutical form of Metronidazol EQL Pharma is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Metronidazol EQL Pharma have been shown in studies?

Because Metronidazol EQL Pharma is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Flagyl.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Metronidazol EQL Pharma?

Because Metronidazol EQL Pharma is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Metronidazol EQL Pharma approved?

It was concluded that, in accordance with EU requirements, Metronidazol EQL Pharma has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Flagyl. Therefore, the Swedish Medical Products Agency decided that, as for Flagyl, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Metronidazol EQL Pharma?

A risk management plan has been developed to ensure that Metronidazol EQL Pharma is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Metronidazol EQL Pharma, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Metronidazol EQL Pharma

The full PAR for Metronidazol EQL Pharma can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Metronidazol EQL Pharma please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2021-10.