LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Farghess
(promethazine hydrochloride)

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Summary Public Assessment Report

Farghess
promethazine hydrochloride

Film-coated tablet, 25 mg

This is a summary of the public assessment report (PAR) for Farghess. It explains how Farghess 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 Farghess.

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

What is Farghess and what is it used for?

Farghess is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Lergigan.

Farghess can be used in the following situations:
- to treat sleep disorders
- to treat severe anxiety
- to help you feel more relaxed before an operation or a dental procedure
- to treat or stop motion sickness (e.g. sea sickness)
- to treat allergic reactions of different origins
- to treat or stop you feeling sick and dizzy
- to treat nervous anxiety and tension states

How does Farghess work?

Farghess contains a medicine called promethazine hydrochloride. It belongs to a group of medicines called phenothiazines. It works by blocking the natural substance histamine in your body that causes itching during an allergic reaction. Like many histamine-blocking agents, it has a sedative effect.

How is Farghess used?

The pharmaceutical form of Farghess 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 Farghess have been shown in studies?

Because Farghess is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Lergigan.

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

What are the possible side effects from Farghess?

Because Farghess 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 Farghess approved?

It was concluded that, in accordance with EU requirements, Farghess has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Lergigan. Therefore, the Swedish Medical Products Agency decided that, as for Lergigan, 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 Farghess?

A risk management plan has been developed to ensure that Farghess 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 Farghess, 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 Farghess

The full PAR for Farghess can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Farghess

This summary was last updated in 2022-02.