LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bysimin
(hyoscine butylbromide)

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Summary Public Assessment Report

Bysimin

(hyoscine butylbromide)

Solution for injection 20 mg/ml

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

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

What is Bysimin and what is it used for?

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

Bysimin is used to relieve cramps of your:
- Gastrointestinal tract
- Biliary tract
- Pancreas
- Urogenital tract

Bysimin can also be used in diagnostic medical procedures.

How does Bysimin work?

Bysimin contains the active substance hyoscine butylbromide. Hyoscine butylbromide is an antispasmodic agent which relaxes smooth muscle of the organs of the abdominal and pelvic cavities. It is believed to act predominantly on the intramural parasympathetic ganglia of these organs.

How is Bysimin used?

The pharmaceutical form of Bysimin is solution for injection.

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.

What benefits of Bysimin have been shown in studies?

No additional studies were needed as Bysimin is a generic medicine and is given by a solution for injection and contains the same active substance as the reference medicine, Buscopan.

What are the possible side effects of Bysimin?

Because Bysimin 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 restrictions, see the package leaflet.

Why is Bysimin approved?

It was concluded that, in accordance with EU requirements, Bysimin has been shown to have comparable quality and to be similar to the reference medicine Buscopan. Therefore, the Medical Products Agency in Sweden decided that, as for Buscopan, 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 Bysimin?

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

The marketing authorisation for Bysimin was granted on 2017-04-10 in Sweden.

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

This summary was last updated in 2017-04.