Summary Public Assessment Report

Generics

Nobabelle 0.075 mg/0.020 mg and 0.075 mg/0.030 mg tablets

(gestodene/ethinylestradiol)

NL/H/2954/001-002/DC

Date: 21 October 2015

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Active substance: gestodene/ethinylestradiol

This is a summary of the public assessment report (PAR) for Nobabelle 0.075 mg/0.020 mg and 0.075 mg/0.030 mg tablets. It explains how this medicine 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 Nobabelle.

For practical information about using this medicine, users should read the package leaflet or contact their doctor or pharmacist.

What is Nobabelle and what is it used for?
Nobabelle 0.075 mg/0.020 mg and 0.075 mg/0.030 mg tablets are 'generic medicines'. This means that they are similar to 'reference medicines' already authorised in the European Union (EU) called Meliane 0.075 mg/0.020 mg and Gynovin 0.075 mg/0.030 mg tablets.

These medicines are oral contraceptives. They are used to prevent pregnancy and are often called 'the pill'.

How does this medicine work?
Nobabelle is a contraceptive tablet that contains two hormones, which is called a 'combination tablet'. The two hormones are an estrogen, named ethinylestradiol and a progesterone type, named gestodene. These hormones stop the ovary from releasing an egg each month (ovulation). They also thicken the fluid (mucus) at the neck of the womb (cervix) making it more difficult for the sperm to reach the egg, and alter the lining of the womb to make it less likely to accept a fertilised egg.

How is this medicine used?
The pharmaceutical form of Nobabelle is a film-coated tablet and the route of administration is oral. The medicine can only be obtained with a prescription.

One tablet should be taken every day, if necessary with a small amount of water. The tablets can be taken with or without food, but every day at approximately the same time.

Nobabelle is a 21-day pill. One tablet should be taken each day for 21 days, followed by 7 days when no tablets are taken.

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

How has this medicine been studied?
Because Nobabelle is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicines, Meliane 0.075 mg/0.020 mg and Gynovin 0.075 mg/0.030 mg tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Nobabelle is a generic medicine and is bioequivalent to the reference medicines, its benefits and possible side effects are taken as being the same as the reference medicine's.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicines. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Meliane and Gynovin, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Nobabelle, including the appropriate precautions to be followed by healthcare professionals and users

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

Other information about this medicine
In the Netherlands, the marketing authorisation for Nobabelle 0.075 mg/0.020 mg and 0.075 mg/0.030 mg tablets was granted on 8 July 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human.
For more information about treatment with Nobabelle, read the package leaflet (Nobabelle 0.075 mg/0.020 - http://mri.medagencies.org/download/NL_H_2954_001_FinalPL.pdf; Nobabelle 0.075 mg/0.030 - http://mri.medagencies.org/download/NL_H_2954_002_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in October 2015.