Summary Public Assessment Report

non-generics

APLEEK
60 micrograms/24 hours + 13 micrograms/24 hours, Transdermal patch

Gestodene/ Ethinylestradiol

FR/H/0547/001/DC

Date: December 2014

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

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

What is Apleek and what is it used for?

Apleek is a contraceptive patch, used to prevent pregnancy.

How does Apleek work?

Apleek is a combined contraceptive patch that contains two hormonal substances, namely gestodene (a progestogen) and ethinylestradiol (an estrogen) which are delivered continuously in small amounts over a period of 7 days.
Apleek works by changing the body's hormonal balance to prevent ovulation, by altering the cervical mucus and by thinning the endometrium (the linig of the womb).

How is Apleek used?

The pharmaceutical form of Apleek is a patch and the route of administration is transdermal.

Please read section 3 of the PL 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 Apleek have been shown in studies?

The company provided its own data on efficacy and safety studies.
Apleek was investigated in one main study involving a total a 1631 women aged 18 to 35 years old. The participants were given Apleek for one year (13 menstrual cycles). The main measure of effectiveness was the number of women aged 18 to 35 who became pregnant during or shortly after treatment, expressed in terms of a pregnancy rate using the 'Pearl Index'. The Pearl Index is a standard way of measuring the effectiveness of contraceptives, which measures how many unwanted pregnancies occur in 100 women-years (corresponding to 1,300 menstrual cycles). A lower Pearl Index represents a lower chance of getting pregnant.

No clinical study data on Apleek are available in adolescents under 18 years old.

In women aged 18 to 35, the Pearl Index was around 0.76 with Apleek in the European population.

This study has shown that Apleek is effective in preventing pregnancy.

What are the possible side effects from Apleek?

The most common side effect with Apleek (which may affect more than 1 in 10 women) is Application site reaction. Side effects which may affect up to 1 in 10 women are: emotional lability, migraine, nausea, genital tract bleeding and breast pain.

Side effects with very low frequency or with delayed onset of symptoms which are considered to be related to the group of combined hormonal contraceptives include: blood clots in a vein or artery, breast cancer and liver tumour.

For the full list of all side effects reported with Apleek, see section 4 of the package leaflet.

Apleek should not be used in women who are hypersensitive (allergic) to gestodene, ethinylestradiol or any of the other ingredients. It must not be used when a woman has, or has ever had blood clots in the veins or arteries including a stroke or a heart attack or when a woman has some of the risk factors for thrombosis (severe high blood pressure, diabetes with damage to the blood vessels, a condition known as hyperhomocysteinaemia or high cholesterol levels). It should not be used in women who have a disorder affecting blood clotting (such as protein C deficiency), migraine with aura (visual or other symptoms), severe liver problems with the liver still not functioning normally, certain types of cancer, or abnormal bleeding from the genital area whose cause has not been diagnosed. It should not be used if the woman need an operation or is off her feet for a long time. For the full list of restrictions, see the package leaflet.

Why is Apleek approved?

The French Medicine Agency (ANSM) and the Member States involved in the procedure decided that Apleek's benefits are greater than its risks and recommended that it be approved for use.

Apleek has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Apleek?"

What measures are being taken to ensure the safe and effective use of Apleek?

A risk management plan has been developed to ensure that Apleek 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 Apleek, 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.

A specific study will be performed after the marketing of Apleek to characterize the risk of blood clots.

Other information about Apleek

The marketing authorisation for Apleek was granted on 12 February 2014.

The full PAR for Apleek can be found on the website <add link to product index>. For more information about treatment with Apleek, read the package leaflet (link) or contact your doctor or pharmacist.

This summary was last updated in 12-2014.