

MAYNE PHARMA LAUNCHES GENERIC QUARTETTE® IN THE U.S., ANOTHER WOMEN'S HEALTH PRODUCT

March 26, 2018, Adelaide, Australia: Mayne Pharma Group Limited (ASX: MYX) is pleased to announce the launch of an authorized generic of Quartette® (levonorgestrel and ethinyl estradiol tablets, 0.15mg/0.02mg; 0.15mg/0.025mg; 0.15mg/0.03mg and ethinyl estradiol tablets, 0.01mg) in the United States. Quartette® is an oral contraceptive indicated for the prevention of pregnancy.

Mayne Pharma's CEO Scott Richards said, "Generic Quartette adds to our women's health portfolio of 22 marketed products including oral contraceptives, hormone replacement therapy and breast cancer products. Mayne Pharma is the second largest supplier of oral contraceptive products in the United States and continues to invest in growing its pipeline of women's health products with high value, complex formulations such as generic NuvaRing®, an intravaginal hormonal contraceptive delivery device which recently was accepted for filing by the FDA."

Mayne Pharma directly markets more than 55 products and has a growing pipeline of approximately 30 drug products targeting U.S. markets with IQVIA sales greater than \$5 billion. According to IQVIA, U.S. brand and generic sales for this product were approximately \$10 million for the 12 months ending Jan. 31, 2018.

IMPORTANT SAFETY INFORMATION

Who should not take levonorgestrel/ethinyl estradiol tablets and ethinyl estradiol tablets?

WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs should not be used by women who are over 35 years of age and smoke.

The pill does not protect against HIV infection (AIDS) and other sexually transmitted infections. Do not take levonorgestrel/ethinyl estradiol tablets and ethinyl estradiol tablets if you have or ever had:

- Breast cancer or any cancer that is sensitive to female hormones
- Liver disease, including liver tumors
- Been prescribed any Hepatitis C combination containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme "alanine aminotransferase" (ALT) in the blood
- Blood clots in your arms, legs, eyes, or lungs
- Stroke
- Heart attack
- Certain heart valve problems or heart rhythm abnormalities that can cause blood clots to form in the heart
- An inherited problem with your blood that makes it clot more than normal
- High blood pressure that medicine cannot control
- Diabetes with kidney, eye, nerve or blood vessel damage





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- Ever had certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision, or have any migraine headaches if you are over age 35

Also, do not take birth control pills if you:

- Smoke and are over 35 years old
- Are pregnant
- Have any unexplained bleeding from the vagina

What are the most serious risks of taking levonorgestrel/ethinyl estradiol tablets and ethinyl estradiol tablets? Levonorgestrel/ethinyl estradiol tablets and ethinyl estradiol tablets increases the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or are older than 35. This increased risk is highest when you first start taking birth control pills, and when you restart the same or different birth control pills after not using them for a month or more.

Call your health-care provider right away if you have: Persistent leg pain; sudden shortness of breath; sudden blindness, partial or complete; severe pain or pressure in your chest, sudden, severe headache unlike your usual headaches, weakness or numbness in an arm or leg, or trouble speaking, yellowing to the skin or eyeballs.

Depression can occur when taking levonorgestrel/ethinyl estradiol tablets and ethinyl estradiol tablets, especially if you have had depression in the past. Call your health-care provider immediately if you have any thoughts of harming yourself.

The most common side effects are: Spotting or bleeding between menstrual periods, nausea, breast tenderness, and headache. This is not a complete list of possible side effects. Talk to your health-care provider if you develop any side effects that concern you.

Tell your health-care provider about all medicines and herbal products you take including daily long-term treatment for chronic conditions such as seizures or thyroid disease.

Full prescribing information, including warnings, can be found [here](#). To report a suspected adverse reaction from one of our products, please contact Mayne Pharma at 1-844-825-8500 or maynepharmamc@dlss.com, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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About Mayne Pharma

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialize branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide. Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialized in numerous products that have been marketed around the world. Mayne Pharma has two product development and manufacturing facilities based in Salisbury, Australia, and Greenville, N.C., USA, with expertise in formulation complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

Quartette® is a registered trademark of Teva Women's Health, LLC, and NuvaRing® is a registered trademark of N.V. Organon Corporation.

