RU P0101.171.001
Corresponding with RU M0101.071.001

মারভেলন®

মারভেলন® ব্যবহারকারীর প্যাকেজ লিফলেট

মারভেলন® ব্যবহারের পূর্বে এই লিফলেটটি ভালভাবে পড়ুন। এই লিফলেটের মাধ্যমে জন্মনিয়ন্ত্রণের খাবার বড়ির উপকারিতা ও ঝুঁকিসমূহ সম্পর্কে তথ্য পরিবেশন করা হবে। মারভেলন® খাওয়ার সঠিক পদ্ধতি এবং কখন ডাক্তারকে আপনার স্বাস্থ্য অবস্থা জানাবেন সে সম্পর্কে উপদেশও এতে দেয়া আছে। আপনার যদি কোন প্রশ্ন থাকে বা আরও কোন উপদেশ আপনার প্রয়োজন হয় তবে আপনার ডাক্তার, দায়িত্বপ্রাপ্ত স্বাস্থ্য কর্মী বা ফার্মাসিষ্টের সাথে যোগাযোগ করুন।

মারভেলন® কি?
গঠন ও বড়ির ধরণ

মারভেলন® একটি কমবাইন্ড্ জন্মনিয়ন্ত্রণ বড়ি (দি কমবাইন্ড্ পিল)। প্রতি ট্যাবলেটে স্বল্প পরিমাণে দুটি ভিন্ন স্ত্রী হরমোন আছে। এ দুটি হলো ডিসোজেসট্রেল (একটি প্রজেস্টোজেন) এবং ইথিনাইলএস্ট্রাডিওল (একটি ইস্ট্রোজেন)। উপাদানগুলির পূর্ণ তালিকা 'ভেষজ বিষয়াবলী'তে উল্লেখ করা হয়েছে। অল্প পরিমান হরমোন থাকার কারণে মারভেলন® স্বল্প মাত্রার জন্মনিয়ন্ত্রণ বড়ি হিসাবে বিবেচিত। প্যাকেটের সকল ট্যাবলেটে একই হরমোন একই মাত্রায় দেয়া হয়েছে, তাই মারভেলন® একটি মনোফেজিক কমবাইন্ড্ জন্মনিয়ন্ত্রণ খাবার বড়ি হিসাবে বিবেচনা করা হয়।

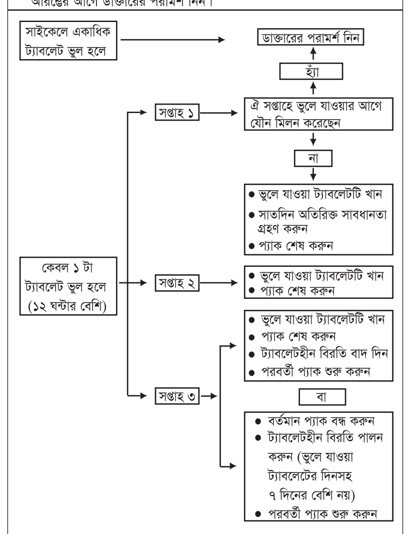
কেন মারভেলন® ব্যবহার করবেন?

গর্ভনিরোধক হিসাবে।
মুখে খাওয়া জন্মনিয়ন্ত্রণ বড়ি জন্মনিয়ন্ত্রণের সবচেয়ে নির্ভরযোগ্য পদ্ধতি। সঠিকভাবে গ্রহণ করা হলে (কোন বড়ি বাদ না দিয়ে) গর্ভধারণের ঝুঁকি নেই বললেই চলে।

আপনি কখন মারভেলন® ব্যবহার করবেন না?

যদি নিম্নবর্ণিত অবস্থাগুলির কোন একটি আপনার হয়ে থাকে, তবে কমবাইন্ড পিল ব্যবহার করবেন না। যদি এইগুলির একটিও আপনার ক্ষেত্রে প্রয়োজ্য হয়, তবে মারভেলন® খাবার পূর্বে ডাক্তারকে বলুন। ডাক্তার আপনার জন্য ভিন্ন ধরণের পিল বা সম্পূর্ণ ভিন্ন (হরমোন বহির্ভূত) জন্মনিয়ন্ত্রণ ব্যবস্থা দেবেন।

- আপনার এমন কোন জটিলতা আছে বা ছিল যাতে রক্ত সরবরাহ বিঘ্নিত হয়, বিশেষ করে থ্রম্বসিস সম্পর্কিত অবস্থাসমূহ। থ্রম্বসিসে রক্ত জমাট বেধে যায়। এ অবস্থা পায়ের রক্তনালীতে (ডিপ ভেইন থ্রম্বসিস), ফুসফুসে (পালমোনারী এমবলিজম), হৃদপিন্ডে (হৃদরোগ), মস্তিষ্কে (স্ট্রোক), বা দেহের অন্য কোথাও সৃষ্টি হাতে পারে। (এই লিফলেটের অন্য স্থানে 'পিল ও থ্রম্বসিস' দেখুন)।
- আপনার এমন কোন অবস্থা আছে বা ছিল যা হৃদরোগের প্রাথমিক লক্ষণ হ'তে পারে (যেমন এনজিনা, পেক্টরিস বা বুকে ব্যাথা) বা স্ট্রোক (যেমন ক্ষণস্থায়ী ইশকেমিক আক্রমণ বা ক্ষুদ্র পুণঃআক্রমণাত্বক স্ট্রোক) দেখা দিলে।
- আপনার রক্তনালীর ক্ষতিগ্রস্থতা সহ ডায়াবেটিস দেখা দিলে।
- আপনার যদি জন্ডিস (ত্বক হলুদ হওয়া) বা প্রকট যকৃতের ব্যাধি হয়ে থাকে।



Manufactured by:
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Marvelon®

USER PACKAGE LEAFLET FOR MARVELON®

Please read this leaflet carefully before you start using Marvelon®. This leaflet will provide information about the benefits and risks of using oral contraceptives. It will also advise you about how to take Marvelon® properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider or pharmacist.

WHAT IS MARVELON®?
Composition and type of Pill

Marvelon® is a combined oral contraceptive pill ('the combined Pill'). Each tablet contains a small amount of two different female hormones. These are desogestrel (a progestogen) and ethinylestradiol (an estrogen). The full list of ingredients is given under 'pharmaceutical particulars'. Because of the small amounts of hormones, Marvelon® is considered a low-dose oral contraceptive. As all tablets in the pack combine the same hormones in the same dose, it is considered a monophasic combined oral contraceptive.

Why use Marvelon®?
To prevent pregnancy.
Oral contraceptives are a very effective method of birth control. When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

WHEN SHOULD YOU NOT USE MARVELON®?

Do not use the combined Pill if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use Marvelon®. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

- If you have, or have ever had a disorder affecting the blood circulation. In particular, those conditions relating to thrombosis. Thrombosis is the formation of a blood clot. This may occur in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), the brain (stroke), or other parts of the body (See also the section later In this leaflet called 'The Pill and Thrombosis').
- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke).
- If you have diabetes mellitus with blood vessel damage.
- If you have jaundice (yellowing of the skin) or severe liver disease.
- If you have or have had cancer of the breast or the genital organs.
- If you have or have had a benign or malignant tumour in the liver.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.
- If you are allergic to any of the ingredients of Marvelon®.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures. See also ***'General Notes'.***

WHAT DO YOU NEED TO KNOW BEFORE USING MARVELON®?
General Notes

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the Pill may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because the Pill alters the usual changes In temperature and cervical mucus that occur during the menstrual cycle.

Marvelon®, like all contraceptive Pills, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.
Marvelon® has been prescribed for you personally. Do not share it with others.

Before you start to use Marvelon®

If the combined Pill is used in the presence of any of the conditions listed below you may need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use Marvelon®

- you smoke;
- you have diabetes;
- you are overweight;
- you have high blood pressure;
- you have a heart valve disorder or a certain heart rhythm disorder;
- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins;
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- you suffer from migraine;
- you suffer from epilepsy;
- you or someone in your immediate family have or had high blood levels of cholesterol or triglycerides (fatty substances);
- anyone in your immediate family has had breast cancer;
- you have liver or gallbladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus eryhematosus (SLE; a disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS; a disorder of blood coagulation causing failure of the kidneys);
- you have sickle cell disease;
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face): if so, avoid too much exposure to the sun or ultraviolet radiation.

If any of the above conditions appear for the first time, recur or worsen while using the Pill, you should contact your doctor.

The Pill and Thrombosis

A thrombosis is the formation of a blood clot, which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "Pulmonary embolism." Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant. The risk is higher in Pill-users than in non-users, but it is not as high as the risk during pregnancy.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally a thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of having a heart attack or stroke increases, as you get older. It also increases the more you smoke. **When using the Pill you should stop smoking, especially if you are older than about 35 years of age.**

If you develop high blood pressure while using the Pill, you may be told to stop using it.

The risk of having a deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). In women who use the Pill, the risk may be yet higher. Tell your doctor you are using the Pill well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking the Pill several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking the Pill again after you are back on your feet.

If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately **(See also 'When should you contact your doctor'?).**

The Pill and cancer
Breast cancer has been diagnosed, slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier. In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your stomach.

Cervical cancer has been reported to occur more often in women using the Pill for a long time. This finding may not be caused by the Pill but may be related to sexual behaviour and other factors.

The Pill and other Medicines

Some medicines may stop the Pill from working properly. These include medicines used for the treatment of epilepsy (eg. primidone, phenytoin, barbiturates) and tuberculosis (eg. rifampicin); and antibiotics (eg. ampcillin, tetracyclines, griseofulvin) for some other infectious diseases. Always tell the doctor, who prescribes the Pill, which medicines you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use Marvelon®. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

The Pill and Breastfeeding

Marvelon® is generally not recommended for use during breast feeding. If you wish to take the Pill while breastfeeding, please seek the advice of your doctor.

The Pill and Pregnancy

Marvelon® must not be used by women who are pregnant, or who think they may be pregnant.

The Pill and Ability to Drive

There are no observed effects.

WHEN SHOULD YOU CONTACT YOUR DOCTOR?

Regular check-ups

When you are using the Pill, your doctor will tell you to return for regular check-ups. In general, you should have a check-up every year.

Contact your doctor as soon as possible if:

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also when should you not use Marvelon® and before you start to use Marvelon® do not forget about the items related to your immediate family);
- you feel a lump in your breast;
- you are going to use other medications (see also 'The Pill and other Medicines').
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you forgot tablets in the first week of the pack and had intercourse in the seven days before;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor).

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis:

- an unusual cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or prolonged headache or migraine attack;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

The situations and symptoms mentioned above are described and explained in more detail elsewhere in this leaflet.

HOW DO YOU USE MARVELON®?
When and how to take the tablets?

The Marvelon® pack contains 21 tablets. On the pack, each tablet is marked with the day of the week on which it is to be taken. Take your tablet at about the same time each day, with some water if necessary. Follow the direction of the arrows until all 21 tablets have been taken. During the next 7 days you take no tablets. A period should begin during these 7 days (the withdrawal bleed). Usually it will start on day 2-3 after the last Marvelon® tablet. Start taking your next pack on the 8th day even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days, each month.

Starting your first pack of Marvelon®

- ***When no hormonal contraceptive has been used in the past month.***
  Start taking Marvelon® on the first day of your cycle, i.e. the first day of menstrual bleeding. Take a tablet marked with that day of the week. For example, if your period starts on a Friday, take a tablet marked Friday. Then follow the day's in order. You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet taking in the first cycle.
- ***When changing from another combined Pill.***
  You can start taking Marvelon® the day after you take the last tablet from your present Pill pack (this means no tablet free break). If your present Pill pack also contains inactive tablets you can start Marvelon® on the day after taking the last **active** tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present Pill (or the day after the last inactive tablet of your present Pill).
- ***When changing from a progestagen-only Pill (minipill).***
  You can stop taking the minipill any day and start taking Marvelon® the next day, at the same time. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet taking when having intercourse.
- ***When changing from an injectable or implant.***
  Start using Marvelon® when your next injection is due or on the day that your implant is removed. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking when having intercourse.
- ***After having a baby.***
  If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking Marvelon®. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take Marvelon®, you should discuss this first with your doctor.
- ***After a miscarriage or an abortion.***
  Your doctor will advise you.

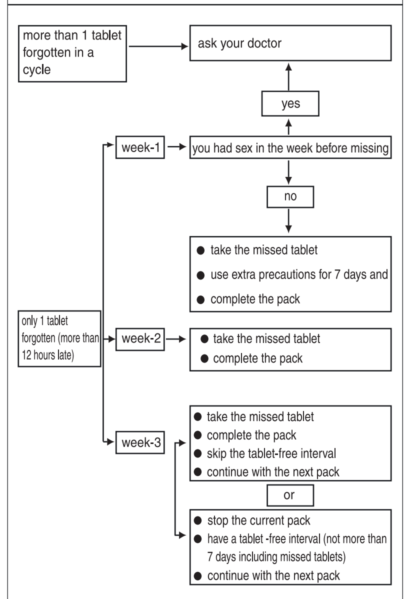
If too many Marvelon® tablets are taken (overdose)
There have been no reports of serious harmful effects from taking too many Marvelon® tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken Marvelon®, ask your doctor for advice.

When you want to stop taking Marvelon®
You can stop taking Marvelon® at any time you want. If you do not want to become pregnant, ask your doctor about other methods of birth control.

If you stop taking Marvelon® because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

WHAT TO DO IF ....
.... you forget tablets

- If you are **less than 12 hours late** in taking a tablet, the reliability of the Pill is maintained. Take the tablet as soon as you remember and take the next tablets at the usual times.
- If you are **more than 12 hours late** in taking any tablet, the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning or at the end of the pack. Therefore you should follow the rules given below (see also the diagram below).
  More than one tablet forgotten in a pack
  Ask your doctor for advice.
  1 tablet missed in week 1
  Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days. If you had sexual intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. So tell your doctor immediately.
  1 tablet missed in week 2
  Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. The reliability of the Pill is maintained. You need not use extra contraceptive precautions.
  1 tablet missed in week 3
  You may choose either of the following options, without the need for extra contraceptive precautions.
  1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Start the next pack as soon as the current pack is finished so that **no gap is left between packs.** You may not have a withdrawal bleed until the end of the second pack but you may have spotting or breakthrough bleeding on tablet-taking days. Or
  2. Stop taking tablets from your current pack, have a tablet-free break of 7 days or less (**also count the day you missed your tablet)** and continue with the next pack. When following this method, you can always start your next pack on the same day of the week as you usually do.
- If you have forgotten tablets in a pack and you do not have the expected period in the first normal tablet-free break, you may be pregnant. Consult your doctor before you start with the next pack.



.... you vomit
If you vomit within 3 to 4 hours after taking your Marvelon® tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Therefore, follow the advice for missed tablets.

..... you want to delay your period
you can delay your period if you start with your next pack of Marvelon® immediately after finishing your current pack. You can continue with this pack for as long as you wish, until this pack is empty. When you wish your period to begin, just stop tablet-taking. While using the second pack you may have some breakthrough bleeding or spotting on tablet-taking days. Start with your next pack after the usual 7 day tablet-free break.

..... you want to change the starting day of your period
If you take your tablets as directed, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten, (never lengthen) the next tablet-free break. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) you should now start your next pack 3 days sooner than you usually do. If you make your tablet-free break very short (e.g. 3 days or less) you may not have a bleeding during the break. You may have some breakthrough bleeding or spotting during the use of the next pack.

..... You have unexpected bleeding
With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the pill (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

.....you have missed a period
If you have taken all of your tablets at the right time, and you have not vomited, or used other medicines then you are very unlikely to be pregnant. Continue to take Marvelon® as usual.
If you miss your period twice in a row, you may be pregnant. Tell your doctor immediately. Do not start the next pack of Marvelon® until your doctor has checked you are not pregnant.

WHAT SIDE EFFECTS MIGHT YOU HAVE WHILE TAKING MARVELON®?
Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the Pill.

Serious Side Effects
Serious reactions associated with the use of the Pill, as well as the related symptoms, are described in the following sections: 'The Pill and Thrombosis/The Pill and Cancer'. Please read these sections for additional information and consult your doctor at once where appropriate.

Other possible side effects
The following side effects have been reported by users of the Pill, although they need not be caused by the Pill. These side effects may occur in the first few months that you are using the Pill and usually lessen with time.

- breast tenderness, pain and secretion;
- headache;
- changes in sexual drive; depressive moods;
- contact lens intolerance;
- nausea, vomiting and feeling sick;
- changes in vaginal secretion;
- various skin reactions;
- fluid retention;
- changes in body weight;
- hypersensitivity reactions.

ADVERSE DRUG REACTION
Severe psychiatric disorders: panic attack, suicidal ideation and self-induced injurious behavior.

ADVERSE EFFECTS
Panic attack, suicidal ideation and self-induced injurious behavior.

MORE ABOUT THE PILL
The combined Pill may also have non-contraceptive health benefits.

- Your period may be lighter and shorter. As a result, the risk of anaemia may be lower. Your period pains may become less severe or may completely disappear.
- In addition, some serious disorders have been reported to occur less frequently in users of Pills containing 50 µg of ethinylestradiol ('high -dose Pills'). These are benign breast disease, ovarian cysts, pelvic infections (pelvic inflammatory disease or PID), ectopic pregnancy (pregnancy in which the embryo implants outside of the uterus) and cancer of the endometrium (lining of the womb) and ovaries. This may also be the case for low-dose Pills but this has not been confirmed.

PHARMACEUTICAL PARTICULARS OF MARVELON®

Composition in Full
Marvelon® tablets contain:

- active ingredients: desogestrel BP (0.150 mg) and ethinyl estradiol USP (0.030 mg)
- other ingredients: colloidal sillicon dioxide; lactose; magnesium stearate; maize starch; povidone; stearic acid; dl-α-tocopherol.

Storage Condition
Store in a cool & dry place in between 2-25° C, protect from light. Keep out of the reach of children.

Commercial Pack

Marvelon® Tablet: Each box contains 1 x 21 tablets in Alu-PVC blister strip in a sealed sachet.

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প্রস্তুতকারকঃ
নুভিস্‌তা ফার্মা লিমিটেড
৪৮, টঙ্গী শিল্প এলাকা, গাজীপুর, বাংলাদেশ
বেক্সিমকো ফার্মাসিউটিক্যালস্ লিঃ এর একটি সাবসিডিয়ারী প্রতিষ্ঠান