

Binovum® Oral Contraceptive Tablets

Norethisterone, ethinylestradiol

INFORMATION FOR PEOPLE TAKING BINOVUM ORAL CONTRACEPTIVE TABLETS.

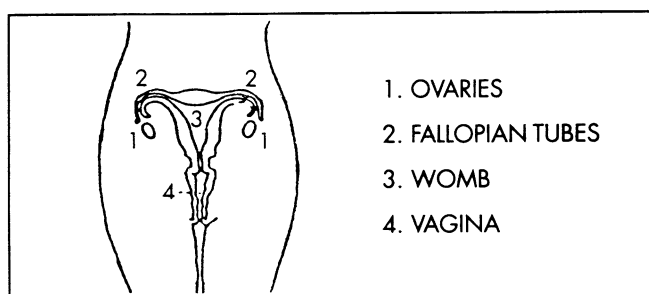
WHY SHOULD YOU READ THIS LEAFLET?

This leaflet contains important information about your Binovum pills.

Please read it carefully **before** you start taking Binovum. If you have any questions about what is written here or wish for any further information please ask either your doctor, nurse or pharmacist (chemist).

HOW DOES YOUR BODY GET READY FOR PREGNANCY?

- You are able to become pregnant throughout your fertile years, that is to say, from the time when you start to have menstrual periods until you reach an age when your periods stop (usually your late 40s).
- The time between the beginning of one menstrual period and the next is called the menstrual cycle. It lasts about 28 days. In the middle of the menstrual cycle one of the ovaries releases an egg into a Fallopian tube (see picture); this is called ovulation. The egg moves down the Fallopian tube towards the womb.



The egg will then either be:

- Fertilised by one sperm (conception).

For the egg to be fertilised, it must encounter a sperm in the Fallopian tube. When you have sex, your partner releases millions of sperm into your vagina; some of the sperm travel up through the womb into the Fallopian tubes. If there is an egg in the Fallopian tube, one sperm will fertilise it. The fertilised egg will move towards the womb, become implanted in the lining and start growing into a baby.

or

- Discarded with the lining of the womb (menstrual period).

If the egg does not encounter a sperm in the Fallopian tube and is not fertilised, it will be discarded with the lining of the womb at the end of the menstrual cycle and you will have a period.

It is important to know that

- a released egg can live for up to 2 days
- sperm can live for up to 5 days within a woman's body; so if you have unprotected sex up to 5 days before ovulation or a few days after it you may become pregnant.

HOW DO YOUR NATURAL HORMONES WORK?

Your ovaries make two hormones which control your menstrual cycle; these are called:

- oestrogen
- progesterone.

During the first part of your menstrual cycle (before ovulation) your body is preparing itself for pregnancy; more **oestrogen** is produced because it makes the lining of the womb thicker so that a fertilised egg can grow in it.

During the second part of the cycle (after ovulation) more **progesterone** is produced. This stops the growth of the lining of the womb.

If the egg is not fertilised, the amounts of the two hormones decrease and this makes the lining of the womb break down. The lining will be discarded, together with the unfertilised egg as a menstrual bleed.

If the egg is fertilised, the two hormones will continue to be produced throughout pregnancy. The presence of high levels of these two hormones stops your ovaries releasing any other eggs, to prevent any further conceptions during pregnancy.

Pills such as Binovum protect you against pregnancy because they contain two synthetic hormones similar to those produced by your body. While taking Binovum, your ovaries will not release eggs, so there will be no eggs to be fertilised by the sperm. These pills also thicken vaginal fluid so that sperm cannot get to the womb and they change the lining of the womb so that eggs cannot grow there.

HOW EFFECTIVE IS THE PILL?

The pill is an extremely effective method of contraception **if taken properly** so you must take the pill exactly as described in this leaflet (see section "HOW YOU SHOULD TAKE BINOVUM").

It is important to remember that no form of contraception, not even the pill, can offer 100% protection against pregnancy.

WHAT IS IN BINOVUM?

Each Binovum pill contains two types of female hormones:

- A progestogen called norethisterone
- An oestrogen called ethinylestradiol.

One of the active ingredients in this medicine is ethinylestradiol. This is the new name for ethinyloestradiol. The ingredient itself has not changed.
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Each white pill contains 500 micrograms norethisterone and 35 micrograms ethinylestradiol.

Each peach coloured pill contains 1 milligram norethisterone and 35 micrograms ethinylestradiol.

Binovum also contains some inactive ingredients. These are as follows: anhydrous lactose (a type of sugar), magnesium stearate and pregelatinised starch.

The peach coloured tablets also contain a dye called FD&C yellow No 6 (E110).

WHAT SHOULD BINOVUM LOOK LIKE?

Binovum comes in a carton containing 3 blister strips, each containing 21 pills (7 white pills engraved 'C535' and 14 peach coloured pills engraved 'C135').

WHAT TYPE OF MEDICINE IS BINOVUM?

Binovum is a low dose combined oral contraceptive.

WHO IS LICENSED TO SELL BINOVUM?

Janssen-Cilag Ltd
50-100 Holmers Farm Way
High Wycombe
Bucks
HP12 4EG
UK

RELEASED BY

Janssen Pharmaceutica NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

WHAT IS BINOVUM USED FOR?

Binovum is used to prevent pregnancy. It may also be recommended by your doctor for conditions where combined oestrogen/progestogen therapy is appropriate.

HOW DO BINOVUM PILLS WORK?

1. They stop a woman's ovaries releasing eggs
2. They thicken vaginal fluid so that sperm cannot get to the womb
3. They change the lining of the womb so that eggs are unable to grow there.

IS BINOVUM SUITABLE FOR YOU?



Do not use these pills if:



- You are or think you may be pregnant

- You have, or have ever had, problems with:
 - your circulation e.g. phlebitis or blood clots
 - severe liver disease
 - hepatitis or jaundice
 - systemic lupus erythematosus (SLE).

- You have, or you or a member of your family have ever had, venous thrombo-embolic disease (VTE) (blood clots which may travel through blood vessels.

- You have had any of the following problems while you were pregnant or taking steroids:
 - jaundice
 - severe skin itching
 - herpes of pregnancy
 - a problem of hearing called otosclerosis.

- You have any of the following conditions:
 - Rotor syndrome
 - Dubin-Johnson syndrome
 - porphyria
 - liver cell tumours
 - moderate or severe high blood pressure
 - the high blood cholesterol or lipid (fat) disorder known as hyperlipoproteinaemia
 - gallstones.

- You have, or have ever had, tumours of:
 - breast
 - womb
 - ovary.

- You have other gynaecological problems, eg:
 - thickening of the lining of the womb
 - unusual or irregular vaginal bleeding which your doctor does not know about.

If you are not sure about any of these conditions you should talk to your doctor - he/she will consider your medical history and decide whether Binovum is suitable for you to take.

There are certain conditions which you may have, or have had, in the past, where you can still use Binovum but your doctor may need to monitor you more regularly. If you already have any of these, or you develop any whilst you are taking Binovum, please tell your doctor - he/she can then decide whether you should continue to take this pill.

These include the following:

- Severe varicose veins
- A prolonged period of bed rest

- Blood clotting problems
- Smoking
- High blood pressure
- High blood cholesterol or lipids (fats)
- Heart or kidney problems or diabetes
- Obesity
- Epilepsy
- Migraine
- Gallstones
- Fibroids, endometriosis
- Severe depression
- Liver problems
- Sickle cell disease
- If you are to have an operation/major surgery.

It is **important** to tell your doctor about any of these. Again, if you are not sure about any you should discuss it with your doctor.

ARE YOU TAKING OTHER MEDICINES?

It is important that you tell your doctor about any other medicines you are taking including any that you have bought yourself. Some other medicines may prevent Binovum from working properly so that you could get pregnant.

These include:

- Drugs used for epilepsy/fits
- Antibiotics and certain anti-fungal drugs e.g. griseofulvin
- Laxatives and charcoal
- Barbiturates.

Binovum may still be used if you are taking certain antibiotics to treat acne but you should discuss this with your doctor.

If you take insulin or other drugs for diabetes, you may need to change their dose.

The herbal remedy St John's Wort should not be taken at the same time as this medicine. If you already take a St John's Wort preparation, stop taking the St John's Wort and mention it to your doctor at your next visit.

SPECIAL WARNINGS:

Binovum should not be used while breast feeding as it may reduce the amount of breast milk.

- You should have talked to your doctor about any present and past medical problems. Your doctor will check your blood pressure and will decide whether you need any other examination before starting the pill. Your blood pressure should be checked regularly once you have started the pill.
- Cigarette smoking increases the risk of serious side effects to oral contraceptive use, such as heart and blood vessel problems, blood

clots/thrombosis. The increased risk of serious side effects such as blood clots/thrombosis is highest during the first year of taking the pill.

- You are strongly advised to give up smoking, especially if you are aged over 35 years.

- If your periods are not regular before you start taking the pill, you should tell your doctor.

- Binovum should not be used for 4-6 weeks before an operation/surgery and not used again until 2 weeks after you are fully mobile. This also applies to any situation where you may need to rest or be immobile for some time.

- Some women may develop patches of darkened skin whilst taking Binovum. This is more likely to happen if you developed patches of darkened skin during a previous pregnancy. If you develop such patches, you should avoid the sun and ultraviolet light (sunbeds). These patches of darkened skin may not disappear, even when you have stopped taking the pill.

- Binovum may affect the results of certain blood and urine tests - please tell the doctor/nurse that you are taking Binovum when you have any such tests.

HOW YOU SHOULD TAKE BINOVUM

The pill is a very effective contraceptive when used properly. It is important to take Binovum exactly as your doctor told you and as stated below:

1. When to start

- It is best that you start taking Binovum on the first day of your period - if you do this no extra contraceptive cover is required.

- If your period has already begun, start taking Binovum on day 5 (counting the first day of period as day 1) whether or not your bleeding has stopped. In this case, extra contraception (e.g. condoms) must be used for the first 7 days of pill taking.

- If your period started more than 5 days ago, do not start taking Binovum until the first day of your next period. Use extra contraception until then.

2. How to take BINOVUM

Binovum comes in a pack marked with the days of the week. Take your first **white** pill marked with the right day.

- Take a white pill each day until all white pills have been used. Then choose a coloured pill marked with the correct day of the week (the day after you finish the white pills) and take a coloured pill each day until the pack is empty.

- It is best to take your pill at around the same time each day - most people find it easier to remember taking it before bedtime.

- When you have taken all 21 pills and the pack is empty leave a break of exactly 7 days after the last pill and the start of your next pack.

- During this "pill-free" week you should have some days of bleeding similar to a 'period'.

- Start your next pack of Binovum after exactly 7 "pill-free" days. Each new pack of Binovum will begin on the same day of the week as the previous pack; so it is easy to remember when to start again.
- Continue with this pack and future packs in the same way as described above.
- If you take Binovum as above, extra contraception is not required.

NB In some cases your doctor may tell you to start taking your next pack without leaving a 7 day gap. (See "EXTRA CONTRACEPTION: THE 7 DAY RULE").

- If you do not have any bleeding during the "pill-free" week of any pack and if you have no other reason why Binovum should not have worked properly (ie you did not have to use extra contraception - see later) then you are highly unlikely to be pregnant. Start your next pack of Binovum even though you have not had a period. If you still do not have a period during the "pill-free" week of this pack, go to your doctor. He/she will check that you are not pregnant before you continue to take Binovum.

- If you do not have any bleeding during the "pill-free" week of any pack and you have a reason why Binovum may not have worked properly i.e. you DID need to take extra contraception (see later), go to your doctor. He/she will check that you are not pregnant before you re-start Binovum.

3. After having a baby

- You can start using Binovum after 21 days if you are not breast feeding and you had a vaginal delivery with no complications and you are fully mobile.

- If you do have intercourse before you start taking Binovum or before your first period, wait until your period starts before you take Binovum and then take it on the first day of bleeding. This is because you can get pregnant very soon after having a baby and you have to make sure that you are not pregnant before taking Binovum.

- If you start taking Binovum more than 21 days after delivery and you haven't had intercourse or a period, you should use extra contraception for the first 7 days.

- If you are breast feeding, you should not use Binovum or any other combined oral contraceptive as this may affect your breast milk. You may be able to use a progestogen-only pill - discuss this with your doctor.

4. After miscarriage or abortion

- You can start taking Binovum on the first day after a miscarriage or abortion. You will not need extra contraception if you start taking the pill straight away. Ask your doctor about other contraception if you are not starting Binovum immediately.

5. Changing from another type of pill

What sort of pill were you on?

i) Another 21 day pill

Finish the pack of contraceptive pills you are on. Start taking Binovum on the very next day. Do not leave a break between packs or wait for your period to begin.

You may get a light period whilst you are taking tablets or no period at all until after you have finished your first pack of Binovum.

ii) Every day pill ('ED' pack)

Finish the first 21 pills of your ED or 28 day pack. Take your first Binovum pill the next day. Do not leave a break between packs or wait for your next period to begin. You may not have a period until after you have finished your first pack of Binovum or you may get a light period whilst taking Binovum.

Safely dispose of the remaining 7 pills from your old 28 day pack.

iii) Mini pill (progestogen-only pill)

Start taking Binovum on the first day of your period, even if you have already taken a mini pill on that day.

Safely dispose of the rest of the pills in your old pack of mini pills. No extra contraceptive cover is required.

If you do not have a period, start taking Binovum on the day after the last mini pill in your pack.

You **must** use extra contraception for the first 7 days of taking Binovum.

6. To skip a period

- Start a new pack of Binovum on the next day after finishing the pack you are taking i.e. do not leave a 7 day gap between packs. Pill taking should then continue as usual.

- You may have some spotting or slight bleeding whilst taking the pills of the second pack. Do not worry - this will not affect your contraceptive cover. Take the next pack after the usual 7 day break even if you are still spotting/bleeding.

WHAT MIGHT STOP YOUR PILL WORKING?

- FORGETTING TO TAKE A PILL

If you forget to take a pill, check when your missed pill was due and then follow the instructions as outlined in the Missed Pill Guide.

- HAVING A STOMACH UPSET - Vomiting/Diarrhoea

- If your symptoms stop within 12 hours of taking a pill, just take an extra pill of the same colour from a spare pack of Binovum and carry on taking pills as usual from the next day.

- If the upset carries on over 12 hours, use extra contraception for as long as you are ill and for the next 7 days after that.

- Carry on with the rest of your pack as usual.

- If you are sick or have diarrhoea in the last 7 days of the pack, start your next pack without a break. If you do not have a period following the end of this new pack, discuss this with your doctor before starting another pack.

MISSED PILL GUIDE:

What to do if you miss or forget to take your pill

1. When was your missed pill due?

Less than 12 hours ago:

- Don't worry
- Take the forgotten pill now
- Take the rest of your pills at the usual times
- That's all.

More than 12 hours ago:

- Take the latest pill now
- Throw away any others you missed
- Take the rest of your pills at the usual times
- Use extra contraception for the next 7 days
- Go to 2.

2. How many pills are left in your pack?

7 or more pills:

- Use extra contraception for the next 7 days
- When you finish your pack leave a break of 7 days before you take the first pill in your next pack.

Less than 7 pills:

- Use extra contraception for the next 7 days
- Do not leave a break between packs, ie start a new pack of Binovum the day after finishing the current pack. If you do not have a period following the end of this new pack discuss this with your doctor before starting another pack
- Use other contraception, such as a condom, in the meantime.

EXTRA CONTRACEPTION: THE 7 DAY RULE

It is important that extra contraception is used in the following situations:

- If a pill is missed or forgotten for more than 12 hours

- If sickness or diarrhoea lasts for more than 12 hours
- If you are taking any of the medicines, eg antibiotics, listed under "ARE YOU TAKING OTHER MEDICINES?".

You should still take your Binovum pill each day but use other contraception as well for 7 days after any of these events.

If there are less than 7 pills left in your Binovum pack when any of the above events happen, you must start the next pack as soon as you have finished the one before without leaving a 7 day gap. If you do not have a period following the end of this new pack, discuss this with your doctor before starting another pack.

Extra contraception:

You can use:

- a condom
- a cap or diaphragm with a spermicide
- a contraceptive sponge.

If you use any of these, follow the instructions carefully.

WHAT TO DO IF YOU TAKE TOO MANY BINOVUM PILLS

If a large number of Binovum pills is taken, contact your doctor for advice. There have been no reports of serious problems from an overdose of Binovum.

HOW SAFE IS THE PILL?

The pill is one of the most thoroughly tested products of medical research and vast experience has confirmed that it can be safely used by most women **BUT it is important to know that even if a product has been used by a great number of patients for a large number of years, it is not possible to guarantee that the product is completely safe for all patients, because each person is unique. So, with the pill (as with any other medicine), some risk to health must be accepted.**

WHAT SIDE EFFECTS MAY BINOVUM HAVE?

As with any other oral contraceptive pill, Binovum may cause some unwanted effects but this is not common.

The most serious side effects are:

(1) Blood clots and thrombosis which can occur in different blood vessels causing problems such as a pulmonary embolus (blood clot in the lung), a stroke or a heart attack. These are rare but serious and may be fatal.

Certain conditions themselves increase the risk of venous thrombosis (eg blood clots in the legs): heavy smoking, obesity, severe varicose veins, high cholesterol, high blood pressure, diabetes. The risk of arterial thrombosis (eg

heart attack and stroke) associated with the pill increases with age, and this risk is increased by cigarette smoking. Certain conditions, in addition to those mentioned above, can also increase the risk of arterial thrombosis, eg migraine.

If any of these conditions applies to you, you have a greater risk of having a thrombosis. This risk is increased if you take Binovum.

The signs and symptoms of a blood clot are described under "REASONS FOR STOPPING BINOVOUM IMMEDIATELY"; if you develop any of those signs or symptoms, stop taking Binovum at once and see your doctor.

Women who do not take the oral contraceptive pill can also have blood clots and thrombosis, but statistics show that women who take the pill have a higher risk of these disorders than those who don't. However, the risk of venous thrombo-embolism in women using combined oral contraceptives remains very small and well below the risk associated with pregnancy (see below). It is thought that the risk of thrombosis is lower for modern pills such as Binovum, because they contain lower levels of oestrogen than the older types of pill.

Incidence of VTE in:	Estimated cases per 100,000 women per year
- Healthy non-pregnant women not taking the oral contraceptive pill	5
- Women using combined oral contraceptive pills, such as Binovum	15
- Pregnant women	60

(2) There have been many studies of women taking combined oral contraceptives (COCs) looking at the effects of these pills on the risk of developing cancer of the ovary, uterus, cervix and breast. These have shown clearly that COCs offer good protection against cancer of the ovary and uterus.

Some studies showed an increased risk of cancer of the cervix in women using COCs for a long time but it is not clear whether this is due to other factors such as sexual behaviour or to the COCs alone.

Breast Cancer

Every woman is at risk of breast cancer whether or not she takes the Pill. Breast cancer is rare under the age of 40 years, but the risk increases as a woman gets older.

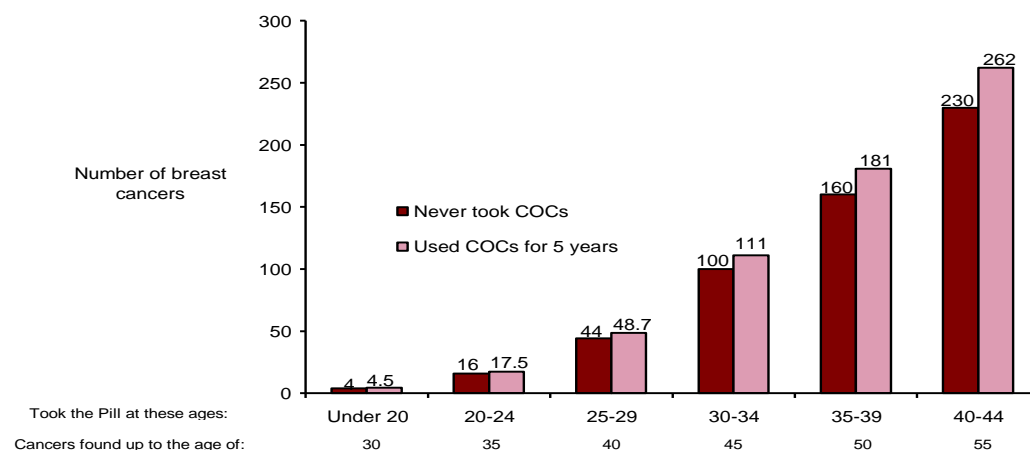
Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. If women stop taking the Pill, this reduces the risk so that 10 years after stopping the Pill, the risk of finding breast cancer is the same as for women who have never taken the

Pill. Breast cancer seems less likely to have spread when found in women who take the Pill than in women who do not take the Pill.

It is not certain whether the Pill causes the increased risk of breast cancer. It may be that women taking the Pill are examined more often, so that breast cancer is noticed earlier. The risk of finding breast cancer is not affected by how long a woman takes the Pill but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older.

The chart below shows the background chances of breast cancer at various ages for 10,000 women who have never taken the Pill (black bars) and for 10,000 women whilst taking the Pill and during the 10 years after stopping it (grey bars). The small extra risk of finding breast cancer can be seen for each age group. This small possible additional risk in women who take the Pill has to be balanced against the fact that the Pill is a very effective contraceptive and it helps prevent cancer of the womb or ovary.

Estimated number of breast cancers found in 10,000 women who took the Pill for 5 years then stopped, or who never took the Pill



If anything is unclear about this you should ask your doctor about it at your next routine visit.

- (3) Benign and malignant liver tumours
- (4) Gallstones
- (5) Jaundice
- (6) Systemic lupus erythematosus (SLE)
- (7) Involuntary limb movements.

If any of the above (1-7) occurs or is suspected, you should stop taking Binovum immediately and consult your doctor.

Other effects may include:

- raised blood pressure
- bleeding between periods; changes in vaginal discharge; fibroids; very severe period pains; thrush; worsening of endometriosis; no periods on stopping the pill

- your breasts may feel tender, painful or they may get slightly larger or ooze a little milk
- feeling or being sick
- skin rashes, patches of darkened skin, small red marks on skin, red lumpy swellings on the legs
- problems with contact lenses
- headaches, migraines, moodiness or depression
- fluid retention - you may notice swollen ankles or stomach or changes in weight
- raised blood sugar
- change in libido (interest in sex)
- loss of scalp hair or excessive hair growth
- leg cramps, premenstrual-like symptoms.

If you notice any of these effects or any other unusual symptoms please tell your doctor or pharmacist as soon as possible. Never miss your check ups with your doctor. Your doctor can check for side effects which you may not notice yourself.

REASONS FOR STOPPING BINOVOUM IMMEDIATELY:

You must **stop** taking Binovum **immediately** and **consult your doctor** if you experience any of the following signs/symptoms of a blood clot:

- severe pain or tenderness or swelling in the calf of one or both legs
- unexpected chest pain, shortness of breath or coughing up blood
- unexpected numbness, tingling, severe headache, dizziness, fainting, fitting, problems with eyesight or speech
- unexpected stomach pains.
- you become jaundiced
- you are to have an operation/major surgery
- you have to take bed rest or remain immobile for a long time
- you develop high blood pressure, high blood cholesterol or lipids
- you develop heart or kidney problems or existing problems become worse
- you develop epileptic fits or your existing epilepsy worsens
- you develop migraine or your existing migraine worsens
- you develop severe depression or your existing depression worsens
- you develop fibroids or endometriosis or your existing fibroids/endometriosis worsen
- you develop gallstones
- you develop blood clotting problems or your existing problems worsen
- you know or suspect that you may be pregnant, as the pill might affect the normal development of the child in the early stages of pregnancy and there is a very small risk of foetal malformation.

DOES THE PILL OFFER ANY EXTRA BENEFITS?

- your periods will become very regular and bleeding will probably become lighter
- period pains will usually lessen
- long term use of the pill reduces the risk of cancers of the ovaries and of the lining of the womb by approximately a half
- the pill may prevent painful lumpy breasts

- the pill offers some protection against some infections of the internal genital organs.

WHAT IF YOU DECIDE TO HAVE A BABY?

The periods you get during the "pill free" week are not true periods. It is important that you have a true period before getting pregnant so that your doctor is able to know when your baby is due to be born. So, once you have stopped taking Binovum because you wish to try to become pregnant, use another method of contraception until you have had a true period.

HOW SHOULD YOU STORE BINOVUM?

- Do not store above 30°C.
- Protect from light.

Other important points:

Keep out of reach of children.

Do not use these pills:

- After the expiry date shown on the label
- If the pack is damaged.

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