

# MERCILON<sup>®</sup>

Ethinylestradiol/Desogestrel (0.020mg/0.150mg)

## What is in this leaflet

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## What MERCILON is used for

MERCILON is a combined oral contraceptive ('the combined Pill'). Each tablet contains a small amount of two different female hormones. These are desogestrel (a progestogen) and ethinylestradiol (an estrogen). Because of the small amounts of hormones, MERCILON 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.

MERCILON is used to prevent pregnancy. When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

## How MERCILON works

Mercilon releases two female sex hormones that prevents the release of an egg cell from the ovaries. If no egg is released you cannot become pregnant.

## Before you take MERCILON

### When you must not use it

Do not use the MERCILON if you have any of the conditions listed below. If anything on this list applies to you, tell your doctor before starting to use MERCILON. 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 had in the past a blood clot (thrombosis) in a blood vessel of the leg, lung (embolus) or other organs.

- If you have or have had in the past a heart attack or stroke.

- 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 a disturbance of blood clotting (for example, protein C deficiency).

- If you have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see section '**The Pill and Thrombosis**').

- If you have (had) a type of migraine called 'migraine with aura'.

- If you have diabetes mellitus with blood vessel damage.

- If you have a serious risk factor, or several risk factors for developing thrombosis, this may also be a reason why you cannot use MERCILON (See also '**The Pill and Thrombosis**').

- If you have or have had a pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.

- If you have jaundice (yellowing of the skin) or have (had) severe liver disease and your liver is not yet working normally.

- If you have or have had a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).

- If you have or have had a liver tumour.
- 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 MERCILON.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also 'Things to be careful of'.

### Before you start to take it

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 MERCILON.

- 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 have had high cholesterol or triglycerides (fats in the blood);
- 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 erythematosus (SLE; a chronic connective tissue disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS; an abnormal premature destruction of red blood cells that cause kidney failure when the destructed red blood cells clog the filtering system in the kidneys.);
- you have sickle cell anemia (a rare blood disease);
- you have an operation, or if your ability to move around is limited for a long period of time (see section '**The Pill and Thrombosis**');
- if you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using Mercilon (see section '**The Pill and Thrombosis**').
- you have a condition that occurred for the first time or got worse during pregnancy or previous use of sex hormones (e.g., hearing loss, a disease called porphyria, a skin disease called

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herpes gestationis, a disease called Sydenham's chorea);

- 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 light.

If any of the above conditions appear for the first time, come back or get worse 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. The risk is higher in Pill-users than in non-users. The chance of getting a thrombosis is highest during the first year after you start using the Pill for the very first time. The risk is also higher if you restart using the Pill (the same product or a different product) after a break of 4 weeks or more.

The risk is not as high as the risk of developing a thrombosis during pregnancy.

The risk of getting a deep venous thrombosis for women using Pills with desogestrel may be slightly higher than for women using Pills with levonorgestrel. The absolute numbers remain very small. If 10 000 women use a Pill with levonorgestrel for one year, 2 women would get a thrombosis. If 10 000 women use a Pill with desogestrel for a year approximately 3 to 4 women would get a thrombosis. For comparison, if 10 000 women get pregnant, approximately 5-20 would get a thrombosis. These findings are based on the results of some studies. Other studies did not find a higher risk for Pills with desogestrel.

Blood clots can also occur very rarely in an artery (arterial thrombosis). For example 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 thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of venous thrombosis in users of combined pills increases:

- with increasing age
- if you are overweight,
- if one of your close relatives has had a blood clot (thrombosis) in the leg, lung, or other organ at a young age,
- if you must have an operation or if your ability to move around is limited for long period of time, or if you have had a serious accident. It is important to tell your doctor in advance that you are using MERCILON as the treatment may have to be stopped. Your doctor will tell you when to start MERCILON again. This is usually about two weeks after you are able to move around. See also section "When you must not use Mercilon".
- if you gave birth less than a few weeks ago.

The risk of arterial thrombosis in users of combined pills increases:

- **if you smoke. You are strongly advised to stop smoking when you use MERCILON, especially if you are older than 35 years.**
- if you have an increased fat content in your blood (cholesterol or triglycerides)
- if you have high blood pressure
- if you have migraine
- if you have a problem with your heart (valve disorder, a disturbance of the heart rhythm)

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 abdomen.

Cervical cancer is caused by an infection with the human papilloma virus. It has been reported to occur more often in women using the Pill for a long time. It is unknown if this finding is due to the use of hormonal contraceptives or to sexual behaviour and other factors (such as better cervical screening).

## Taking other medicines

Some medicines may stop the Pill from working properly. These include medicines used for the treatment of epilepsy (e.g., primidone, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g., rifampicin) and HIV infections (e.g., ritonavir); antibiotics (e.g., ampicillin, tetracyclines, griseofulvin) for some other infectious diseases; and the herbal remedy St. John's wort (*Hypericum Perforatum*, primarily used for the treatment of depressive moods). The Pill may also interfere with how other medicines work (for instance cyclosporin and lamotrigine).

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use MERCILON. They can tell

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you if you need to take additional contraceptive precautions and if so, for how long.

## More about hormonal contraceptives

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.

## How to take MERCILON

### How much to take

The MERCILON 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 liquid 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 MERCILON tablet. Start taking your next pack on the 8<sup>th</sup> 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.

### When to take it

#### Starting your first pack of

#### MERCILON

- *When no hormonal contraceptive has been used in the past month.* Start taking MERCILON 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 days in order. MERCILON will work immediately, it is not necessary to use an additional contraceptive method.

You may also start on days 2-5 of your cycle, but if you do, 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 hormonal contraceptive (combined oral contraceptive pill (COC), vaginal ring, or transdermal patch)* You can start taking MERCILON 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 MERCILON 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). In case you use a vaginal ring or transdermal patch, it is best to start using MERCILON on the day you remove the ring or patch. You can also start, at the latest, on the day you would have started using the next ring or patch.

If you have used the Pill, patch or ring consistently and correctly and if you are sure that you are not pregnant, you can also stop taking the Pill or remove the ring or patch on any day and start using MERCILON immediately.

If you follow these instructions, it is not necessary to use an additional contraceptive method.

- *When changing from a progestogen-only pill (minipill).* You can stop taking the minipill any day and start taking MERCILON the next day, at the same time. But if you are having intercourse, make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking MERCILON.

- *When changing from a progestogen-only injectable, implant or a progestogen releasing intrauterine device (IUD).*

Start using MERCILON when your next injection is due or on the day that your implant or IUD is removed. But if you are having intercourse, make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking MERCILON.

- *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 MERCILON. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take MERCILON, you should talk to your doctor first.

- *After a miscarriage or an abortion.*

Your doctor will advise you.

### How long to take it

Continue taking MERCILON tablets for as long as your doctor recommends.

### If you forget to use it

- 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

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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, it's possible that you could be 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. Provided that you have taken your tablets correctly in the 7 days preceding the first missed tablet, there is no need to use extra contraceptive precautions. However, if this is not the case, use extra contraceptive precautions (barrier method) for the next 7 days.

### 1 tablet missed in week 3

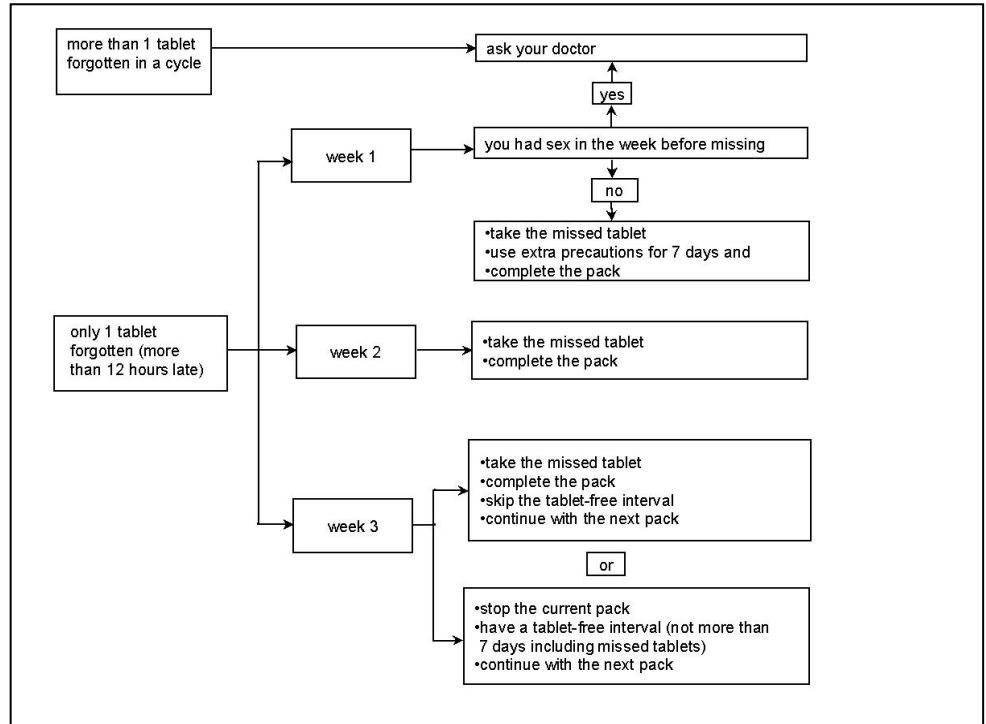
You may choose either of the following options, without the need for extra contraceptive precautions, provided that you have taken your tablets correctly in the 7 days preceding the first missed tablet. However, if this is not the case, use extra contraceptive precautions (barrier method) for the next 7 days.

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 (**including the day you missed your tablet**) and then start the next pack.

- If you do this, 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 your period in the first normal tablet-free break, you may be pregnant. Tell your doctor before you start with the next pack.



### If you use too much (overdose)

There have been no reports of serious harmful effects from taking too many MERCILON 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 MERCILON, ask your doctor for advice.

### While you are using MERCILON

#### Things you must do

#### If you want to stop taking MERCILON

You can stop taking MERCILON 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 MERCILON because you want to get pregnant, you should 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 suffer from gastro-intestinal disturbances (e.g., vomiting, severe diarrhea)

If you vomit, or have severe diarrhea, the active ingredients of your MERCILON tablet may not have been completely

absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. You must follow the advice for missed tablets. If you have severe diarrhea, please tell your doctor.

#### ....you want to delay your period

You can delay your period if you start with your next pack of MERCILON 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 correctly, you will have your period on about the same day every 4 weeks. If you want to change this day, 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) start your next pack 3 days sooner than you usually do. If you make your tablet-free break very short

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(e.g. 3 days or less), you may not bleed during the break. You may have some breakthrough bleeding or spotting while using 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 keep taking your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 months).

If bleeding 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. Keep taking MERCILON 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 MERCILON until your doctor has checked you are not pregnant.

**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. You should usually 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 section 'When you must not use it' and 'Before you start to use it'; do not forget about changes in the health of your immediate family);
- you feel a lump in your breast;
- you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing;
- you are going to use other medicines (see also section 'Taking other medicines');
- your ability to move around is limited

for a long period of time or you are to have surgery (tell 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 have severe diarrhea;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until your doctor tells you).

**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.

For more information, see section '**The Pill and Thrombosis**'.

**Things you must not do**

MERCILON has been prescribed for you personally. Do not share it with others.

**The Pill and Pregnancy**

MERCILON must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already using MERCILON, you should tell your doctor as soon as possible.

**The Pill and Breast-feeding**

MERCILON is not usually recommended for use during breast-feeding. If you wish to take the Pill while breast-feeding, please ask your doctor.

**Things to be careful of**

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 sexual intercourse 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.

**MERCILON, like all contraceptive Pills, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

**Laboratory tests**

If you are having any blood or urinary test, tell your health care professional that you are using Mercilon as it may affect the results of some tests.

**The Pill and Driving and Using machines**

There are no observed effects.

**Important information about some of the ingredients of MERCILON**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before starting with MERCILON.

**Side effects**

Like all medicines, MERCILON can have side effects, although not everybody gets them.

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 reactions seen with the Pill, as well as the related symptoms, are described in the sections '**The Pill and Thrombosis**' and '**The Pill and Cancer**'.

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Common (occurring in more than one per 100 users):

- depressed mood, mood changes
- headache
- nausea, abdominal pain
- breast pain, breast tenderness
- increase in body weight.

Uncommon (occurring in more than one per 1000 users but not more than one per 100 users):

- fluid retention
- decreased sexual drive
- migraine
- vomiting, diarrhoea
- rash, hives
- breast enlargement.

Rare (occurring in less than one per 1000 users):

- hypersensitivity reactions
- blood clot in a vein
- blood clot in an artery
- increased sexual drive
- contact lens intolerance
- erythema nodosum, erythema multiforme (these are skin conditions)
- breast secretion, vaginal secretion
- decrease in body weight.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)”

## Storage and Disposal of MERCILON

### Storage

- Do not use MERCILON after the expiry date stated on the package.
- Store your tablets below 30°C in the original package. Do not freeze.
- Store protected from light and moisture.
- Do not use the product if you notice, for example, color change in the tablet, crumbling of the tablet or any other visible signs of deterioration.

- **Keep MERCILON out of reach and sight of children!**

### Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### What it looks like

MERCILON comes in 1, 3 or 6 strips of 21 tablets packed in a ply carton.

The tablets are biconvex, round and 6 mm in diameter. Each tablet is marked TR above 4 on one side and Organon\* on the reverse side.

### Ingredients

- The active substances are: ethinyl estradiol (0.020 mg) and desogestrel (0.150 mg)
- The other ingredients are: silica colloidal anhydrous; lactose monohydrate; potato starch; povidone; stearic acid; all-*rac*- $\alpha$ -tocopherol.

### MAL number:

MAL19962539A

## Manufacturer

ORGANON (IRELAND) LTD,  
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## Product Registration Holder

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