

# MICROGYNON<sup>®</sup> 30

## *Levonorgestrel 0.15 mg and Ethinyloestradiol 0.03 mg tablets*

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### **What is in this leaflet**

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Please read this leaflet carefully before you start using MICROGYNON 30. It will advise you about how to take MICROGYNON 30 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.

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### **What is MICROGYNON 30 used for and how does it work**

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MICROGYNON 30 is a combined oral contraceptive (often called "the Pill"). Each small beige tablet contains a small amount of two different female hormones. These are levonorgestrel (a progestogen) and ethinyloestradiol (an oestrogen). Because of the small amount of hormones, MICROGYNON 30 is considered to be a low-dose combined oral contraceptive preparation.

#### ***How does MICROGYNON 30 work?***

Combined oral contraceptive Pills, such as MICROGYNON 30, provide one of the most effective reversible methods of contraception known. Usually, when MICROGYNON 30 is taken according to the instructions, the egg cells (normally released by the ovary each month) are prevented from maturing to the point where they can be fertilized. In addition, the cervical mucus remains thick, so it is more difficult for a man's sperm to enter the womb. Also, the lining of the womb is not prepared sufficiently for a fertilized egg to grow in.

#### ***What is MICROGYNON 30 used for?***

MICROGYNON 30 is used to prevent pregnancy. Combined oral contraceptives are a very effective method of birth control. When taken correctly (without missing tablets) the chance of becoming pregnant is very low (approximately 1% per year). The failure rate may increase when tablets are missed or taken incorrectly.

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### **Before you use MICROGYNON 30**

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Do not use MICROGYNON 30 if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use MICROGYNON 30. Your doctor may advise you to use a different type of hormonal contraception or an entirely different (non-hormonal) method of birth control.

#### ***You must not use MICROGYNON 30 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 "MICROGYNON 30 and thrombosis").
- you have or have ever had a stroke caused by a rupture of a blood vessel in the brain
- 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 ischemic attack or small reversible stroke)
- you have a history of migraine accompanied by visual symptoms or speech disability or weakness or numbness in any part of your body
- you have diabetes mellitus with blood vessel damage
- you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances)
- you have or have had pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- you have jaundice (yellowing of the skin) or severe liver disease, as long as liver function test results have not returned to normal
- 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)
- you have or have had a benign or malignant liver tumor
- you have any unexplained vaginal bleeding
- you are pregnant or think you might be pregnant
- you are allergic (hypersensitive) to any of the ingredients of MICROGYNON 30.

If any of these conditions appear for the first time while using MICROGYNON 30, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures.

***Tell your doctor if:***

If MICROGYNON 30 is used in the presence of any of the conditions listed below or they appear for the first time, recur or worsen during treatment, you may need to be kept under close observation. Your doctor can explain this to you. You should tell your doctor if:

- 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 thrombosis, a heart attack or a stroke

- you suffer from headaches
- you suffer from epilepsy
- anyone in your immediate family has had breast cancer
- you have liver, kidney or gallbladder disease
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- you have systemic lupus erythematosus (SLE; a disease affecting the skin all over the body)
- you have hemolytic uremic syndrome (HUS; a blood clotting disorder causing failure of the kidneys)
- you have sickle cell disease
- you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological 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 radiation
- you have hereditary angioedema; taking oestrogens may induce or exacerbate symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing.

### ***What else you should know***

**MICROGYNON 30 does not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

In this leaflet, several situations are described where you should stop taking MICROGYNON 30, or where the reliability of MICROGYNON 30 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 MICROGYNON 30 alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

- **MICROGYNON 30 and thrombosis**

Thrombosis is the formation of a blood clot which may block a blood vessel.

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. The risk is highest during the first year a woman ever uses the Pill.

Venous thrombosis 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 not as high as 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 MICROGYNON 30 you should stop smoking, especially if you are older than about 35 years of age.**

If you develop high blood pressure while using MICROGYNON 30, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilization (for example, when you have your leg or legs in plaster or splints). In women who use the Pill (such as MICROGYNON 30) the risk may be even higher. Tell your doctor you are using MICROGYNON 30 well in advance of any expected hospitalization or surgery. Your doctor may tell you to stop taking MICROGYNON 30 several weeks before surgery or at the time of immobilization. Your doctor will also tell you when you can start taking MICROGYNON 30 again after you are back on your feet.

If you notice possible signs of thrombosis, stop taking the Pill and consult your doctor immediately. (See also the section called "*Tell your doctor if:*").

- **MICROGYNON 30 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 ten 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, and even more rarely, malignant liver tumors have been reported in users of the Pill. These tumors may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

The most important risk factor for cervical cancer is persistent human papilloma virus infection. Some studies have indicated that long-term use of the Pill may further contribute to this increased risk, but there continues to be controversy

about the extent to which this finding is attributable to other factors, e.g. cervical screening and sexual behavior including use of barrier contraceptives.

- **MICROGYNON 30 and other medicines**

Some medicines may stop MICROGYNON 30 from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate and felbamate); tuberculosis (e.g. rifampicin and rifabutin) and HIV infections (e.g. ritonavir and nevirapine); antibiotics (e.g. penicillins, tetracyclines and griseofulvin) for some other infectious diseases; and the herbal remedy St. John's wort (primarily used for the treatment of depressive moods).

The Pill may also interfere with the working of other medicines (e.g. medicines containing cyclosporin or the anti-epileptic 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.

Always tell the doctor who prescribes MICROGYNON 30 which medicines you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use MICROGYNON 30. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

- **MICROGYNON 30 and breast-feeding**

MICROGYNON 30 is generally not recommended for use during breast-feeding. If you wish to take the Pill while breast-feeding, please seek the advice of your doctor.

- **MICROGYNON 30 and pregnancy**

MICROGYNON 30 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 using MICROGYNON 30 you should see your doctor as soon as possible.

- **MICROGYNON 30 and ability to drive and use Machines**

There are no observed effects.

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## **How to use MICROGYNON 30 properly**

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When you follow the starting instructions and continue to take MICROGYNON 30 correctly, the contraceptive protection provided by MICROGYNON 30 is continuous. This includes your tablet-free week.

Additional contraceptive precautions are only required when special circumstances (e.g. forgetting tablets) reduce the reliability of the preparation.

Remember that MICROGYNON 30 has been prescribed for you personally. Do not share it with others.

### ***When and how to take the tablets***

The MICROGYNON 30 pack contains 21 small round beige 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 (the withdrawal bleed) should begin during these 7 days. 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 will have your withdrawal bleed on or about the same day each month.

### ***Starting your first pack of MICROGYNON 30***

- **When no hormonal contraceptive has been used in the past month**

Start taking MICROGYNON 30 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 Monday, take the tablet marked Monday. Then follow the days in order of the directional arrows. When you start taking MICROGYNON 30 your very first cycle may be shorter than usual. MICROGYNON 30 will work immediately, it is not necessary to use an additional contraceptive method.

You may also start taking MICROGYNON 30 on days 2-3 of your cycle, but in this case make sure that you use an additional barrier contraceptive method (such as condoms) for the first 7 days of tablet-taking in the first cycle.

- **When changing from a combined Pill, vaginal ring or transdermal (contraceptive) patch**

You can start taking MICROGYNON 30 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 non-hormonal tablets you can start MICROGYNON 30 on the day after taking the last hormonal 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 non-hormonal tablet of your present Pill). In case you have used a vaginal ring or transdermal patch, you should start using MICROGYNON 30 preferably on the day of removal, but at the latest when the next application would have been due. 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 MICROGYNON 30 the next day, at the usual time. But make sure you also use an additional barrier

contraceptive method for the first 7 days of tablet-taking when having intercourse.

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

Start using MICROGYNON 30 when your next injection is due or on the day that your implant or IUD is removed. But make sure you also use an additional barrier contraceptive 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 MICROGYNON 30. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take MICROGYNON 30, you should discuss this first with your doctor.

- **After a miscarriage or an abortion**

Your doctor will advise you.

### ***Special circumstances***

The following describes special circumstances that could alter the way you take MICROGYNON 30. In all situations where the reliability of MICROGYNON 30 is reduced (such as missing tablets) additional contraceptive precautions are required following the advice given below. This advice should also be followed in situations where other medicines may stop MICROGYNON 30 from working properly and in the case of vomiting or severe diarrhea after taking MICROGYNON 30.

### ***If you forget to take your tablets***

If you forget to take your tablets, follow the instructions below. This is often called the "7 day rule". The more tablets you have missed, the higher the risk that the contraceptive effect 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.

#### ***WHAT TO DO IF .....***

##### ***..... you forget tablets***

- If you have forgotten to take one or more of the **large white non-hormonal tablets** - there is no need to be concerned, simply take your next tablet, the next day as usual. However to make sure that you do not change your Pill taking rhythm, which is important for the contraceptive reliability of your Pill, you should proceed with your next tablet the next day at the normal time and discard the forgotten non-hormonal tablet(s) to avoid any confusion.
- If you are less than 12 hours late in taking one of the small hormonal MICROGYNON 30 ED tablets, you are still protected against pregnancy.

Take the tablet as soon as you remember and take the next one at your usual time. This may mean that you are taking 2 tablets in one day.

- If you are more than 12 hours late in taking one of your small hormonal MICROGYNON 30 ED tablets, you will not be protected. Take the last tablet as soon as you remember and take the next one at your normal time. This may mean taking 2 tablets in one day. You must take extra contraceptive precautions and you must follow the 7 day rule. Read the section on "*Extra contraceptive precautions*" and "*The 7 day rule*" carefully.
- If you forget tablets in the first week after taking the large non-hormonal tablets and had intercourse in the seven days before, consult your doctor as the possibility of pregnancy should be considered.
- If you have forgotten to take your small hormonal MICROGYNON 30 ED tablets for a few days, consult your doctor to be sure you are not pregnant, then discard the missed tablets and follow the 7 day rule.

#### ***Extra contraceptive precautions***

When you need extra contraceptive precautions, either:

- don't have sex; or
- use a cap plus spermicide; or
- use a condom

Do not use the rhythm or temperature methods as extra contraceptive precautions. This is because oral contraceptives alter the usual menstrual cycle changes, such as changes in temperature and cervical mucus.

#### ***The 7 day rule***

- Continue taking your Pills
- You will not be protected from pregnancy until you have taken your daily small hormone Pill for the next 7 days in a row
- Use another method of contraception (*Extra contraceptive precautions*) such as condoms or do not have sexual intercourse for these next 7 days
- If there are fewer than 7 small hormone Pills left before the non-hormonal pills, go straight on to the small hormone Pills in the green section of the next pack. This means you miss out the large white non-hormonal pills. You may not have a period until the end of the next pack. This is not harmful.

#### **If you vomit or have severe diarrhea after taking MICROGYNON 30**

If you vomit or have severe diarrhea within 3 to 4 hours after taking your MICROGYNON 30 tablets, the active ingredients may not have been completely absorbed. This is like missing a tablet. Therefore, follow the advice for missed tablets.

### **If you are taking medicines that affect MICROGYNON 30**

Some medicines may stop MICROGYNON 30 from working properly. These medicines are listed in an earlier section. For the time that you are taking the medicine and for the next 7 days follow the advice for missed tablets. If you are taking rifampicin, or you are taking these medicines continuously, your doctor will advise you on the length of time you need to take extra contraceptive precautions.

### **If you want to delay a period**

You can delay your period if you start your next pack of MICROGYNON 30 immediately after finishing your current pack. You can continue with this pack for as long as you wish, until the pack is empty. When you wish your period to begin again, just stop tablet taking. While using the second pack, you may have some breakthrough bleeding or spotting on tablet-taking days. Start your following pack after the usual 7 day tablet-free break.

### **If 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 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 bleeding during the break. You may have some breakthrough bleeding or spotting during the use of the next pack.

### **If you have unexpected bleeding**

As with other Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) with MICROGYNON 30 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 MICROGYNON 30 (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

### **If you have missed a period**

If you have taken all of your tablets at the right time, and you have not vomited, had severe diarrhea or used other medicines, then you are very unlikely to be pregnant. Continue to take MICROGYNON 30 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 MICROGYNON 30 until your doctor has checked that you are not pregnant.

### ***When you want to stop taking MICROGYNON 30***

You can stop taking MICROGYNON 30 at any time you want. If you stop 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.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

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## **Overdosage**

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There have been no reports of serious harmful effects from taking too many MICROGYNON 30 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 MICROGYNON 30, ask your doctor for advice.

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## **When using MICROGYNON 30**

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### ***Tell your doctor immediately if:***

**You should stop treatment and see your doctor immediately if you get a blood clot, heart attack or stroke while you are taking MICROGYNON 30. Warning signs for a blood clot, heart attack or stroke to look out for are:**

- 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

### ***Tell your doctor if:***

#### **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; do not forget about the items related to your immediate family. (See also the section called "*Before you use MICROGYNON 30*").
- you feel a lump in your breast
- you are going to use other medications. (See also the section called "*MICROGYNON 30 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 have severe diarrhea
- you have missed your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor)

### Regular check-ups

When you are using MICROGYNON 30, your doctor will tell you to return for regular check-ups. In general, you should have a check-up every year.

### Side effects

Tell your doctor if you notice any unwanted side effects, especially if severe or persistent, or if there is a change in your health that you think might be caused by MICROGYNON 30.

#### ***Serious side effects***

Serious side effects associated with the use of combined oral contraceptives such as MICROGYNON 30, as well as the related symptoms, are described in the following sections "*The Pill and thrombosis*" and "*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 in users of combined oral contraceptives such as MICROGYNON 30, although they may not be caused by the contraceptive Pill. Such side effects that occur in the first few months that you are using MICROGYNON 30 will probably lessen with time.

<b>System Organ Class</b>	<b>Common (≥ 1/100)</b>	<b>Uncommon (≥ 1/1000 and &lt; 1/100)</b>	<b>Rare (&lt; 1/1000)</b>
Eye Disorders			Contact lens intolerance
Gastrointestinal Disorders	Nausea, abdominal pain	Vomiting, diarrhea	
Immune System Disorders			Hypersensitivity reactions
Investigations	Weight gain		Weight loss

<b>System Organ Class</b>	<b>Common (≥ 1/100)</b>	<b>Uncommon (≥ 1/1000 and &lt; 1/100)</b>	<b>Rare (&lt; 1/1000)</b>
Metabolism and Nutrition Disorders		Fluid retention	
Nervous System Disorders	Headache	Migraine	
Psychiatric Disorders	Depression, mood changes	Increased libido	Decreased libido
Reproductive System and Breast Disorders	Breast pain, breast tenderness	Breast enlargement	Vaginal discharge, breast discharge
Skin and Subcutaneous Tissue Disorders		Rash, hives	Skin reactions (erythema nodosum and erythema multiforme)

If you have hereditary angioedema, taking oestrogens may induce or exacerbate symptoms of angioedema. (See also "*Before you start to use MICROGYNON 30*").

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

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## **Storage**

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Do not use after the expiry date stated on the package.

Store all medicines properly and keep them out of reach of children.

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## **Further information**

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Like other combined oral contraceptive Pills, MICROGYNON 30 may also have non-contraceptive health benefits.

- Your period may be lighter and shorter. As a result, the risk of anemia may be lower. Your period pains may become less severe or may completely disappear.
- Some serious disorders have been reported to occur less frequently in users of "high-dose" oral contraceptive 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 womb) and cancer of the endometrium (lining of the womb) and

ovaries. This may also be the case for "low-dose" Pills such as MICROGYNON 30, but so far this has only been confirmed for endometrial and ovarian cancer.

**MICROGYNON 30 tablets contain:**

*active substances (per tablet):*

levonorgestrel (0.15 mg) and ethinyloestradiol (0.03 mg)

*other substances:*

lactose monohydrate, maize starch, povidone 25 000, magnesium stearate, sucrose, povidone 700 000, macrogol 6000, calcium carbonate, purified talc, glycerol 85%, ferric oxide pigment (yellow), titanium dioxide, montanglycol wax

**If you have any further questions please consult your doctor or pharmacist.**

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**Name and Address**

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Bayer New Zealand Limited  
3 Argus Place  
Hillcrest  
North Shore  
AUCKLAND 0627

Free Phone: 0800 233 988

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**Date of Preparation**

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5 January 2011