

Contraception! Important information



For Liderma® patients

This brochure contains important information on birth control (contraception) for you as a woman.

Women who are treated with Liderma® must **absolutely not become pregnant**. Liderma® causes damage to the developing baby. You must use effective and reliable birth control for one month before, during, and one month after treatment with Liderma®.

This brochure describes **methods of contraception** which are the most effective in preventing pregnancy.

Read the brochure through carefully. You will almost certainly have questions, which you should note down in the space provided. Discuss the various methods of contraception with your doctor. Use the method(s) you choose exactly according to instructions.

Keep this brochure somewhere safe for the entire period of Liderma® treatment

Doctor (Stamp)

Family name of patient _____

Given name of patient _____

This brochure is also available in other languages. Ask your doctor who will be pleased to provide the right one for you.

Liderma®
Warning: Don't get pregnant

If you take Liderma®, you must absolutely not become pregnant. You must use very reliable birth control.

If you are not sexually active, or have never used any contraceptive before, it may be difficult to consider and talk about such matters. Read this brochure carefully before talking to your doctor. You will find that it makes the discussion a lot easier for you.

There are many different forms of contraception. Not all methods are equally effective and not all are suitable for you. You must use only **reliable methods**.

A woman is fertile for about 40 years. Approximately once a month, an egg cell ripens in one of the two ovaries. Ovulation releases the mature egg cell into the funnel of the fallopian tube which lies over the ovary, from where it is transported along the fallopian tube into the womb (uterus).

On its way to the uterus, the egg may meet a sperm and be fertilised. (Sperm require 4 to 6 hours to travel from the neck of the womb to the fallopian tube.)

If the egg is not fertilised, however, it dies within 12 hours and is washed out with the next monthly period (menstruation).

Menstruation signals the start of a new cycle.

If the egg is fertilised (conception), pregnancy begins. The fertilised egg is transported to the womb and embeds in the mucosal lining (uterine mucosa). The unborn baby grows and develops there.

The cycle and the hormones

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Hormones, from head to abdomen

The cycle is regulated by the increase and decrease of various hormones that are produced in the hormonal glands and secreted into the blood stream. The whole process is regulated by the brain – women often experience that stress and emotional upheaval can disturb or even block the normal cycle.

The regulating centre lies at the base of the brain, the hypothalamus. Directly below the hypothalamus lies the pituitary gland (hypophysis). This is regulated by the hypothalamus and, amongst other functions, it releases sex hormones into the blood. These in turn regulate the sex glands (ovaries in women, testes in men).

The ovaries produce the hormone **oestrogen** until the egg is released. Then, once ovulation has occurred, **progesterone** is also produced.

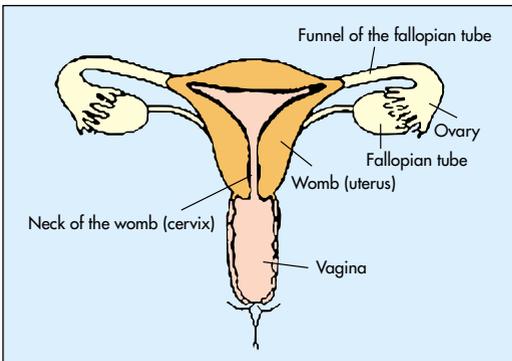
In a 28-day cycle, ovulation occurs between the 10th and 23rd day (most often on the 14th day). If the cycle is of longer or shorter duration, the difference almost always lies in the length of time before ovulation.

Pearl Index

The Pearl Index gives the number of women in a hundred who, with a normal frequency of sexual intercourse, become pregnant within one year despite using a method of contraception carefully, correctly and consistently. A Pearl Index of 0.1 to 3 is considered reliable. Not all birth control methods reach this level.

Basically, any method of contraception is all the more reliable

- the better it is accepted by the sexual partner
- the better the information and instruction on the method
- the longer the method is used
- the more both partners feel responsible for birth control



Methods of contraception

Today there are many, at times very different, methods used for birth control. Some methods can easily be combined with others to increase reliability even further.

Not all the methods of contraception described in the following are suitable for all women or all situations. Not all are equally effective (higher or lower Pearl Index). In addition, only very reliable methods of contraception can be recommended if you accept treatment with Liderma®. Your doctor will discuss this with you and help you decide on the most suitable methods for you to use.

Methods of contraception

Hormonal methods

- The pill, micropill (combination oral contraceptives with oestrogens and progestagens)
- Monophasic, biphasic and triphasic preparations

Pure progestagen preparations

- Progesterone-only pill (POP, minipill)
- Three-monthly injections
- Implants
- Hormonal IUDs

Intrauterine contraceptive devices (IUDs, coils)

- Hormonal IUDs
- Copper-containing IUDs

Barrier methods

- Condom (French letter, rubber)
- Femidom
- Diaphragms and cervical caps

Chemical methods (spermicides)

- Vaginal pessaries, sponges, foams, creams, gels

Unreliable methods

Natural methods of birth control

- Calendar method (Ogino-Knauss method, rhythm method)
- Temperature method
- Cervical mucus method (Billings method)

Withdrawal (coitus interruptus)

Emergency measures

- Morning-after pill
- Insertion of IUD

Unreliable methods of contraception

You must absolutely not use an unreliable method of contraception.

The likelihood of getting pregnant during sexual intercourse is high if you do not use a reliable method of contraception.

There are no «safe days»

During any menstrual cycle, there are days when a woman is more fertile than others. Even in a woman with a regular cycle, ovulation can occur at an unexpected time. The fertile period is never wholly predictable.

An egg can be fertilised for a maximum of 12 hours after it has left the ovary. After unprotected intercourse, sperm cells can survive in a woman's body for five days or even longer. So pregnancy may still result more than a week after unprotected intercourse.

«Withdrawal» is not reliable

Withdrawal (coitus interruptus) is an extremely unreliable method. The man pulls his penis out of the woman's vagina shortly before ejaculation.

- The man does not always succeed in removing his penis in time.
- Seminal fluid can enter the vagina even before ejaculation.
- Sperm which are deposited outside the vagina can still succeed in entering the vagina.

Natural methods of birth control are not reliable

Since there are no absolutely «safe days», it can never be reliably predicted whether and when a woman is fertile or not. These methods require great experience, are time-consuming and need a close understanding and «feel» for the individual's cycle.

External factors, such as life-style and working patterns, stress, illness or emotional problems may affect the cycle. This additionally increases the risk of not recognising the fertile days correctly, and becoming pregnant anyway.

Sure With reliable methods of contraception

You will possibly be treated with the medicine Liderma® and must therefore use a reliable method of birth control. Your doctor will help you to decide which method is the right one for you.

NOTE: The reliable methods are only reliable so long as they are always used correctly and without fail. There can be no «exceptions». Don't allow yourself to grow careless, since that will greatly increase the risk of a pregnancy.

The most reliable methods

Hormonal preparations and IUDs (intrauterine devices) are the most **reliable methods**. The pill, micropills, IUD, three-month injections and implants protect against pregnancy with the greatest degree of certainty. These are only available on prescription and will be prescribed by your doctor only after a full discussion about your state of health and possibly a gynaecological examination. You will also be asked about illnesses in your family in order to recognise possible risk factors.

The Pearl Index is between 0.3 and 3; reliable.

Taking other medicines at the same time can reduce the effectiveness of hormone preparations. You must discuss this with your doctor each time.

The pill / micropill

Combination oral contraceptives contain active ingredients which have similar structures and actions to the natural hormones oestrogen and progesterone (a progestagen).

When you take the pill, you supply the body with oestrogen and progestagens once daily, as a rule for 21 days. The pituitary gland (hypophysis) is no longer stimulated to secrete its own hormones. Ovulation does not occur (effects of oestrogens) and the uterine mucosa does not become so thick. In addition, the cervical mucus does not liquefy and forms a plug which prevents the passage of sperm (progestagen effects). At the end of a pill cycle there is a break of 7 days. No hormones are supplied to the body during this time so that bleeding will occur – referred to as withdrawal bleeding. After this break, the pill is taken again, always starting a new pack on the same day of the week.

There are mono-, bi- and triphasic preparations which differ in the extent to which they are adjusted to the natural female hormonal cycle.

In **monophasic methods**, a fixed oestrogen/progestagen combination is taken for 21 days. With-drawal bleeding occurs 3–4 days after the last pill has been taken.

In the **biphasic methods**, oestrogens alone or oestrogens with a low-dose progestagen are taken in the first phase of the cycle; the usual oestrogen/progestagen dose is taken in the second phase of the cycle. Withdrawal bleeding occurs 3–4 days after the last pill has been taken.

Triphasic methods are adjusted even more closely to the female cycle. The pills contain low doses of oestrogen and progestagen for the first six days after the onset of the menstrual period, the dose is then increased for the next five days, reverting to the low doses of the first phase for the remaining 10 days. Withdrawal bleeding occurs 3–4 days after the last pill has been taken.

Combination oral contraceptives (the pill, micropill) are suitable for women who can reliably take regular medication.

What should you do if you have forgotten to take a pill?

- Within 12 hours of forgetting: take the missed pill immediately and continue taking the rest in the usual way. You must:
 1. take the missed pill immediately
 2. continue to take the rest of the pack in the prescribed way
 3. use a second method of contraception in addition (condom with spermicide) and continue to do so until you start a new pack of pills. This also includes the time when you have your period.
- Tell your doctor if you are unsure about this. He/she will be able to advise you what to do in this situation.

Pure progestagen preparations

There are many different forms of progestagen preparations. The contraceptive effect of all of them depends on changing the viscosity (thickness) of the mucus at the neck of the womb (cervix) so that the sperm can no longer pass through. As there is little effective oestrogen, the uterine mucosa is built up only slightly, which also changes the pattern of bleeding. Periods will be much lighter and of shorter duration, and in some instances may disappear altogether. At first, breakthrough bleeding and spotting may be seen, although this should disappear in the first few months. Ovulation is not suppressed.

Progesterone-only pills (POPs, minipills)

require a high degree of discipline. They must be taken strictly at the same time each day. They are therefore considered moderately reliable (Pearl Index 1.1 – 9). Today, there is a new generation of progesterone-only pills that is as effective as the combination pill and can be taken according to the same schedule.

Minipills are particularly suitable for women who can be relied on to swallow a pill regularly, who do not smoke and who have no medical reasons for not taking the pill.

Injections of progestagen

(three-monthly injections) effectively prevent pregnancy for three months. However, they have the disadvantage that any undesirable effects will continue until the effects of the injection have worn off.

Progestagen implants

are plastic rods that are applied under the skin on the inner aspect of the upper arm. They work for two to five years. During this time, you do not have to think about birth control. Implants have the advantage over three-monthly injections that they can be removed by your doctor at any time.

Hormonal IUDs

are inserted into the womb by your doctor and release progestagens continuously. The hormonal IUD has a two-fold action. As a foreign body, it changes the uterine mucosa and in addition the progestagen is active. Depending on the type, the IUD may remain in place for years. (See also the next section → Intrauterine contraceptive devices)

Hormonal IUDs are particularly suitable for women who have already given birth.

Intrauterine contraceptive devices (IUDs, coils)

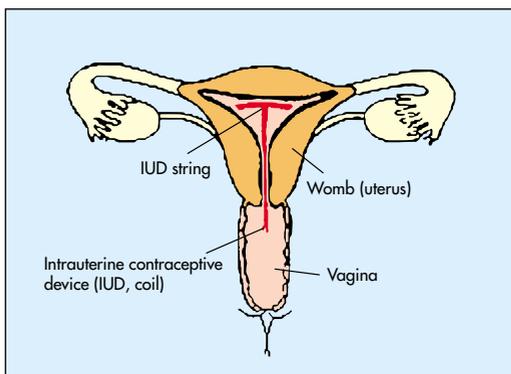
Intrauterine contraceptive devices (IUDs, coils) are the most popular method of contraception for women who have already given birth. An IUD is a small, flexible piece of plastic with a short nylon thread attached. It is inserted into the cavity of the uterus. IUDs generally contain copper or a progestagen (→ Hormonal IUD). Depending on the type, the IUD can remain in place for years.

The effects of IUDs are based on changes in the mucosal lining of the womb due to the IUD acting as a foreign body. Copper adversely affects the sperm. The progestagen hinders the build-up of the uterine mucosa and makes the cervical mucus thicker. Both types of IUD prevent a fertilised egg cell from embedding in the uterine mucosa.

The Pearl Index is between 0.3 and 3; reliable.

AN IUD can be inserted (and taken out) by your doctor during your menstrual period, once a gynaecological examination has shown that there are no reasons for not using an IUD. A newly-inserted IUD may cause menstrual cramps for the first few months, and make the bleeding heavier. Depending on the type, the IUD can remain in place for years.

IUDs are particularly suitable for women who have already given birth.



Barrier methods

Barrier methods are not so reliable as hormonal contraception or IUDs, but are still considered relatively effective methods of birth control. Correct use and sufficient experience are required to give effective protection. Practice makes perfect.

Barrier methods act in a mechanical way to prevent the sperm reaching the egg. There are various methods, one of which – the condom – can be used by the man. All the rest have to be used by the woman (diaphragm, cervical cap, Femidom).

For all barrier methods, it is generally true that both partners have to take responsibility for the correct use. In this way, the likelihood of correct use and thus contraceptive effect are increased.

To be on the safe side, barrier methods should always be used together with a spermicidal agent.

If you take Liderma®, you are recommended to use a barrier method in addition to e.g. hormonal contraception.

Condom

The **condom**, also referred to as a rubber or French letter, is made from ultra-thin latex (natural rubber). It is put onto the erect penis before sexual intercourse and catches the sperm. Additional protection is given by using a condom with a spermicide.

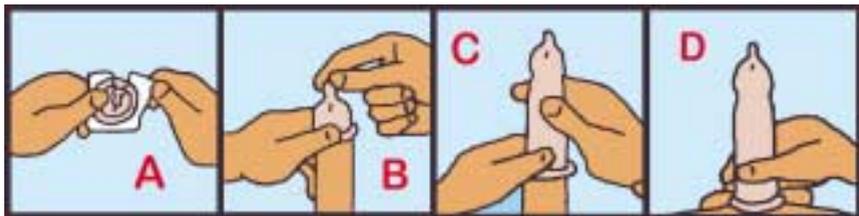
Only use condoms with the seal of quality (OK) and check the expiry date.

Condoms are only reliable if they are used absolutely correctly (Pearl Index 7–14). If you have not had much practice or make mistakes when using a condom, the Pearl Index rapidly becomes greater than 10, which means the method is not reliable.

Barrier methods

How to use a condom correctly:

- Tear the foil package carefully where indicated. Take care if you have long or pointed finger nails.
- Put on the condom before any contact with the vagina (sperm can leave the penis before ejaculation occurs)
- First push back the foreskin of the erect penis over the glans.
- Hold the tip (reservoir) of the rolled condom between thumb and index finger and place it on the glans. Do not let go of the reservoir (no air must enter the condom). The rolled-up rim must be on the outside.
- Now roll the condom as far as possible down over the erect member.
- must be held firmly at the base of the penis when doing this.
- After removing the condom, you must wash your hands before any further contact with the vaginal area.
- Use a new condom for every act of sexual intercourse.
- Never use Vaseline, skin lotion, suppositories or fat- or oil-based vaginal medications with a condom. Risk of the condom tearing.
- Store condoms in a cool, dry place.



Use a condom together with spermicides to make contraception more effective. You can use a condom in addition to another method of birth control.

Barrier methods

Diaphragm

The diaphragm is a domed shaped cap made from latex (natural rubber) with a thick elastic rim. It closes off the cervix and so prevents the sperm entering the womb and travelling to the fallopian tubes. **A diaphragm is used together with a spermicidal gel** that renders the sperm immotile.

The diaphragm has to be the correct size for the individual, since the neck of the womb varies from woman to woman. It should not be uncomfortable whilst being worn. Depending on how often it is worn, a diaphragm has a useful life of one to two years.

The Pearl Index is between 4 and 10, so the method is considered relatively reliable. **Used alone, this method does not provide adequate protection during treatment with Liderma®.**

How to use a diaphragm correctly:

- Insert the diaphragm with a spermicide gel, immediately before sexual intercourse (maximum of 2 hours before ejaculation). Never use Vaseline, skin lotion, suppositories or fat- or oil-based vaginal medications with a diaphragm.
- Leave the diaphragm in the vagina for at least 8 hours after ejaculation. In this time the sperm will be rendered immobile and fertilisation can no longer take place.
- Then remove it carefully and wash with water and/or soap.



Do not use a diaphragm as the only method of contraception. Always use it with a spermicide gel.

If you use a condom in addition to the diaphragm, contraception is even more effective.

The **cervical cap** is similar to the diaphragm, but is used without spermicide.

The **Femidom** – also referred to as the «condom for women» – is a tube sealed at one end which is inserted into the vagina. The lower open end remains outside the vagina. Since the Femidom is made from polyurethane, it can be used by people who have a latex allergy.

Emergency measures

No method of contraception gives absolute protection, especially when it is not used correctly. If you realise that your contraception has failed, a condom has torn or the actions of the pill cannot be guaranteed (not been taken regularly, vomiting, diarrhoea) or you have had unprotected intercourse, it is still possible to prevent pregnancy – with the **«morning after pill»** or the **insertion of an IUD**. The interval between the «failure» of the contraceptive method and the emergency measure should be as short as possible, so do not delay and **contact your doctor immediately!**

At the point in time when these emergency measures have to be introduced, a pregnancy test will not yet be positive, since the egg which may have been fertilised has not yet embedded in the lining of the womb.

Morning-after pills and IUDs are therefore not methods of contraception and should on no account be used regularly. They are purely and simply emergency measures.

What should you do if...

... you suspect or are sure that the method of contraception has failed?

- Call your doctor immediately;
emergency measures can only be introduced for a short time after intercourse has taken place.

... your period is unexpectedly late?

- Stop taking Liderma® at once. Do not take any more Liderma® capsules.
- Call your doctor immediately.

The **morning-after pill** contains a relatively high dose of hormones – oestrogens and progestagens or progestagens alone, depending on the preparation. This «pill» has to be prescribed by your doctor and you must take it exactly as instructed. Barrier methods (condom, diaphragm) must be used consistently until your next menstrual period.

The *morning after pill* works all the better the sooner it is taken. Ideally this should not be longer than 48 hours afterwards, although it is still effective up to a maximum of 72 hours after the last sexual intercourse.

If more than 72 hours have elapsed, there remains only the possibility of **inserting an IUD** (→ Intrauterine contraceptive devices). The IUD can be inserted up to 5 days after the last sexual intercourse. The IUD can then be kept in place as a method of birth control, unless there is any reason why a coil should not be used.

Pregnancy test

The pregnancy test determines whether a pregnancy has begun, before a woman recognises the typical signs of pregnancy.

The pregnancy test becomes positive at the time of the expected bleeding, since the embryo (trophoblast) has embedded itself in the lining of the womb and the hormone known as hCG starts to be produced to maintain the pregnancy. There is a pregnancy.

The precise time from when a pregnancy test first shows a positive result (= pregnant) depends on the type of test used.

Before treatment with Liderma®, a pregnancy test will be performed. You may only start treatment if the pregnancy test is negative (= not pregnant). Your doctor may also carry out pregnancy tests during treatment with Liderma®.

The **urine test** today can determine pregnancy at about the time of the expected menstruation and with certainty 1–3 days after the menstrual period has been missed. Morning or daytime urine can be used for this test. It is very reliable. To make absolutely sure, the test may be repeated the following day.

Urine tests can be bought in pharmacies, drugstores and department stores. They are very easy to use.

A **blood test** can reliably confirm a pregnancy about 10 days after successful sexual intercourse, i.e. before the missed period. At this time there are no false positive test results.

If the pregnancy test shows a positive result, you are pregnant. The only measure now to prevent the pregnancy continuing is an abortion.

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