



Pregnancy  
Prevention  
Programme

Toctino<sup>®</sup> (alitretinoin)

# Table of Contents

1.	Myths and facts	3
2.	Pregnancy prevention and Toctino	4
3.	Pregnancy testing	5
4.	Suitable contraceptive methods for you	6
5.	Primary contraceptive methods	7
5.1	Hormonal contraception	7
5.1.1	Oral contraception (the pill)	7
5.1.2	Contraceptive patch	9
5.1.3	Vaginal ring	11
5.1.4	Contraceptive implant	12
5.1.5	Contraceptive injection	13
5.1.6	Hormonal intrauterine system	14
5.2	Non-hormonal contraception (intrauterine device)	15
5.3	Sterilisation	16
6.	Secondary contraceptive methods	18
6.1	Condoms	18
6.2	Diaphragm and cervical cap with spermicide	19
7.	Emergency contraception	21
7.1	Emergency contraception pills	21
7.2	Intrauterine devices	21
8.	Other methods not suitable during treatment with Toctino	22
9.	Important points to remember	23

# 1. Myths and facts

There are many myths about pregnancy and contraception, for example:

- I cannot become pregnant if I am having sexual intercourse for the first time
- I cannot become pregnant if I do not have an orgasm
- I cannot become pregnant if my partner withdraws his penis before he ejaculates
- I cannot become pregnant during my menstrual period
- I cannot become pregnant if I am breast feeding
- I cannot become pregnant if I flush my vagina with water after sexual intercourse
- I cannot become pregnant in certain positions, for example if I have sex standing up

**All these statements are wrong! You can become pregnant any time you have unprotected sexual intercourse.**

## 2. Pregnancy prevention and Toctino

The active ingredient of Toctino is alitretinoin. Alitretinoin belongs to a class of drugs called (retinoids) known to cause severe birth defects. This means that if you take Toctino during pregnancy there is a very high risk that your baby will be born with birth defects which could include:

- Defects of the central nervous system, e.g., hydrocephaly
- Cerebral malformations
- Microcephaly
- Defects of the face, e.g., depressed bridge of the nose
- Cleft palate
- Deformed or absent ears
- Defective eye formation, e.g., microphthalmia
- Cardiovascular abnormalities
- Defects of the thymus gland and parathyroid gland

### **Also, taking Toctino while pregnant increases the risk of miscarriage**

You must not take Toctino if you think you might be pregnant or are trying to become pregnant. You must avoid becoming pregnant during treatment and for one month after stopping treatment with Toctino.

You must use one and preferably two effective methods of contraception for one month before treatment, during treatment and for one month after stopping treatment. Two effective methods are preferred because no method offers 100% reliability. You and your partner have to understand the importance of contraception and the potential consequences if you become pregnant during Toctino treatment. You also have to use contraception if you are currently sexually inactive, unless your doctor is confident that there is no risk of you becoming pregnant (e.g., after hysterectomy).

This brochure explains the use and the effectiveness of various methods of contraception. By using at least one and preferably two methods of effective contraception, you significantly decrease the risk of pregnancy. This brochure complements but does not replace the instructions from your doctor or family planning advisor. You should discuss the methods of contraception of your choice with your doctor before starting Toctino treatment.

# 3. Pregnancy testing

Pregnancy testing must be performed under medical supervision and must have a minimum sensitivity of 25 mIU/ml. The date and the result of the pregnancy test should be recorded by your doctor.

Your doctor will confirm the arrangements your clinic has in relation to performing medically supervised pregnancy tests.

In order to exclude an existing pregnancy before starting contraception and treatment, it is recommended to first perform a medically supervised pregnancy test during the first 3 days of your menstrual cycle. In case you have an irregular cycle, the timing of the pregnancy test should be adapted to your sexual activity, e.g., the test should be performed about 3 weeks after you last had unprotected sexual intercourse.

Your doctor will discuss contraceptive measures with you and ask you to start the selected methods of contraception after having obtained a negative pregnancy test. Your doctor will ask you to return to the clinic after you have been using your selected methods of effective contraception for 4 weeks, at which point a second medically supervised pregnancy test will be performed to ensure you are not pregnant before starting treatment.

Only if you fulfil all of these requirements will Toctino be prescribed for you for one month. You will be requested to visit your doctor every 4 weeks. During each visit a pregnancy assessment will be made.

Pregnancy testing 5 weeks after stopping treatment with Toctino is required to confirm that pregnancy has been avoided during Toctino treatment.

## 4. Suitable contraceptive methods for you

A variety of different contraceptive methods are available. To find the most suitable method for you personally, you need to discuss with your doctor the available methods. The choice depends on your age, your general health, your medical history, the medical history of your family as well as your individual preference. You may already be on an appropriate effective method of contraception, which can be continued during treatment.

Not all available methods of contraception are equally effective. It is therefore important to know which methods may be the most effective for you and how they should be used. Informing yourself about the available methods in advance will facilitate your discussion with your doctor.

Most contraceptives need to be prescribed. If your GP does not provide all methods they should be able to tell you of the nearest GP or family planning clinic that does. If you would prefer not to see your own GP about contraception you can sometimes go to another GP for contraception only. Many sexual health clinics offer contraception.

It is recommended to use a primary method (for example a combination oral contraceptive, 'the pill') combined with a secondary barrier method (for example a condom for men), in order to achieve the best possible protection.

The effectiveness of the methods listed overleaf are classified according to the number of women who may become pregnant even if they correctly use the respective contraceptive method over a period of time.

You should also read carefully the pack leaflets of the birth control methods you are using and discuss any questions you have with your doctor.

# 5. Primary contraceptive methods

## 5.1 Hormonal contraception

### 5.1.1 Oral contraception (the pill)

There are two forms of oral contraception:

- The combination pill including oestrogen and progestogen
- The progestogen only pill (mini-pill)

#### Combination pills

There are various kinds of combination pills. Single-phase pills containing the same amount of hormones in each pill have to be taken for 21 days, followed by an interruption of 7 days before the next course is started.

Double and triple-phase pills contain different amounts of hormones and have to be taken for 21 days in the correct order, also followed by an interruption of 7 days between courses.

The 'daily' pill has to be taken each day without interruption between courses. Each pack contains 21 active pills followed by 7 inactive pills.

To ensure that the combination pill is as effective as possible:

- The pill must be taken every day. If the pill is taken 12 hours late there is less protection
- In case you have to take other medications, always remind your doctor that you are taking the pill. Some medications, e.g., antibiotics, limit the effectiveness of the pill
- If vomiting or diarrhoea occurs within 3 hours of taking the pill the protection may also be reduced
- The herbal medication St. John's Wort should not be taken together with the pill because it can reduce the effectiveness of the pill

*Effectiveness: Over 99% effective if taken according to instructions. Less than 1 woman in 100 will get pregnant in a year.*

## How it works

Contains two hormones – oestrogen and progestogen. It stops ovulation, thickens cervical mucus to prevent sperm reaching an egg and thins the lining of the womb to prevent an egg implanting.

## Advantages

- Often reduces bleeding, period pain and pre-menstrual symptoms
- Protects against cancer of the ovary and womb and some pelvic infections
- Suitable for healthy non-smokers up to the menopause

## Disadvantages

- Not suitable for smokers over 35 and some other women
- Very low-risk but serious side effects may include blood clots (thrombosis), breast cancer and cervical cancer
- Can be temporary minor side effects such as headaches, mood changes and breast tenderness

## Comments

- Pill users should not smoke

## Mini-pill

The mini-pill is not as effective as the combination pill.

To ensure that the mini-pill is as effective as possible:

- For the best protection the first pill must be taken on the first day of your period. If you take the pill later, you will not be protected until the end of this cycle and an additional contraceptive method must be used
- The mini-pill should always be taken at the same time of the day and should not be interrupted at any time
- In case you forget to take the pill at the usual time of the day, take the pill as soon as you remember. If you take it with a delay of 3 hours or less, protection is still given. If you take it with a delay of more than 3 hours, you are not protected anymore until the end of this cycle and other methods of contraception have to be used

*Effectiveness: 99% effective if taken according to instructions. 1 woman in 100 will get pregnant in a year.*

## How it works

It contains the hormone progestogen, which thickens cervical mucus to prevent sperm reaching an egg and thins the lining of the womb to prevent an egg implanting. In some women it stops ovulation.

## Advantages

- Useful for older women who smoke or who cannot use the combined pill

## Disadvantages

- May be minor side-effects such as acne, headaches and ovarian cysts
- Periods may be irregular, with some bleeding in between, or be missed
- May be less effective in women who weigh over 70kg (11 stone)

## Comments

- Not effective after vomiting or severe diarrhoea
- Some drugs may make it less effective or stop it working but antibiotics do not affect the mini-pill

## 5.1.2 Contraceptive patch

The contraceptive patch is a small, thin, self-adhesive patch containing oestrogen and progestogen.

The first patch is applied on the first day of your menstruation. The patch has to be applied to clean, dry, hairless skin, for example on an arm, buttock or the abdomen. The patch should not be applied to the breast or to sore or irritated skin. The patch is applied on a weekly basis for 3 weeks, each time on a new area of skin. During the 4th week, when no patch is applied, you should expect to have your menstrual period. Usually the patch sticks very well, even when taking a bath or when exercising. In case the patch detaches and cannot be re-attached, a new patch should be applied. If the patch has been detached for less than 24 hours, protection is still given.

*Effectiveness: Over 99% effective when used correctly and according to the instructions. Less than 1 woman in 100 will get pregnant in a year.*

## How it works

A constant daily dose of hormones (oestrogen and progestogen) are released into the bloodstream through the skin. Its main action is the same as the combination oral contraceptive pill; it stops the ovaries from releasing an egg each month (ovulation), thickens the cervical mucus to prevent sperm reaching an egg and thins the lining of the womb to prevent an egg implanting.

## Advantages

- You don't have to remember to take it every day; you only have to remember to replace the patch once each week
- As the hormones do not need to be absorbed by the stomach, they are not affected by vomiting or diarrhoea
- It may help with premenstrual symptoms and may make your periods regular, lighter and less painful

## Disadvantages

- It may be visible
- For a small number of women it may cause skin irritation
- Side effects are similar to those seen with combined oral contraceptive pill. Temporary minor side effects may include headaches, mood changes, breast tenderness, nausea, increased blood pressure, breakthrough bleeding and spotting
- Very low risk but serious side effects may include blood clots (thrombosis), breast cancer and cervical cancer
- Not suitable for all women

## Comments

- Some drugs or herbal medicines such as St John's Wort may stop the patch working
- Women who are unable to use the combined oral contraceptive pill cannot use the patch
- The effectiveness of the patch is reduced in women who weigh 90kg (14 stone) or over
- Patch users should not smoke

### 5.1.3 Vaginal ring

The hormonal vaginal contraceptive ring is an alternative to oral hormonal contraceptives that is not available in all countries.

*Effectiveness: 99% effective. One woman in 100 will get pregnant in a year, if used according to instructions.*

#### How it works

It is a small, round, flexible device containing oestrogen and progestogen, released in a continuous low dose every day over a 21-day period of use. Its action is similar to an intrauterine system or combined oral contraceptive pill in that it thickens cervical mucus to stop sperm reaching an egg, thins the lining of the womb to prevent an egg implanting and stops ovulation. The ring is worn for 3 weeks continuously, and then removed and disposed. A new ring is inserted one week later. Your menstruation should occur during this 7 day interruption.

#### Advantages

- You can insert and remove the ring easily yourself
- Most women do not feel the ring if inserted correctly
- You don't have to think about contraception for as long as the ring is in place
- As the hormones do not need to be absorbed by the stomach, they are not affected by vomiting or diarrhoea

#### Disadvantages

- Very low-risk but serious side effects may include blood clots (thrombosis), breast cancer and cervical cancer
- Temporary minor side effects may include headaches, mood changes, acne and breast tenderness

#### Comments

- Only suitable for women aged between 18 and 40 years
- Contains a lower dose of hormones than the oral contraceptive pill
- It is unclear whether the effectiveness of the vaginal ring is affected by other medicines such as antibiotics

## 5.1.4 Contraceptive implant

The implant, inserted on the first day of your menstruation is effective for 3 years. It can be removed at any time.

*Effectiveness: Over 99% effective. Less than 1 woman in 1000 will get pregnant over 3 years.*

### How it works

Small flexible tube placed under the skin of the inner upper arm. Releases the hormone progesterone into the bloodstream to stop ovulation, thickens cervical mucus to prevent sperm reaching an egg and thins the lining of the womb to prevent an egg implanting.

### Advantages

- You don't have to think about contraception while the implant is in place
- When the implant is removed normal level of fertility will return immediately

### Disadvantages

- Periods are often irregular, very long or stop for at least the first year
- Some women gain weight
- Other possible side effects include headaches, acne, mood changes and breast tenderness

### Comments

- Implant is usually put in under a local anaesthetic and no stitches are needed. The area may be tender for a day or two with bruising and some swelling
- Most women can feel the implant with their fingers, but it can't be seen
- Minor surgery necessary to take the implant out

### 5.1.5 Contraceptive injection

This method of hormonal contraception involves the injection of progestogen into your arm or buttock. Similar to the contraceptive implant, it is applied on the first day of your menstrual period, for immediate protection. If applied later the injection does not protect during the first 7 days.

*Effectiveness: Over 99% effective. Less than 1 woman in 100 will get pregnant in a year.*

#### How it works

Releases the hormone progestogen slowly into the body. This stops ovulation, thickens cervical mucus to prevent sperm reaching an egg and thins the lining of the womb to prevent an egg implanting.

#### Advantages

- Lasts for 12 weeks (Depo-Provera) or 8 weeks (Noristerat)
- May protect against cancer of the womb and some protection from pelvic inflammatory disease
- You don't have to think about contraception for as long as the injection lasts

#### Disadvantages

- Periods may be irregular, longer or stop
- Regular periods and fertility may take a year or more to return after stopping the injections
- Some women gain weight
- Other possible side effects include headaches, acne, mood changes and tender breasts

#### Comments

- The injection cannot be removed from the body so any side effects may continue for as long as it works and for some time afterwards
- Not affected by other medicines

## 5.1.6 Hormonal intrauterine system (IUS)

The IUS has to be inserted by a doctor who verifies the correct placement by ultrasound. If inserted during the first week of your cycle, this device confers immediate protection. If inserted at other times, no protection is given during the first 7 days.

*Effectiveness: Over 99% effective. Less than 1 woman in 100 will get pregnant in a year.*

### How it works

A small plastic device which releases the hormone progestogen is put into the womb. It thickens cervical mucus to stop sperm reaching an egg, thins the lining of the womb to prevent an egg implanting and may stop ovulation.

### Advantages

- Works for five years but can be taken out at any time
- Periods will be much lighter, shorter and usually less painful
- You don't have to think about contraception for as long as the IUS is in place
- When the IUS is removed, your normal level of fertility will return

### Disadvantages

- Irregular light bleeding is common for the first three months and sometimes longer
- May be temporary side effects such as headaches, mood changes, acne and breast tenderness
- Very small chance of risk of infection in the first few weeks after insertion

### Comments

- Women are taught to check the IUS is in place
- Very useful for women with very heavy or painful periods
- Not affected by other medicines
- If fitted after the age of 45 it can stay in place until the menopause

## 5.2 Non-hormonal contraception

### Intrauterine device (IUD)

This device has to be inserted by a doctor. Correct placement can be verified using ultrasound. This device is effective immediately after insertion.

*Effectiveness: 98% to over 99% effective depending on the type of IUD. Less than 1 to 2 women in 100 will get pregnant in a year.*

#### How it works

A small plastic and copper device is put into the womb. It stops sperm reaching an egg and may also stop an egg implanting in the womb. It does not work by causing an abortion.

#### Advantages

- Works as soon as it is put in
- Can stay in for 3 to 10 years depending on type, but can be taken out at any time
- You don't have to think about contraception for as long as the IUD is in place
- When the IUD is removed, your normal level of fertility will return

#### Disadvantages

- Periods may be heavier, longer or more painful
- Not suitable for women at risk of getting a sexually transmitted infection
- Very small chance of risk of infection in the first few weeks after insertion

#### Comments

- If fitted after the age of 40 it can stay in place until the menopause
- Women are taught to check the IUD is in place
- Not affected by other medicines

## 5.3 Sterilisation

Sterilisation is a permanent contraceptive method which requires surgery and cannot be undone.

These methods are only recommended for individuals who have decided to have no more children.

Similar to other primary methods, it is recommended to be used in combination with a secondary method.

### Female sterilisation

*Effectiveness: Over 99% effective. The lifetime failure rate is about 1 in 200, depending on the method used.*

### How it works

The fallopian tubes are cut or blocked so the egg cannot travel down them to reach sperm. Female sterilisation usually involves general anaesthetic.

### Advantages

- It is permanent and has no known long-term side effects

### Disadvantages

- The fallopian tubes may rejoin so the woman is fertile again
- Contraception must be used up to the time you are sterilised and until you have had your first period after sterilisation

### Comments

- Should not be chosen if in any doubt and counselling is important
- Time in hospital varies from one to three days depending on the type of operation
- A few days' rest needed afterwards

## Male sterilisation

*Effectiveness: Over 99% effective. The lifetime failure rate is 1 in 2000.*

### How it works

The tubes carrying the sperm are cut, so sperm are not present in the semen.

### Advantages

- It is permanent and has no known long-term side effects
- Minor operation takes 10-15 minutes and can be done at a doctor's surgery or clinic

### Disadvantages

- It usually takes a few months for all the sperm to disappear from the semen
- Contraception must be used until there are two negative semen tests (no sperm seen)
- The tubes may rejoin so the man is fertile again. This is not common

### Comments

- Should not be chosen if in any doubt and counselling is important
- Likely to be bruising, swelling and some discomfort or pain for a short time after the operation
- Requires rest for 24-36 hours and avoidance of strenuous exercise for at least a week

# 6. Secondary contraceptive methods

## 6.1 Condoms

Condoms for men and women are barrier contraceptive methods, physically preventing sperm from joining with the egg.

Condoms for women are considered less efficient compared with other barrier methods and are not suitable in connection with Toctino treatment.

It is recommended to use condoms containing spermicide that offer increased protection by killing the sperm.

*Effectiveness: 98% effective if used according to instructions. 2 women in 100 will get pregnant in a year.*

### How it works

Made of very thin latex (rubber) or polyurethane. It is put over the erect penis and stops sperm from entering the woman's vagina.

### Advantages

- Free from family planning clinics and also sold widely
- Helps protect both partners from sexually transmitted infections, including HIV
- No major side effects
- A wide variety of types to choose from and additional spermicide is not needed or recommended

### Disadvantages

- Putting it on can interrupt sex
- May slip off or split if not used correctly
- Man needs to withdraw as soon as he has ejaculated and be careful not to spill any semen

## Comments

- Men can take responsibility for contraception
- Use a new condom each time
- Must be put on before the penis touches the woman's genital area
- Oil-based products damage latex condoms, but can be used with polyurethane condoms

## 6.2 Diaphragm and cervical cap with spermicide

Cervical caps are similar to diaphragms but a bit smaller. Both the diaphragm and cap are available for single and multiple use. Because the size of the cervix differs from woman to woman, diaphragms and caps have to be custom-fitted by a doctor.

### Inserting a diaphragm

Once the appropriate size of the diaphragm has been determined, your doctor will explain to you how to insert it.

Spermicide jelly or cream has to be placed in the diaphragm and around the rim before insertion. Fresh spermicide should be applied following each sexual intercourse or if 6 hours have elapsed between insertion and having sexual intercourse. The diaphragm should be left in place for at least 6 hours after the last sexual intercourse, but not for longer than 30 hours.

### Inserting a cervical cap

Inserting and removing a cervical cap can be somewhat more difficult than inserting and removing a diaphragm. With sufficient instructions from a doctor and with practice it should become easier. The cap has to be filled with spermicide before insertion. The cap fits over the cervix and should be left in place for at least 6 hours after sexual intercourse but not for longer than 48 hours because of the infection risk. Additional spermicide should be added with each sexual intercourse or after taking a bath, as the spermicide may be washed out or diluted.

*Effectiveness: 92% to 96% effective if used according to instructions. Between 4 and 8 women in 100 will get pregnant in a year.*

### How it works

A flexible latex (rubber) or silicone device used with spermicide is put into the vagina to cover the cervix. Must be specially fitted to make sure it is the right size. This stops sperm from entering the womb and reaching an egg.

## Advantages

- Can be put in any time before sex
- May protect against some sexually transmitted infections and cancer of the cervix
- A variety of types to choose from
- No major side effects

## Disadvantages

- Putting it in can interrupt sex
- Extra spermicide is needed if you have sex again
- Cystitis can be a problem for some diaphragm users

## Comments

- Fitting should be checked every 6 months and if you gain or lose more than 3kg (7lbs), or have a baby, miscarriage or abortion
- They come in a wide variety, including disposable and reusable types

# 7. Emergency contraception

Emergency contraception, also known as 'morning after pill', is used to prevent pregnancy following unprotected sexual intercourse. In such cases, e.g., if you missed taking the pill or in the event of a ruptured condom or a misplaced diaphragm, the treatment with Toctino should be stopped immediately and emergency contraception should be considered.

## 7.1 Emergency contraception pills

Emergency hormonal contraception pills should be taken as soon as possible to provide good protection, ideally within 12 hours and not later than 3 days (72 hours) after you had unprotected sexual intercourse.

## 7.2 Intrauterine devices

An IUD can be inserted by a doctor within 5 days of having unprotected sexual intercourse or for up to 5 days after a potential ovulation. This device, which prevents an egg from being fertilised or attached to the womb, is a good alternative for women who cannot take the emergency pill (more than 3 days have past since the woman had unprotected sexual intercourse) or who do not tolerate progestogen pills.

## 8. Other methods not suitable during treatment with Toctino

Other methods, not mentioned above, are usually less reliable and cannot be recommended for use while taking Toctino. Such methods include: coitus interruptus (withdrawal prior to ejaculation) and methods based on calendar (Knaus-Ogino) or cycle including temperature control.

## 9. Important points to remember

- Toctino can cause severe birth defects. You must not take Toctino if you are pregnant or become pregnant during treatment with Toctino or for one month after your treatment ends
- You must use at least one and preferably two effective methods of contraception for one month before, during and for one month after Toctino treatment
- There are many different types of contraception. Long-acting contraceptives such as monthly injections or the intrauterine device do not depend on your remembering to take or use them. If you use other methods, such as the pill and the condom, you have to remember to use them each day or just before having sex. Whichever methods you use, you must use them according to the instructions given in order for these methods to be effective
- Make sure you explain to your partner the importance of contraception for one month before, during and for one month after treatment with Toctino. It is important that your sexual partner also understands the facts about contraception and the risks of birth defects occurring in babies born to women taking Toctino. Explain what you and he must do: choose (together with your doctor or nurse) and use at least one, but preferably two, effective forms of contraception for one month before, during and for one month after Toctino treatment
- As it is vitally important that you do not become pregnant when you are taking Toctino, you should stop taking Toctino immediately and contact your doctor, nurse or family planning clinic immediately if you have had unprotected sex or you think you might be pregnant

### Acknowledgement

The information on contraception in this brochure is adapted from the Family Planning Association (fpa) leaflets 'Your guide to contraception' (April 2007) and 'Your guide to the contraceptive patch' (April 2007).

You can obtain further information from the fpa by visiting their website: [www.fpa.org.uk](http://www.fpa.org.uk)

