



Pregnancy Prevention Programme

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

Toctino[®] (alitretinoin)

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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 Tactino

The active ingredient of Tactino is alitretinoin. Alitretinoin belongs to a class of drugs called retinoids known to cause severe birth defects. This means that if you take Tactino 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. water in the brain (hydrocephalus), brain malformations or small head (microcephaly).
- Defects of the face, e.g. depressed bridge of the nose, cleft palate, deformed or absent ears.
- Defective eye formation, e.g. small eyes (microphthalmia)
- Cardiovascular abnormalities
- Defects of the thymus gland and parathyroid gland

Also, taking Tactino while pregnant increases the risk of miscarriage

You must not take Tactino 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 Tactino.

You must use one and preferably two effective methods of contraception, including a barrier method, 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 Tactino 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 Tactino 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 combined pill including oestrogen and progestogen
- The progestogen only pill (mini-pill)

Combined pills (including oestrogen and progestogen)

There are various kinds of combined pills. Single-phase pills containing the same amount of hormones in each pill have to be taken for 21 days, followed by a break 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 a break 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 combined 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
- Missing doses, vomiting or severe, long lasting diarrhoea can make it less effective
- In case you have to take other medications, always remind your doctor that you are taking the pill. Some medications, e.g. antibiotics, may make it less effective
- 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 uterus to prevent a fertilised egg implanting.

Advantages

- Usually makes periods regular, lighter and less painful.
- Reduces risk of cancer of the ovary, uterus and colon.
- Suitable for healthy non-smokers up to the age of 50.
- When you stop using the combined pill your fertility will return to normal

Disadvantages

- Not suitable for very overweight women or smokers over 35 years.
- Low risk of serious side-effects such as blood clots, breast and cervical cancer.
- Can be temporary side-effects such as headaches, nausea, mood changes and breast tenderness

Comments

- Pill users should not smoke

Mini-pill (progestogen only)

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 (12 hours for Cerazette) or after vomiting or severe, long-lasting diarrhoea, 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 cycles it stops ovulation.

Advantages

- Can be used by women who cannot use oestrogen
- Can be used by women who smoke and are over 35
- You can use it if you are breastfeeding

Disadvantages

- Periods may stop or be irregular, light or more frequent
- May be temporary side-effects such as acne, breast tenderness, weight change and headaches
- May get ovarian cysts

Comments

- It needs to be taken at the same time each day
- Not effective if taken over three hours late (12 hours for Cerazette) or after vomiting or severe, long-lasting diarrhoea
- Some medicines may make it less effective

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 period. 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 small patch stuck on the skin releases a constant daily dose of hormones (oestrogen and progestogen) which 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 think about it every day
- It is not affected if you vomit or have diarrhoea
- Periods will usually become more regular, lighter and less painful
- It improves acne for some women

Disadvantages

- Not suitable for very overweight women or smokers over 35 years
- Low risk of serious side-effects such as blood clots, breast and cervical cancer
- Can have temporary side-effects such as headaches, nausea, mood changes and breast tenderness
- Possible skin irritation

Comments

- May be seen
- New patch is used for three weeks out of four
- Some medicines can make it less effective
- Breakthrough bleeding and spotting is common in the first few months

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

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 period should occur during this 7 day interruption.

Advantages

- You don't have to think about it every day.
- It is not affected if you vomit or have diarrhoea.
- Can make periods regular, lighter and less painful.
- It is easy to insert and remove.

Disadvantages

- Not suitable for very overweight women or smokers over 35 years.
- Low risk of serious side-effects such as blood clots, breast and cervical cancer.
- Can have temporary side-effects including increased vaginal discharge, headaches, nausea, breast tenderness and mood changes.

Comments

- Women must be comfortable with inserting and removing it.
- Ring is used for three weeks out of four.
- Some medicines can make it less effective.
- Breakthrough bleeding and spotting may occur in the first few months.

5.1.4 Contraceptive implant

The implant, inserted on the first day of your period 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 rod put under the skin of the upper arm. Releases the hormone progestogen. It stops ovulation, thickens cervical mucus to prevent sperm reaching an egg, and thins the lining of the uterus to prevent a fertilised egg implanting.

Advantages

- Works for three years but can be taken out sooner.
- You don't have to think about contraception for as long as the implant is in place.
- When the implant is removed your fertility will return to normal.

Disadvantages

- Periods may stop, be irregular or last longer.
- Acne may occur, or worsen.
- It requires a small procedure to fit and remove it.

Comments

- Put in using a local anaesthetic and no stitches are needed.
- Tenderness, bruising and some swelling may occur.
- You should be able to feel the implant with your fingers, but it can't be seen.
- Some medicines may stop the implant from working.

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 4 women in 1000 will get pregnant over 2 years.

How it works

Releases the hormone progestogen which stops ovulation, thickens cervical mucus to prevent sperm reaching an egg, and thins the lining of the uterus (womb) to prevent a fertilised egg implanting

Advantages

- Lasts for 12 weeks (Depo- Provera), eight weeks (Noristerat) or 13 weeks (Sayana Press).
- You can use it if you are breastfeeding.
- You don't have to think about contraception for as long as the injection lasts.

Disadvantages

- Periods may stop, be irregular or last longer.
- Periods and fertility may take time to return after stopping the injection.
- Some women gain weight.

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, diarrhoea or vomiting.

5.1.6 Hormonal intrauterine system (IUS)

The IUS has to be inserted by a doctor. 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 over 5 years.

How it works

A small T-shaped plastic device which slowly releases the hormone progestogen is put into the uterus. It thins the lining of the uterus to prevent a fertilised egg implanting and thickens the cervical mucus which makes it difficult for sperm to meet an egg.

Advantages

- Works for five years but can be taken out sooner
- 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 fertility will return to normal

Disadvantages

- Irregular bleeding or spotting is common in the first six months.
- Periods may stop altogether.
- Very small chance of getting an infection during the first 20 days after insertion.
- May get ovarian cysts.
- Insertion can be uncomfortable.

Comments

- If fitted after 45 it can stay in place until the menopause.
- Women are taught to check the IUS is in place.
- Can be useful for women with very heavy and/or painful periods.
- A check for any existing infection is usually advised before an IUS is put in.
- Not affected by other medicines.

5.2 Non-hormonal contraception

Intrauterine device (IUD)

This device has to be inserted by a doctor. This device is effective immediately after insertion.

Effectiveness: Over 99% effective. Less than 2 women in 100 will get pregnant over 5 years.

How it works

A small plastic and copper device is put into the uterus. It stops sperm reaching an egg, and may also stop a fertilised egg implanting in the uterus

Advantages

- Works as soon as it is put in.
- Can stay in 5–10 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 fertility will return to normal.

Disadvantages

- May not be suitable for women at risk of getting a sexually transmitted infection.
- Periods may be heavier or longer and more painful.
- Very small chance of getting an infection during the first 20 days after insertion.
- Insertion can be uncomfortable.

Comments

- If fitted after 40 it can stay in place until the menopause.
- Women are taught to check the IUD is in place.
- A check for any existing infection is usually advised before an IUD is put in.
- 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

The overall failure rate is about one in 200. This is a permanent method, suitable for people who are sure they never want children or do not want more children.

How it works

The fallopian tubes are cut, sealed or blocked by an operation. This stops the egg and sperm meeting.

Advantages

- It cannot easily be reversed.
- Once the operation has worked, you don't have to think about contraception.
- Periods are unaffected.

Disadvantages

- All operations carry some risk, but the risk of serious complications is low.
- There is a small increased risk of ectopic pregnancy if female sterilisation fails.
- You will need a general or local anaesthetic.

Comments

- Should not be chosen if in any doubt, and counselling is important.
- You may experience discomfort or some pain for a short time after sterilisation. It is important to rest and avoid strenuous activity for a while after the procedure.

Male sterilisation

About one in 2,000 male sterilisations fail. This is a permanent method, suitable for people who are sure they never want children or do not want more children

How it works

The tubes (vas deferens) that carry sperm from the testicles to the penis are cut, sealed or tied.

Advantages

- It cannot easily be reversed.
- Once the operation has worked, you don't have to think about contraception.
- Usually performed under a local anaesthetic.

Disadvantages

- Contraception must be used until a semen test shows that no sperm are left. This can take at least eight weeks.
- Some men may experience ongoing testicle pain but this is not common. Treatment for this is often unsuccessful.

Comments

- Should not be chosen if in any doubt, and counselling is important.
- You may experience discomfort or some pain for a short time after sterilisation. It is important to rest and avoid strenuous activity for a while after the procedure.

6. Secondary contraceptive methods

6.1 Condoms

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

6.1.1 Male Condoms

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 vagina.

Advantages

- Free from contraception and sexual health clinics and young people's services, and some general practices and GUM clinics, and sold widely.
- Can help protect from sexually transmitted infections.
- No serious side-effects.
- Additional spermicide is not needed or recommended.

Disadvantages

- May slip off or split if not used correctly or is the wrong size or shape.
- Man needs to withdraw as soon as he has ejaculated and before the penis goes soft, being careful not to spill any semen.

Comments

- 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.
- Available in different shapes and sizes.
- Advised to use extra lubricant when using condoms for anal sex.

6.1.2 Female condoms

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: 95% effective if used according to instructions. 5 women in 100 will get pregnant in a year.

How it works

Made of soft thin polyurethane which loosely lines the vagina and covers the area just outside, and stops sperm from entering the vagina.

Advantages

- Can be put in any time before sex..
- Can help protect both partners from sexually transmitted infections.
- Oil-based products can be used with female condoms.
- No serious side-effects.
- Additional spermicide is not needed or recommended.

Disadvantages

- Need to make sure the man's penis enters the condom and not between the vagina and the condom.
- May get pushed into the vagina.
- Not as widely available as male condoms.

Comments

- Use a new condom each time and follow the instructions carefully.
- Sold online and in some pharmacies and free from contraception and sexual health clinics and young people's services, and some general practices and GUM clinics.

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: Diaphragms and caps are 92–96 per cent effective when used with spermicide. Between four and eight women in 100 will get pregnant in a year.

How it works

A flexible latex or silicone device, used with spermicide, is put into the vagina to cover the cervix. This stops sperm from entering the uterus and meeting an egg.

Advantages

- Can be put in any time before sex.
- You only have to use it when you have sex.
- No serious health risks.

Disadvantages

- Extra spermicide is needed if you have sex again.
- Some people can be sensitive to spermicide.
- Can take time to learn how to use correctly.

Comments

- You need to use the correct size.
- You may need a different size after you have had a baby, miscarriage or abortion.
- Needs to be left in for six hours after sex.

7. Emergency contraception

If you have had sex without contraception, or think your method might have failed, there are different types of emergency contraception you can use.

- The emergency contraceptive pill, Levonelle - can be taken up to three days (72 hours) after sex. It is more effective the earlier it is taken after sex. It is available with a prescription or to buy from a pharmacy.
- The emergency contraceptive pill, ellaOne - can be taken up to five days (120 hours) after sex. It is only available with a prescription.
- An IUD - can be fitted up to five days after sex, or up to five days after the earliest time you could have released an egg (ovulation).

Ask your doctor, nurse or pharmacist about getting emergency pills in advance, just in case you need them.

How does emergency contraception work?

Emergency contraceptive pills are most likely to stop or delay ovulation (the release of an egg). They may also stop a fertilised egg settling (implanting) in the uterus. The emergency IUD may stop an egg being fertilised or implanting.

How effective is emergency contraception?

Emergency contraception can be very effective, especially if you have an IUD fitted or if the emergency contraceptive pill is taken soon after sex. However, it is not as effective as using other methods of contraception regularly and does not protect you against sexually transmitted infections.

8. Other methods not suitable during treatment with Toctino

Barrier methods of contraception should not be used alone for pregnancy prevention in those receiving treatment with Toctino, but they should be used as a secondary method.

Female condoms are not recommended and other methods, not mentioned in this booklet, are unreliable and cannot be used in connection with Toctino treatment. 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

- Tactino can cause severe birth defects. You must not take Tactino if you are pregnant or become pregnant during treatment with Tactino 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 Tactino 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 Tactino. 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 Tactino. 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 Tactino treatment
- **As it is vitally important that you do not become pregnant when you are taking Tactino, you should stop taking Tactino 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' (January 2014) and 'Your guide to the contraceptive patch' (January 2014).

You can obtain further information from the fpa by visiting their website: www.fpa.org.uk