



Isotretinoin 5mg Capsules (Isotretinoin)

Isotretinoin 20mg Soft Capsules (Isotretinoin)

Pregnancy Prevention Programme

Brochure on contraception

CONTRACEPTION AND ISOTRETINOIN

Isotretinoin is an effective treatment for severe acne. However, it is well known that Isotretinoin can cause **severe birth defects in babies born to mothers taking Isotretinoin**. There is also an increased risk of miscarriage.

It is vital that you do not start Isotretinoin treatment if you are pregnant, may become pregnant during treatment, or in the first month after treatment. This means that you will need to have at least one negative pregnancy test just before starting treatment, your doctor may require you to have a pregnancy test each month during your treatment, as well as 5 weeks after the end of treatment.

You must use at least one effective method of contraception, for 1 month before starting treatment, throughout the treatment period and for 1 month after treatment has finished.

The most highly effective methods include contraceptive injections, implants, intrauterine devices with copper or hormone and combined contraceptive pills and patches when used carefully. Preferably you should use **two methods of contraception including a barrier method such as the male condom, as no method is 100% safe on its own**. Barrier methods on their own are not recommended. It is vital that both you and your sexual partners understand the importance of this and what the consequences may be if you become pregnant whilst on Isotretinoin. Contraception must be used even if you are not currently sexually active, unless in your doctor's opinion there are compelling reasons for assuming that there is no risk of pregnancy.

This brochure discusses the different types of contraception, how to use them and how effective they are. Any method of contraception, however effective, may fail, and **by using two methods at once you will minimise the risk of pregnancy**.

This leaflet is intended as an aid only – it won't replace medical advice given by a healthcare professional. You will need to discuss your contraceptive options with your doctor or nurse before you begin treatment with Isotretinoin.

YOUR GUIDE TO CONTRACEPTION

There are many different contraceptive methods available and different methods suit people at different times of their lives. This leaflet will help you and your partner to decide on the method of contraception most suited to you both. It shows all the available methods, explains how they work, how effective they are and the main advantages and disadvantages. You can ask your doctor for more information on any method you are interested in.

The figures quoted in this leaflet for how well each method works are based on extensive independent research. Most contraceptives need to be prescribed. Your GP should be able to guide you on all the methods or he can refer you to a gynaecologist if the need arises.

You can buy male condoms and spermicides without going to a doctor or clinic. Spermicides on their own are not recommended as a reliable contraceptive.

USING CONTRACEPTION

How effective any contraceptive is depends on how old you are, how often you have sex and whether you follow the instructions. If 100 sexually active women don't use any contraception 80 to 90 of them will become pregnant in a year. The methods shown in this brochure are divided into two types:

No user failure: do not depend on you remembering to take or use contraception. These are long acting methods: contraceptive injection, implant, intrauterine system (IUS), intrauterine device (IUD), female sterilisation, male sterilisation (vasectomy).

User failure: methods you have to use and think about each day or each time you have sex. For these methods to be effective you must use them according to the instructions given: Combined pill, the contraceptive patch, progestogen-only pill, male condom, diaphragm/cap with spermicide, female condom and natural family planning (the female condom and natural family planning are not recommended as contraception methods in patients taking Isotretinoin and are not discussed further in this brochure).

SOME FACTS ABOUT CONTRACEPTION

There are a lot of myths around about contraception. These are the facts.

A woman can still get pregnant:

- If it is the first time she has sex
- If she does not have an orgasm
- If a man pulls out of her vagina before he comes
- If she has sex when she has a period
- If she is fully breastfeeding
- If she douches (squirts water into the vagina). This can be harmful to women
- Whatever positions the couple has sex in.

CONTRACEPTIVE INJECTION

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 and thickens cervical mucus to prevent sperm meeting an egg.

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.

IMPLANT

Effectiveness

Over 99% effective. Less than 1 woman in 1,000 will get pregnant over three years.

How it works

Small flexible rod placed under the skin of the inner upper arm. Releases the hormone progesterone into the bloodstream to stop ovulation and thickens cervical mucus to prevent sperm meeting an egg.

Advantages

- Works for three years but can be taken out at any time.
- You don't have to think about contraception for as long as 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.
- Other possible side-effects include headaches, acne, mood changes and tender breasts.

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.

INTRAUTERINE SYSTEM (IUS)

Effectiveness

Over 99% effective. Less than 1 woman in 100 will get pregnant over five years.

How it works

A small plastic device which slowly releases the hormone progestogen is put into the womb. It thickens cervical mucus to stop sperm meeting an egg. It may stop an egg settling in the womb or stop ovulation.

Advantages

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

Disadvantages

- Irregular light bleeding or spotting is common for the first six months and sometimes longer.
- Periods may stop altogether.
- May be temporary side-effects such as headaches, acne and tender breasts.
- Very small chance of getting an infection during the first 20 days after insertion.
- May get ovarian cysts.

Comments

- If fitted after the age of 45 it can stay in until the menopause.
- Women are taught to check the IUS is in place.
- Very useful for women with very heavy or painful periods.
- A check for any existing infection is usually advised.

INTRAUTERINE DEVICE (IUD)

Effectiveness

Over 99% effective. Less than 1 woman in 100 will get pregnant in a year. Older IUDs have less copper and are less effective.

How it works

A small plastic and copper device is put into the womb. It stops sperm meeting an egg or may stop an egg settling in the womb.

Advantages

- Works as soon as it is put in.
- Can stay in 5 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 normal level of fertility will return immediately.

Disadvantages

- Periods may be heavier or longer and more painful.
- Not suitable for women at risk of getting a sexually transmitted infection.
- Very small chance of getting an infection during the first 20 days after insertion.
- A small increased risk of ectopic pregnancy if the IUD fails.

Comments

- If fitted after the age of 40 it can stay in until the menopause.
- Women are taught to check the IUD is in place by feeling the threads high in their vagina.
- A check for any existing infection is usually advised.

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 meet sperm.

Advantages

- It is permanent and has no known long-term side-effects.
- You don't have to think about contraception.
- Periods are unaffected.

Disadvantages

- There is a small increased risk of ectopic pregnancy if female sterilisation fails.
- 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 after sterilisation.

MALE STERILISATION (VASECTOMY)

Effectiveness

Over 99% effective. The lifetime failure rate is 1 in 2,000.

How it works

The tubes carrying the sperm are cut, so sperm are not present in the semen that is ejaculated when the man 'comes'.

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.
- You don't have to think about contraception.

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.
- Rest for 24-36 hours and avoid strenuous exercise for at least a week.

CONTRACEPTIVE VAGINAL RING

Effectiveness

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

How it works

A small, flexible plastic ring which slowly releases the hormones estrogen and progestogen is put into the vagina. It thickens cervical mucus to stop sperm meeting an egg. It may stop an egg settling in the womb or stop ovulation.

Advantages

- You don't have to think about it every day.
- It is not affected if you have sickness and diarrhoea.
- Periods may be lighter, regular and less painful.
- May protect against cancer of the ovary, colon and womb.
- When the ring is removed normal level of fertility will return immediately.

Disadvantages

- Not suitable for very overweight women or smokers over 35 years of age.
- Very low risk of serious side effects including blood clots, breast and cervical cancer.
- Temporary side effects including increased vaginal discharge and infections, headaches, sickness, tender breasts and mood changes.

Comments

- You must be comfortable with inserting and removing the ring.
- Ring must be used for three out of four weeks.
- Breakthrough bleeding or spotting may occur in the first few months.

COMBINED 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 – which stop ovulation.

Advantages

- Often reduces bleeding, period pain and pre-menstrual tension.
- May protect against cancer of the ovary, womb, colon and some pelvic infections.
- Suitable for healthy non-smokers up to the menopause.
- When you stop using the pill normal level of fertility will return immediately.

Disadvantages

- Not suitable for very overweight women or smokers over 35 years of age.
- Rare but serious side-effects may include blood clots (thrombosis), breast cancer and cervical cancer.
- Can have temporary minor side-effects.

Comments

- Not effective if taken over *12 hours* late or after vomiting or severe diarrhoea.
- Some drugs or herbal medicines such as St John's wort may stop the pill working.
- Breakthrough bleeding or spotting may occur in the first few months.
- Pill users should not smoke.

THE CONTRACEPTIVE PATCH

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 are released into the bloodstream through the skin. The main action is the same as the combined oral contraceptive pill; it stops the ovaries from releasing an egg each month (ovulation).

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.
- Periods may be lighter, regular and less painful.
- May protect against cancer of the ovary, womb and colon.
- When you stop using the pill normal level of fertility will return immediately.

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.

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.
- New patch must be used each week for three out of four weeks.
- Breakthrough bleeding or spotting may occur in the first few months.

PROGESTOGEN-ONLY PILL (POP)

Effectiveness

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

How it works

The hormone progestogen, taken at the same time each day, thickens cervical mucus to prevent sperm meeting an egg or an egg settling in the womb. In some women it prevents ovulation.

Advantages

- Useful for women over 35 years of age who smoke or who cannot use the combined pill.
- You can use it if you are breastfeeding.
- You can use it if you cannot use estrogen.

Disadvantages

- Periods are often irregular, stop, light or more frequent.
- May be temporary side effects such as acne, weight change and headaches.
- A small increased risk of ectopic pregnancy if it fails.
- May get ovarian cysts.

Comments

- It must be taken at the same time each day.
- Not effective if taken over 3 hours late or after vomiting or severe diarrhoea.
- Some drugs may stop the pill working but antibiotics do not affect POPs.

MALE CONDOM

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.
- May protect both partners from sexually transmitted infections, including HIV.
- A wide variety of types to choose from.

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 vagina.
- Use a condom with a BSI Kitemark (BS EN 600) and CE Mark on the pack and check the expiry date.
- Oil based products damage latex condoms, but can be used with polyurethane condoms.

DIAPHRAGM/CAP WITH SPERMICIDE

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 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.

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.

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 12 months and if you gain or lose more than 3kg (7lbs), or have a baby, miscarriage or abortion.
- Silicone caps come in disposable and reusable varieties.
- Should be removed 6 hours after intercourse.

EMERGENCY CONTRACEPTION

If you have had sex without using contraception or think your method might have failed there are two emergency methods you can use.

- Emergency pills – must be started up to three days (72 hours) after sex. They are more effective the earlier they are started after sex (preferably within 12 hours).
- An IUD – must be fitted within five days after sex.

As it is vitally important that you do not become pregnant when you are taking Isotretinoin, you should contact your doctor, nurse or family planning clinic immediately if you have had unprotected sex.

SEXUALLY TRANSMITTED INFECTIONS

Male and female condoms can help protect against sexually transmitted infections. Male latex condoms should carry the BSI Kitemark (BS EN 600) and European CE mark. Diaphragms and caps may also protect against some sexually transmitted infections.

HOW DO I FIND A FAMILY PLANNING DOCTOR OR CLINIC?

Contact your pharmacist or doctor if you need more advice on contraception

What if I become pregnant?

If you become pregnant while on Isotretinoin therapy or during the month after treatment has stopped, immediately stop taking the medicine and contact your doctor.

Information in this brochure

This brochure can only give you basic information about contraception. The information is based on the evidence and medical opinion available at the time this leaflet was printed. Different people may give you different advice on certain points.

Remember – *contact your doctor or family planning clinic if you are worried or unsure about anything.*

REMEMBER

- Isotretinoin can cause **severe birth defects** - it is vital that you do not start Isotretinoin treatment if you are pregnant or are not on at least one effective form of contraception.
- **You must not begin Isotretinoin treatment whilst pregnant, or become pregnant during Isotretinoin treatment.** It is very important that you use at least one and preferably two effective forms of contraception, including one barrier method, for one month before, during, and one month after treatment.
- No method of contraception, other than having no sex at all, works 100% of the time. Even if you use one of the recommended methods properly, there is still a small but real risk of getting pregnant.
- There are many different types of contraception. Long-acting contraceptives such as monthly injections or the coil do not depend on your remembering to take or use them and there is hardly any 'user failure'. 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. Whatever 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 one month before, during and for one month after treatment with Isotretinoin. 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 Isotretinoin. 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 Isotretinoin treatment.
- As it is vitally important that you do not become pregnant when you are taking Isotretinoin, you should contact your doctor, nurse or family planning clinic immediately if you have had unprotected sex.
- If you think you are pregnant, stop taking Isotretinoin immediately and contact your doctor or nurse.

ACKNOWLEDGEMENT

The information on contraception in this brochure is adapted from the FPA leaflet 'Your Guide to Contraception' (Your guide July 2009).

You can obtain further information from the FPA by contacting:

FPA Helpline

England

Telephone: 0845 122 8690 (9am to 6pm Monday to Friday)

Northern Ireland

Telephone: 0845 122 8687 (9am to 5pm Monday to Friday)

Written enquiries on any subject

UK office

FPA
50 Featherstone Street
London EC1Y 8QU
Tel: 020 7608 5240
Fax: 0845 123 2349

Northern Ireland offices

FPA
3rd Floor, Ascot House
24–31 Shaftesbury Square
Belfast BT2 7DB
Tel: 0845 122 8687
Fax: 028 90 316 101

FPA
3rd Floor
67 Carlisle Road
Derry BT48 6JL
Tel: 028 7126 0016
Fax: 028 7136 1254

Scotland office

FPA
Unit 10,
Firhill Business Centre, 76 Firhill Road
Glasgow G20 7BA
Tel: 0845 122 8676
Fax: 0141 948 1172

Wales office

FPA
Suite D1
Canton House
435–451 Cowbridge Road East
Cardiff CF5 1JH
Tel: 029 20 644034
Fax: 029 20 644306

Or visit FPA website: www.fpa.org.uk

Malta ADR Reporting Website :
www.medicinesauthority.gov.mt/adrportal

▼ This [medicinal product](#) is subject to additional monitoring.

**Ennogen Healthcare Ltd
Unit G4, Riverside Industrial Estate,
Riverside Way, Dartford DA1 5BS
Tel: 01322 629 220
Fax: 01322 311 897**