Isotretinoin Capsules

Pregnancy Prevention Programme

A BROCHURE ON CONTRACEPTION

Ranbaxy (U.K.) Ltd
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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, intra-uterine 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 leaflet 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.
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 GP practice nurse or family planning clinic 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. If your GP does not provide all the 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.

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.

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).

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 position the couple have sex in
## Male Contraception Methods

### 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.

**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.

### 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.
**Contraceptive injection**

**Effectiveness**
Over 99% effective. Less than 4 woman in 1000 will get pregnant over 2 years.

**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) or 13 weeks (Sayan Press).
- Can use it while breastfeeding

**Disadvantages**
- Periods may be irregular or stop.
- Regular periods and fertility may take a year or more to return after stopping the injections.
- 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

**Implant**

**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 progestogen into the bloodstream to stop ovulation and thickens cervical mucus to prevent sperm meeting an egg. Thins the lining of the uterus (womb) to prevent a fertilised egg implanting.

**Advantages**
- Works for three years but can be taken out at any time.
- 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.
- Acne may occur or worsen.
- It requires a small procedure to fit and remove it.

**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.
- Some medicines may stop the implant from working
FEMALE CONTRACEPTION METHODS

Intrauterine system (IUS)

Effectiveness
Over 99% effective. Less than 1 woman in 100 will get pregnant over 5 years.

How it works
A small plastic device which 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 usually less painful.
- When IUS is removed your fertility will return to normal.

Disadvantages
- Irregular light bleeding is common for the first six months and sometimes longer.
- Very small chance of getting an infection during the first 20 days after insertion.
- May get an ovarian cyst.

Comments
- Women are taught to check the IUS is in place by feeling the threads high in their vagina.
- Very useful for women with very heavy or painful periods.
- A check for an existing infection is usually advised before an IUS is put in.

Intrauterine device (IUD)

Effectiveness
Over 99% effective Less than 1 to 2 women in 100 will get pregnant over 5 years.

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.
- When IUS is removed your fertility will return to normal.

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.

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 an existing infection is usually advised before an IUD is put in.
**Female sterilisation**

**Effectiveness**
The overall 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.

**Disadvantages**
- There is small increased risk of ectopic pregnancy if female sterilisation fails.
- All operations carry some risk but risk of serious complications is low.

**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.

**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.
- 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 all women.
- Rare but serious side-effects may include blood clots (thrombosis), breast cancer and cervical cancer.
- Can have temporary minor side-effects such as headaches, nausea, mood changes and breast tenderness.
- Not suitable for smokers over 35.

**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 and spotting is common in the first few months.
**The contraceptive patch (Evra 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. Its 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 will usually become more regular, lighter and less painful.

**Disadvantages**
- For a small number of women it may cause skin irritation.
- Side-effects are similar to those seen with combined oral contraceptive pill.
- Not suitable for overweight women or smokers over 35 years.

**Comments**
- Some drugs or herbal medicines such as St John’s wort may stop the patch working.
- new patch is used each week for 3 weeks out of 4
- Patch users should not smoke.
- It may be visible.
- Breakthrough bleeding and spotting is common 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 older women who smoke or who cannot use the combined pill.

**Disadvantages**
- May be minor side-effects, such as acne, breast tenderness, weight change and headaches.
- Periods may be irregular, with some bleeding in between, or be missed.
- May get ovarian cyst.

**Comments**
- Not effective if taken over three hours late or after vomiting or severe diarrhoea.
- Some medicines may make it less effective.
**FEMALE CONTRACEPTION METHODS**

### Diaphragm/cap with spermicide

<table>
<thead>
<tr>
<th>Effectiveness</th>
<th>92% to 96% effective if used according to instructions. Between 4 and 8 women in 100 will get pregnant in a year.</th>
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</thead>
<tbody>
<tr>
<td>How it works</td>
<td>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.</td>
</tr>
</tbody>
</table>
| Advantages      | - Can be put in any time before sex.  
                 - A variety of types to choose from.  |
| Disadvantages   | - Extra spermicide is needed if you have sex again.  
                 - Can take time to use it correctly.  |
| Comments        | - You may need a different size after you gain or lose more than 3kg (7lbs), or have a baby, miscarriage or abortion.  
                 - Should be removed 6 hours after intercourse.  |

**EMERGENCY CONTRACEPTION METHODS**

### 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 (Levonelle) 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).
- Emergency pills (EllaOne) can be taken up to five days (120 hours) after sex.
- 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

Contraception is free through the NHS.

- You can get lists of GPs from libraries, advice centres, helplines, health authorities or health boards.
- You can get details of your nearest family planning or sexual health clinic from your telephone directory, health centre, hospital, midwife or health visitor, advice centre, helpline, health authority or health board.
- Young people contact Brook website at www.brook.org.uk or Worth Talking about on 0300 123 2930 for details of the nearest young people’s clinic.
- You can find out all about all clinics from The Family Planning Association (fpa) web-site at www.fpa.org.uk.
- NHS Direct on 0300 123 7123 also gives information on local family planning services in England

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.
Acknowledgements

The information on contraception in this brochure is adapted from the fpa leaflet ‘Your Guide to Contraception’ (January 2014)

You can obtain further information from the fpa by contacting:

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24 - 31 Shaftesbury Square
Belfast
BT2 7DB
Phone 0845 122 8687
(9am-5pm Mon- Fri)

Website: www.fpa.org.uk

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 https://yellowcard.mhra.gov.uk or to Ranbaxy UK Ltd.

Please contact Ranbaxy Drug Safety by emailing medinfoeurope@sunpharma.com or calling + 44 (0) 208 848 8688. By reporting side effects you can help provide more information on the safety of this medicine