

**Information brochure for women treated with oral Isotretinoin,  
PATIENT BOOKLET**

## **Information brochure for women treated with oral Isotretinoin**

This document is part of the risk minimisation plan implemented for oral Isotretinoin.

### **Important Notes:**

- **This brochure summarizes the most important safety information about the teratogenic effect of Isotretinoin. If you would like to know more information, please read the patient information leaflet that comes with your medicine.**
- **The information in this brochure has been reviewed and approved by the Saudi Food and Drug Authority.**

Your doctor has proposed you a treatment for your severe acne by oral Isotretinoin, as prior treatments (oral antibiotics and local treatments) were not efficient enough. It is important that you discuss with your doctor about the risks associated with this treatment.

**You must consult your doctor every month during the treatment**

**by Isotretinoin.**

Full details on oral Isotretinoin can also be found in the patient leaflet included in the box.

## **BEFORE YOU TAKE ORAL ISOTRETINOIN**

### **Do not take oral Isotretinoin:**

- If you are pregnant or breast-feeding. If you can become pregnant and cannot avoid pregnancy. If you intend to become pregnant or if you are at an age of childbearing and you are not following the contraceptive measures that are necessary with this treatment in order to avoid harm to your infant.

### **Stop the treatment immediately and refer to your doctor without delay:**

- If you are pregnant, or you think you might be, during your treatment. You must also immediately tell your doctor if you become pregnant in the 5 weeks after isotretinoin is stopped.

## **WARNING**

**Risk of malformations to the infant / baby in case of exposure to oral Isotretinoin during a pregnancy.**

**Oral Isotretinoin is strictly contraindicated during pregnancy and breast-feeding (see box below).**

- Do not pass your Isotretinoin medicine on to anyone else, and particularly to another woman
- Return any unused capsule to the pharmacist at the end of treatment
- Do not donate your blood during the entire duration of the treatment and for a month after. If a pregnant woman was to receive your blood, her baby could be born with severe malformations.

## **PREGNANCY PREVENTION PROGRAMME:**

### **Warning for female patients:**

Use during pregnancy and breast-feeding:

Isotretinoin is strictly contraindicated during pregnancy and breast-feeding (see box below).

## **Pregnancy and breast-feeding, Important**

**Pregnancy and breast-feeding are absolute contraindications to treatment with isotretinoin.**

**Isotretinoin is teratogenic.** This means that if you are pregnant during the course of treatment or in the month after treatment, this medicine can cause severe malformations for the unborn child.

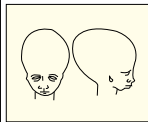


Diagram showing external malformations that are possible as a result of a pregnancy occurring during treatment with isotretinoin: absent ear(s) or ears positioned lower down, large head and small chin, eye abnormalities, malformation of the palate.

There are often associated internal malformations. These malformations involve the heart, thymus, nervous system and parathyroid gland.

This medicine may also cause a miscarriage.

**Do not take Isotretinoin if:**

- You are pregnant; intend to become pregnant at any time during the treatment or in the month after discontinuation of the treatment.
- You are breast-feeding since isotretinoin can pass into your milk and affect the baby.

**PREGNANCY PREVENTION PROGRAMME**

**Isotretinoin is contraindicated in women of child-bearing potential, unless all conditions of the pregnancy prevention programme are met.**

**Conditions for prescribing Isotretinoin for women of child-bearing potential:**

- You have understood the teratogenic risk.
- You have understood why you must not become pregnant.
- Your doctor has explained to you the different methods of contraception that can prevent the occurrence of pregnancy and has given you a leaflet on this subject.

- Your doctor may possibly refer you to a gynaecologist.
- You Must use **two** effective birth control (Contraception) in the following cases:

A. At least one month before starting Isotretinoin treatment.

B. During Isotretinoin treatment.

C. A month after stopping Isotretinoin treatment.

You use this form of contraception even although you are not sexually active or do not have periods. Please, refer to the contraception brochure included in the present document.

- You understand and accept the need for medical follow-up every month. As part of this, your doctor will arrange a pregnancy test for you:

- Prior to starting therapy by Isotretinoin.

- every month throughout the period of treatment

- five weeks after stopping treatment

These pregnancy tests must be done within the 3 days preceding your appointment with the doctor and preferably within the first 3 days of the menstrual cycle (period).

**The result of each pregnancy test must be negative: you must not become pregnant during the treatment or in the month fol-**

lowing the end of the treatment.

**Contact your doctor immediately if you notice period is late, or if for any other reason you might be pregnant.**

#### **AGREEMENT TO TREATMENT AND CONTRACEPTION**

- Your doctor will give you a document called “agreement to treatment and contraception”. You must read it carefully and sign it if you have understood all the information it contains. This document aims to make sure that you have really understood the risks of treatment and that you agree to follow the pregnancy prevention measures needed so that your isotretinoin treatment can start and continue.
- Make sure you ask your doctor or pharmacist all the questions you want.
- In this way, your doctor will be sure you know about the precautions to take so that you DO NOT become pregnant during your isotretinoin treatment or in the month after it ends.
- You must keep a copy of this document in the present brochure.

#### **START OF TREATMENT AND REPEAT PRESCRIPTIONS**

- You **MUST** start your treatment no more than 7 days after it is prescribed. You must have had a negative pregnancy test.

#### **DISPENSING**

- When dispensing the medicine, the pharmacist must check the details in your logbook and check that the prescription is no more than 7 days old. If these conditions are not met, the pharmacist will not dispense the product.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

National Pharmacovigilance and Drug Safety Center (NPC)

Email: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)

Toll Free Number: 19999

Fax: +966 11 2057662

Website: <https://ade.sfd.gov.sa/>

## **Patient contraception brochure**

# **Contraception information brochure for isotretinoin patients**

Updated on  
This document may be modified

## Table of contents

<b>A) ERRONEOUS BELIEFS ABOUT PREGNANCY</b>	<b>3</b>
<b>B) CONTRACEPTION: HOW DOES IT WORK?</b>	<b>3</b>
I HORMONAL CONTRACEPTION	3
1- Combined contraception	3
2- progestogen-only contraception:	4
II THE INTRAUTERINE DEVICE (IUD)	4
III LOCAL (BARRIER) CONTRACEPTION METHODS	5
1- Condoms	5
2- Spermicides	5
3- Diaphragms and caps	5
IV EMERGENCY CONTRACEPTION	6
1- Emergency contraceptive pill	6
2- The copper intrauterine device (IUD):	6
V STERILIZATION	6
<b>C) HOW TO OBTAIN CONTRACEPTIVES, ADVICE AND FOLLOW-UP</b>	<b>7</b>



This brochure sets out the various effective contraception methods; it is simply an educational aid and in no way replaces a consultation with a healthcare professional.

#### **Important Notes:**

• **This brochure summarizes the most important safety information about the teratogenic effect of Isotretinoin and the various contraception methods. If you would like to know more information, please read the patient information leaflet that comes with your medicine.**

• **The information in this brochure has been reviewed and approved by the Saudi Food and Drug Authority.**

#### **A) Erroneous beliefs about pregnancy**

You may have read or heard that it is impossible to become pregnant if:

• It is the first time you have sexual intercourse.

- You do not have an orgasm.
- You do not have your period.
- Your partner withdraws his penis from your vagina before ejaculating (“coming”).
- You have sex during your period.
- You are breast-feeding.
- You give yourself a vaginal douche (you squirt water into your vagina) after sexual intercourse.
- You and your partner have intercourse in a particular position, standing up, for instance.

All these preconceptions are FALSE. You CAN “become pregnant” any time that you have sex without using contraception.

#### **B) CONTRACEPTION: How does it work?**

WHAT METHOD OF CONTRACEPTION SHOULD I USE?

Eighty to ninety percent of sexually active women (those who have sex regularly) who do not use contraception become pregnant within a

year, which is why contraception should be used to prevent pregnancy. A wide variety of contraceptive methods are available both, hormonal and barrier.

The various methods of preventing pregnancy differ in their effectiveness.

For this reason, in order to prevent pregnancy, it is important to understand which methods work best and how to make the method you choose work optimally.

**THE EFFECTIVE HORMONAL CONTRACEPTION METHODS that you can use are: the pill, taken regularly without fail; the monthly vaginal ring; the weekly transdermal patch, to be used in every cycle; and the subcutaneous patch or intrauterine devices. The last two methods of contraception last for several years. Details of all these effective methods are given below, to help you choose one with the help of your doctor.**

**The other, less effective methods, such as condoms, are men-**

**tioned at the end of the document for information because, alone, they are not suitable for your situation where effective contraception is required. But they can be used in addition to effective contraception, to reduce the risk of pregnancy even further (though no method is 100% reliable).**

### **I Hormonal contraception**

There are two types of hormonal contraception: combined contraception (two hormones = estrogen+progestogen) and progestogen-only contraception (just one hormone = progestogen).

#### **1- Combined contraception**

Several types of combined hormonal contraception are available, varying in:

- the type of hormones involved,
- the dose of hormone,
- How the amount of hormones is released during the menstrual cycle (for example, single-phase, two-phase or sequential pills).

- how long the pill is taken during the cycle,
- the route of administration,

There are several possible routes of administration: oral, known in everyday language as the “pill” (a tablet to be taken every day), vaginal (a flexible ring measuring 54 mm in diameter and 4 mm in cross-section, placed in the vagina for 3 weeks), and transdermal (a patch stuck to the skin every week for 3 weeks), in every cycle.

## **2- progestogen-only contraception:**

Here too there are several routes of administration: oral (a tablet taken every day), subcutaneous (a subcutaneous implant inserted under local anesthetic just under the skin of the inner arm), and intramuscular (an injection into the muscle every 3 months).

### Important note:

For oral hormonal contraception, it is essential to take the pill at the

same time every day until all the tablets in the pack have been taken. It doesn't matter what time of day you decide to take the pill, but you must take it at that time every day.

### Managing forgotten doses

If you forget to take one or more tablets the pill will be less effective. Similarly, if you forget to replace the patch or ring on the correct date they will be less effective.

If you forget, however, it is generally possible to make up for this. Read the instructions in the leaflet for the contraceptive you have chosen with your doctor, because the instructions for forgotten doses can differ from one contraceptive to another.

Special situations when oral contraception may be less effective:

- A) - If you experience gastrointestinal disorders such as vomiting or severe diarrhea
- b) - If you have to take new medicines
- C) - Switching pills

D) - If you started your new pack 1 day late: there is a risk of pregnancy,

e) - Missed period

Read the instructions in the package leaflet for your contraceptive once you have chosen it and ask your pharmacist or doctor for advice.

#### Other special situations

f) - You take your pill twice on the same day.

This is not a serious problem, but take the pill at the usual time the next day and continue doing so until the end of the pack. Since the pack will end one day early, the 7-day no-tablet period will start one day earlier in the case of 21-day contraception.

g) - If you want to change the time of day that you take your pill:

You should do this at the beginning of your pack, always starting at an earlier time. There should be no more than 12 hours' difference (for example, if you used to take your pill at 8 pm you can take it earlier, at 12 noon).

Here too, make sure you ask your doctor or pharmacist for advice.

## **II The intrauterine device (IUD)**

The IUD or coil is a small, flexible, T-shaped plastic device coated with metal that is placed inside the uterus by a doctor.

There are various types of IUD. Some of them are made just of copper and others contain a hormone (progestogen) that passes into the blood.

The IUD is inserted during the menstrual period.

Some women find it comfortable right away. Others need some time to get used to it. Having an IUD fitted often changes the menstrual cycle. Women who have never had a baby can have an IUD fitted.

IUDs can be fitted for several years (usually 3 to 5 years, or sometimes 10 years) but they should always be checked by a doctor once a year.

The IUD can be removed by your doctor at any time. It starts working immediately as a contraceptive. Fertility will return to normal as soon as it is removed. Ideally, it should be removed during your menstrual period.

### III LOCAL (BARRIER) CONTRACEPTION METHODS

These methods are less EFFECTIVE: MALE AND FEMALE CONDOMS, SPERMICIDES, DIAPHRAGMS, and CAPS.

#### 1) Condoms

Male and female contraceptives are local or “barrier” contraceptives that prevent fertilization (a sperm reaching an ovum).

A further advantage of male and female condoms is that they protect against sexually transmitted diseases such as AIDS.

It is advisable to combine an effective contraception method with condoms.

#### Male condoms (“rubbers”)

A male condom is a thin, single-use, latex (rubber) or polyurethane (plastic) sheath. Only use approved condoms that are CE marked, showing that they have undergone rigorous testing. Always check the expiry date on the pack. Some condoms contain a spermicide (a chemical that kills sperm). Polyurethane male condoms do not contain a spermicide.

The male condom is less effective than hormonal contraceptives or IUDs.

On average, 14% of women per year become pregnant while using male condoms for contraception.

You should remember that sperm can enter the vagina if:

- The penis touches the genital area before the condom is in place
- The condom tears or slips into the vagina
- The condom is torn, e.g. by sharp nails or jewelry
- You use oil-based products (e.g. Vaseline, plant oil, or some sunscreens), which can cause the condom to tear.

If such an incident occurs while you are on isotretinoin, contact your doctor as soon as possible.

#### How to put on a male condom?

You will find instructions on the package or in the leaflet inside the package. Use a new condom each time you have sex. When you take

the condom out of its wrapper, be careful not to tear it. If intercourse is repeated, use a new condom.

### **Female condoms**

A female condom is a very fine polyurethane sheath fitted with a flexible ring at each end. Once inserted, it lines the vaginal wall and acts as a barrier to sperm. The condom is inserted like a tampon without an applicator, prior to intercourse.

Female condoms are less effective than male condoms. On average, 21% of women per year become pregnant.

### **2) Spermicides**

Spermicides are chemicals that are supplied in various forms: creams, jellies, foams and pessaries. The woman inserts the spermicide into her vagina prior to intercourse. Spermicides can be used alone or together with a diaphragm, cap or male condom.

Spermicides are less effective than condoms.

Read the patient leaflet carefully before using a spermicide.

### **3) Diaphragms and caps**

Diaphragms and caps are inserted into the vagina and cover the uterine cervix.

Vaginal diaphragms are circular domes made of supple rubber with a flexible rim. Cervical caps are smaller. They may be made of silicone rubber and may be single-use disposable or reusable. Initially, the cap has to be inserted by a doctor in order to check that it is the right size. The doctor will teach you how to position the diaphragm or cap correctly in the vagina. In order to be effective, diaphragms and caps must be used with spermicides (chemicals that kill sperm).

Diaphragms and caps are less effective than condoms.

All the various types of diaphragm or cap must be left in place for at least 6 hours after sexual intercourse. You can leave your device in place longer, but rubber caps and diaphragms should not be left in place for more than 30 hours.

#### **IV EMERGENCY CONTRACEPTION**

**If you have unprotected sex or if you are worried that your contraception has failed, you can use emergency contraception. There are two methods available: the emergency contraceptive pill and the copper intra-uterine device (IUD).**

Emergency contraception is **ONLY** used in emergency situations and should **NEVER** replace regular effective contraception.

##### **1) Emergency contraceptive pill**

Emergency contraception can be taken immediately after unprotected sex and for up to three or five days after unprotected sex. The earlier the emergency contraceptive pill is taken after risky sexual intercourse, the more effective it is at preventing pregnancy: it is most effective if taken within 24 hours of unprotected sex.

There are two sorts of emergency contraception: levonorgestrel, which can be taken up to three days (72 hours) after unprotected sexual

intercourse, and ulipristal, which can be taken up to five days (120 hours) after unprotected sex.

If you have taken an emergency contraceptive pill, you need to consult your doctor if your next period is late, or if you experience bleeding or pain, in order to check that you are not pregnant.

##### **2) The copper intrauterine device (IUD):**

A doctor can insert a copper IUD into your uterus up to 5 days after unprotected sex. This method is very effective (almost 100%) in preventing an ovum from being fertilized or a fertilized ovum from being implanted in the uterus. The IUD can then be used for continuing effective contraception.

#### **V STERILIZATION**

If you or your partner have already undergone sterilization (female or male), this counts as an effective contraception method during isotretinoin treatment. In some cases, your doctor may advise you to use a second, barrier method of contraception, such as a condom

or spermicide.

Sterilization is a permanent and irreversible method of contraception. Both male and female sterilization require a surgical procedure. The method prevents sperm from meeting ova. The method consists in closing the Fallopian tubes in women (tubal ligation) or the vas deferens (vasectomy, ligation of the canals carrying sperm from the testes to the penis) in men. In women, it is also possible to insert micro-implants into the Fallopian tubes via the natural passages. These methods are only for people who have decided not to have any more children. Successful vasectomy is confirmed after two sperm tests.

Following female sterilization, about five women in 1000 become pregnant; after male sterilization, around one woman in 1000 nonetheless become pregnant.

### **C) HOW TO OBTAIN CONTRACEPTIVES, ADVICE AND FOLLOW-UP**

Most contraception methods, such as the combined estrogen-progestogen pill, implants, patches and IUDs, have to be prescribed by a doctor. If you prefer not to visit your usual doctor, you can always consult another. Family-planning clinics can give absolutely confidential advice.

Condoms and spermicides are effective contraceptives and can be purchased from pharmacies without consulting a doctor.

Make sure you ask your doctor questions, so that you have all information you need about contraceptive methods suitable for you. This information will help you choose what is right for you.

If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the medicine leaflet. You can also report side effects directly via National Pharmacovigilance and Drug Safety Center (NPC)  
Email: [npc.drug@sfd.gov.sa](mailto:npc.drug@sfd.gov.sa)



Toll Free Number: 19999  
Fax: +966 11 2057662  
Website: <https://ade.sfda.gov.sa/>

OR,

Jazeera Pharmaceutical Industries  
Riyadh gallery- building A1- 4th floor  
Tel:+966 11 2078170  
Fax: +966 11 2078097  
Email: [jpimedical@hikma.com](mailto:jpimedical@hikma.com)

By reporting side effects, you will help to provide more information about the safety of the medicine.

THIS IS A MEDICAMENT

- . Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- . Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- . The doctor and the pharmacist are experts in medicine, its benefits and risks.
- . Do not by yourself interrupt period of treatment prescribed for you.
- . Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children



Manufactured by: Pharmathen International S.A  
For: Jazeera Pharmaceutical Industries  
P.O.Box 106229, Riyadh 11666, Saudi Arabia.