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Consumer Medicine Information

ISOTANE

Isotretinoin 10mg and 20mg Capsules

What is in this leaflet

This leaflet answers some common questions about ISOTANE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking ISOTANE against the benefits they expect it will have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What ISOTANE is used for

ISOTANE contains the active ingredient, isotretinoin. Isotretinoin belongs to a group of medicines called retinoids which are vitamin A derivatives. It works by reducing the amount of sebum (an oily substance produced by the sebaceous glands in your skin), reducing bacteria, reducing inflammation and opening clogged pores.

There are many different types of medicines used to treat acne. ISOTANE is used for more severe cases that are resistant to other forms of treatment. It is available only with a doctor's prescription and is usually prescribed by dermatologists (skin specialist doctors).

Your doctor, however, may have prescribed ISOTANE for another purpose.

Ask your doctor if you have any questions about why ISOTANE has been prescribed for you.

Before you take ISOTANE

When you must not take it

Do not take ISOTANE if you:

1. **are pregnant, or you intend to become pregnant.** If you become pregnant while taking ISOTANE, there is an extremely high risk that your baby will be severely deformed. Effective birth control must be used one month prior to starting ISOTANE treatment, during treatment and for at least one month after treatment has finished.
2. **are breastfeeding.** You must not breastfeed while taking ISOTANE. Isotretinoin is likely to pass into the breast milk and may harm your baby.
3. **have had an allergic reaction to ISOTANE, any other retinoids, including vitamin A, or any of the ingredients listed at the end of this leaflet**
4. **have liver disease**
5. **have hypervitaminosis A.** This is a condition caused by taking an excessive amount of vitamin A in the diet, either from foods, vitamin supplements and/or some medicines.
6. **have very high fat levels (cholesterol, triglycerides) in your blood.**

Before you start to take it

Tell your doctor if you:

1. **are depressed (have feelings of deep sadness and unworthiness or feel “down”), or have felt this way in the past**
2. **have abnormal thoughts or behaviour or a mental illness, or have had them in the past**
3. **have thoughts about harming yourself (suicidal thoughts or tendencies), or you have had them in the past**
4. **have any other health problems, especially the following:**
 - you are considerably overweight
 - diabetes, or a history of diabetes in your family
 - a history of pancreatitis (inflamed pancreas)
 - kidney disease
 - high fat levels (cholesterol, triglycerides) in your blood
5. **drink large amounts of alcohol**
6. **are on the "mini-pill", a progestogen only oral contraceptive pill.** It has been found that this type of contraception is inadequate while taking ISOTANE. It is recommended that two effective forms of contraception (including a barrier method eg. condoms) be used commencing one month prior to starting ISOTANE treatment, during treatment and for at least one month after treatment has finished.
7. **are allergic to any other medicines, foods, preservatives or dyes**
8. **undertake regular vigorous exercise.**

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health shop, or herbal products such as St John's Wort which can interfere with hormonal contraceptives.

Medicines that can interfere with ISOTANE include:

- **tetracycline antibiotics (such as minocycline)**
- **vitamin A, or preparations containing vitamin A (including some dietary supplements)**
- **other medicines you are using to treat your acne.**

These medicines may be affected by ISOTANE, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ISOTANE.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

Male patients

Do not share your medication with anyone, particularly not females.

Isotretinoin treatment does not appear to damage sperm. Although isotretinoin and its metabolites are present in very low levels in your semen, these levels are considered too low to harm the unborn baby of your female partner. No specific contraceptive precautions are necessary for men.

How to take ISOTANE

Follow all directions given to you by your doctor or pharmacist carefully.

How much to take

Take ISOTANE exactly as your doctor has prescribed.

Your doctor will tell you how many ISOTANE capsules to take and when to take them each day. Your dose will be based on your body weight and your individual needs. Your doctor may adjust your dose during therapy, depending on how you respond to ISOTANE.

How to take it

Capsules should be swallowed whole with a glass of water or another non-alcoholic drink. Do not open the capsules and do not take any capsules that are damaged.

When to take it

ISOTANE should always be taken with a meal.

Female patients should wait until the 2nd or 3rd day of the next normal menstrual period, after having used effective birth control for at least one month, before starting ISOTANE therapy. This helps ensure that you are not pregnant before you start taking ISOTANE.

How long to take ISOTANE

Continue taking ISOTANE until your doctor tells you to stop.

Treatment with ISOTANE will usually last 16 to 24 weeks. During the first few weeks of treatment your acne may get a little worse before it gets better. Most patients notice their skin condition continues to improve for up to two months after ISOTANE treatment has finished. Some patients, however, may need more than one course of treatment to notice significant improvement in their acne.

Please note that ISOTANE cannot improve scars or pitting that were present before treatment started but it will help prevent such skin damage in the future.

If you forget to take it

If you forget to take a dose wait until your next dose is due. Do not take an extra dose. Do not try to make up for the dose that you missed by taking more than one dose at a time.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you take too much (overdose)

If you or another person have taken more than the recommended dose of ISOTANE, immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to your nearest Accident and Emergency Centre. Do this even if there are no signs of discomfort or poisoning. You may need

urgent medical attention. Symptoms or signs of overdose include headache, nausea, vomiting, dizziness, sleepiness, blurred vision, itching, redness of the skin and peeling skin.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking ISOTANE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking ISOTANE.

Pregnancy testing should be performed before, during (every month is strongly recommended) and for 5 weeks after treatment has finished.

If you become pregnant while taking ISOTANE, stop taking it and tell your doctor immediately. ISOTANE causes severe birth defects to the unborn baby if the mother is taking ISOTANE.

You must use strict birth control starting at least one month before you begin taking ISOTANE, for the whole time you are taking ISOTANE and for one month after you finish taking ISOTANE. Even if you are infertile or not sexually active, effective birth control is recommended.

If you take further courses of ISOTANE after completing the initial treatment, you must ensure that each time you take ISOTANE you use strict birth control starting at least one month before treatment, for the whole time during treatment and for one month after you have finished taking ISOTANE.

If you do become pregnant while taking ISOTANE or in the month following treatment, you should discuss with your doctor whether to continue with the pregnancy or have the pregnancy terminated.

Tell your doctor if you notice any changes in your mood or behaviour (such as feelings of deep sadness and unworthiness or feeling "down"), or if you start to have suicidal thoughts or tendencies.

Tell your doctor if you notice any changes in your vision or if your eyes start to feel dry.

Tell your doctor if you intend to do a lot of heavy exercise. Your muscles and joints may become tender, feel weak or sore, if you do a lot of heavy exercise while taking ISOTANE.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel ISOTANE is not helping your condition.

Be sure to keep all your appointments with your doctor so that your progress can be checked. Regular follow-up appointments with your doctor on a monthly basis may be necessary. If you have any questions about your follow-up appointments, including how often these will be, you should discuss this with your doctor.

While you are taking ISOTANE your doctor may decide to monitor your bone growth and make-up, particularly if you are a child or young person.

While you are taking ISOTANE your doctor may ask you to have regular blood tests to monitor your liver function, blood sugar levels and blood fat levels.

Things you must not do

Do not stop taking ISOTANE or change the dose without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not donate blood during treatment with ISOTANE or for at least four weeks after treatment has finished.

Do not give ISOTANE to anyone else even if they have the same condition as you.

Do not use ISOTANE to treat other complaints unless your doctor advises you to do so.

Do not take any other medicines whether they require a prescription or not without first consulting your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how ISOTANE affects you. Normally ISOTANE would not affect your ability to drive a car or operate machinery. However, altered night vision and other visual disturbances may occur when taking ISOTANE. Make sure you know how you react to ISOTANE before you drive a car, operate machinery or do anything else that may be dangerous if your vision is impaired.

Wearing contact lenses during treatment with ISOTANE may cause discomfort. ISOTANE may cause dry eyes. An eye lubricant or artificial tears, available from your pharmacy, should relieve this problem. Otherwise, you may temporarily need to wear your contact lenses for shorter periods or wear glasses instead.

Avoid excessive sun exposure and sun beds. Apply a sunscreen while taking ISOTANE. Your skin may be more prone to sunburn while taking ISOTANE.

Avoid waxing (as a means of hair removal), dermabrasion (medical removal of layers of skin), facial peels and electrolysis while taking ISOTANE and for at least six months after stopping ISOTANE. Your skin may be more sensitive while taking ISOTANE. These treatments may cause scarring or dermatitis (inflammation of the skin).

Avoid using hair colouring or perming products. Your skin and hair may be more sensitive during treatment with ISOTANE and for sometime after treatment has stopped.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ISOTANE.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dryness of the lips, mouth, throat, nose, eyes or skin
- skin eruptions, rashes, itching, inflammation, redness, sweating or changes in skin colour
- nail inflammation, infection or altered appearance

- nosebleeds
- tenderness, soreness or stiffness in your bones, joints or muscles
- headache
- an increased sensitivity to sunlight
- hair loss, thinning or increased growth.

These are the more common side effects of ISOTANE. Mostly they are mild. Your doctor or pharmacist can help you with these side effects.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- you feel depressed (have feelings of deep sadness and unworthiness or feel “down”)
- changes in your normal behaviour
- nausea, vomiting, diarrhoea with blood and mucous, stomach pain or fever
- persistent headache, severe headache or seizure
- blurred vision or visual disturbances, including decreased vision at night
- severe stomach pain which passes straight through to your back (infected pancreas)
- blood in your urine
- tiredness, signs of bruising or bleeding easily
- signs of infection such as swelling, tenderness, redness and increased temperature
- sudden signs of allergy such as a skin rash, itching or hives; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or trouble breathing.

These may be serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you should suffer from any of these side effects or any other undesired effect, please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking ISOTANE

Storage

Always keep your ISOTANE capsules in the original blister pack and out of sight and reach of children. Store in a cool dry place where the temperature stays below 25°C and protect from light.

Do not store ISOTANE, or any other medicine, in the bathroom, on windowsills or in the glove box of the car. Do not refrigerate or freeze your ISOTANE capsules.

Do not use this medicine after the expiry date shown on either the outer pack or blister pack.

Disposal

If your doctor tells you to stop taking ISOTANE, or the capsules have passed their expiry date, ask your pharmacist what to do with the remaining capsules.

Product Description

Availability

ISOTANE capsules come in two strengths, 10mg and 20mg.

What ISOTANE capsules look like

10mg Capsule: Oval capsule with a yellow paste fill and a reddish brown opaque gelatin shell bearing the logo "I10" in black ink.

20mg Capsule: Oval capsule with a yellow paste fill and a bicoloured reddish brown/cream opaque gelatin shell bearing the logo "I20" in black ink.

Ingredients

ISOTANE 10MG CAPSULES

Each capsule contains 10mg of the active ingredient, isotretinoin. Each capsule also contains soybean oil, yellow beeswax, hydrogenated vegetable oil, gelatin, glycerol, red iron oxide (E172), lecithin, medium chain triglycerides, purified water and black ink.

ISOTANE 20MG CAPSULES

Each capsule contains 20mg of the active ingredient, isotretinoin. Each capsule also contains soybean oil, yellow beeswax, hydrogenated vegetable oil, gelatin, glycerol, red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171), lecithin, medium chain triglycerides, purified water and black ink.

ISOTANE capsules do not contain sucrose, lactose or gluten.

Where to go for further information

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792 or Freephone 0508 ISOTANE

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