

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ISOTANE

Isotretinoin 10 mg and 20 mg 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).

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

Your doctor may have prescribed it for another reason.

Before you take ISOTANE

Do not take ISOTANE if you:

- are pregnant
- are breast-feeding
- have kidney or liver disease
- have an excessive amount of vitamin A in the diet, (hypervitaminosis A)
- are taking tetracycline antibiotics
- have very high levels of fat (triglycerides, cholesterol) in your blood
- have an allergy to any medicine containing isotretinoin

- have an allergy to any other retinoids, including Vitamin A or any of the ingredients listed at the end of this leaflet
- are a child under 13 years.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Advice for Female Patients

- **Do not take this medicine if you are 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.
- **Do not breast-feed if you are taking this medicine.** The active ingredient in ISOTANE passes into breast milk and there is a possibility that your baby may be affected.
- **Pregnancy testing should be performed before, during (every month is strongly recommended) and for a month after treatment has finished.**
- **If you become pregnant while taking ISOTANE, stop taking it and tell your doctor immediately.**
- **You must use effective 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 effective 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.

Advice for 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.

Before you start to take it

Tell your doctor if you:

- are depressed (have feelings of deep sadness and unworthiness or feel “down”), or have felt this way in the past
- have abnormal thoughts or behaviour or a mental illness, or have had them in the past
- have thoughts about harming yourself (suicidal thoughts or tendencies), or have had them in the past
- drink large amounts of alcohol
- are taking the mini-pill, a progesterone-only oral contraceptive pill
- intend to undertake regular vigorous exercise
- if you have allergies to any other medicines, foods, preservatives or dyes
- have any other health problems.

If you have not told your doctor about any of the above, tell him/her before you start taking ISOTANE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ISOTANE may interfere with each other. These include:

- tetracycline antibiotics medicines used to treat bacterial infections, including doxycycline and minocycline
- vitamin A or preparations containing vitamin A
- other medicines used for acne.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ISOTANE

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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

Swallow the capsules whole with a full glass of water. Do not open the capsules and do not take any capsules that are damaged.

ISOTANE should always be taken with a meal.

When to take it

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

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 it

Continue taking your medicine for as long as your doctor tells you.

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

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ISOTANE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include headache, nausea, vomiting, dizziness, sleepiness, blurred vision, itching, redness of the skin and peeling skin.

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.

While you are taking ISOTANE

Things you must do

Tell your doctor 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
- you or your friends or family 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
- you notice any changes in your vision or if your eyes start to feel dry
- 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
- you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily
- you feel ISOTANE is not helping your condition.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ISOTANE.

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

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 bone structure, 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.

Take care when driving

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.

Things to be careful of

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.

This medicine helps most people with severe acne, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen, tell your doctor **IMMEDIATELY** or go to Accident and Emergency at your nearest hospital:

- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

- dryness of the lips, mouth, throat, nose, eyes, genitals 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
- impaired hearing
- headache
- an increased sensitivity to sunlight
- hair loss, thinning or increased growth.

The above side effects are usually mild and short-lived.

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.

Further Information

Storage

Always keep your ISOTANE capsules in the original blister pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C and protect from light .

Keep it where children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

What it looks 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 10 mg capsules contain 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 20 mg capsules contain 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.

This medicine does not contain lactose, sucrose or gluten.

If you want to know more

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

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

Date of Information

7 May 2015

(Based on datasheet dated 21 January 2015)