

Oratane[®]

isotretinoin

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For further enquiries call 1800 554 414 or visit www.oratane.com.au

It is important to read and understand this information

Acne Treatment Programme
INFORMATION



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Introducing Oratane



Who gets acne?

Acne is common. It affects most people during their teenage years. 85% of people have suffered from acne at some time in their lives. 5% of these people suffer from very severe acne. Acne is a skin disease and it should be treated as one.

What is Oratane?

Oratane capsules contain a medication known as isotretinoin. Isotretinoin is often a treatment for acne. Isotretinoin is a retinoid that is similar to Vitamin A but with a different action. It is indicated for the treatment of severe cystic acne unresponsive to other therapies. Isotretinoin has been used in Australia for over 20 years.

Oratane works on the key components of acne

- It reduces the amount of oily substances produced by the oil making glands in the skin.
- This then reduces the amount of bacteria, called *P.acnes* in the skin.
- It may help reduce the inflammation of the skin.
- It helps to unblock the pores by increasing the skin cell turnover.

Why has Oratane been prescribed for me?

Your dermatologist has probably prescribed Oratane for you because other treatments for your acne have been unsuccessful.

Who can take Oratane?

- Oratane is suitable for almost everyone with acne, regardless of sex or age.
- You may be required to have one or more blood tests taken before and/or during treatment to check your cholesterol/lipid levels and to ensure you are not pregnant if you are a female.
- Please tell your dermatologist if you have any other conditions or take any other medications.

Who cannot take Oratane?

- Pregnant women
- Breast feeding women
- Any female that intends to fall pregnant
- People suffering from certain medical conditions or on certain medications

How do I use Oratane?

- Follow the instructions given to you by your dermatologist.
- Do not to miss any of your Oratane capsules, or take too many Oratane capsules.
- Do not take a double dose if you miss a dose. (Skip any missed doses and take your next dose as normal).
- Do not change the amount of Oratane you are taking, if you think it is too strong or too weak speak to your dermatologist. Only your dermatologist can change your dose.



Before & After



Before isotretinoin



After isotretinoin

Using Oratane



What is the dose and treatment time?

- The dose of Oratane treatment will vary from patient to patient, often depending on the weight of the patient being treated.
- Often patients start on a lower dose initially and gradually build up to an optimal treatment dose.
- Your Dermatologist will advise you how long you need to take your Oratane for.
- In most cases the treatment lasts for around 16 weeks, but could last up to 9 months or more. You should follow your dermatologist's instructions carefully.

In over 80% of cases Oratane will completely clear your acne by the end of one treatment period. The healing process that is started with Oratane may continue after the treatment has ceased. If your acne has not been completely cured, a second course of Oratane may be considered by your dermatologist.

Oratane may only be prescribed by a dermatologist or a specialist physician.

Please note that when first commencing Oratane acne may sometimes get worse but by the 2nd or 3rd month the acne should begin to improve. If you notice significant worsening (or acne flares with commencement of treatment) please see your dermatologist.

What is my dose of Oratane?

In the boxes provided below write the dose (number of capsules) of Oratane that your dermatologist has prescribed for you.

If you ever need to check what your dose is you can refer to the information below. You should continue taking your Oratane for as long as your dermatologist instructs you to.

Morning 10mg 20mg 40mg Capsules

Evening 10mg 20mg 40mg Capsules

How do I take Oratane?

While taking Oratane you MUST:

- Take your Oratane capsules with meals.
- NOT chew or suck the capsules.
- Swallow the capsule whole with water or another non-alcoholic drink. It is preferable to take Oratane with milk.
- Take each dose of Oratane when it's due.
- Follow your dermatologist's instructions.
- Make sure you complete the entire course you have been prescribed.

If you follow the above instructions as closely as possible your Oratane will work better.

What should I expect from Oratane?

When you first start taking Oratane some people find that their acne starts to get worse. This does not always mean the medication is not working. If it happens to you, keep taking your Oratane as prescribed by your dermatologist, but be sure to tell your dermatologist. Within the first four weeks of starting Oratane you will notice that your skin is much drier than before. This is because the Oratane is starting to work by reducing the amount of oil being produced by your skin. You may also find that you need to wash your hair less often. By the 2nd month your acne should be showing signs of improving. The improvement should continue throughout your Oratane treatment.

When I finish my Oratane

If you have any Oratane capsules left when you have finished your treatment it is very important that you return them to your dermatologist or pharmacist. Never give your Oratane to anyone else, even if they have acne. At the conclusion of your Oratane treatment your acne should have significantly cleared. Your skin should continue clearing, possibly for one or two months, after the Oratane treatment has ceased. The side effects associated with Oratane treatment will begin to clear at the conclusion of the treatment.

Before & After



Before isotretinoin



After isotretinoin



NOTE: Oratane can cause birth defects.

If you are female it is extremely important that you read and understand the information in this section.

Why MUST I prevent pregnancy?

Even if you are not sexually active it is important that you understand the effects that Oratane can have on the unborn child should you become pregnant while taking Oratane.

The medication in Oratane, isotretinoin, is teratogenic. This means that it can cause birth defects.

Birth defects can only be caused by Oratane if you take Oratane while you are pregnant, become pregnant while you are taking Oratane or become pregnant within one month of stopping taking your Oratane.

Oratane does not affect your fertility in the long term. So even after taking Oratane you should be able to become pregnant in the future.

Your dermatologist will give you a pregnancy test to ensure that you are not pregnant before allowing you to start taking Oratane. If you do become pregnant while you are taking Oratane or within one month after the end of your treatment, you should immediately stop taking your Oratane and tell your dermatologist straight away to discuss the action that may need to be taken. This is a very serious situation.

For this reason it is vitally important to follow strict birth control procedures.

Who Needs to be REALLY careful?

ALL women of child bearing potential! This means any woman or girl, who is taking Oratane, who has started menstruating needs to follow a strict birth control procedure.

You **MUST** use strict birth control for at least one month before you start your Oratane treatment, during the entire Oratane treatment and for at least one month after you stop taking Oratane.

You should wait until the 2nd or 3rd day of your next menstrual period before you start taking Oratane. This is an extra check to make sure you are not pregnant.

Who is responsible for making sure I don't get pregnant?

You are! The only person who can make sure that you do not get pregnant while you are taking Oratane is you.

It is relatively easy to prevent pregnancy using a recommended strict birth control. The details of this are explained in the following pages.

Before you begin taking Oratane your dermatologist will go through the risks associated with Oratane and pregnancy and may ask you to sign a receipt of important information form.

Signing this form means that you understand these risks and that you will do everything possible to make sure that you do not become pregnant while you are taking Oratane or for one month after you stop taking Oratane.

CAUTION: Oratane should NEVER be used by pregnant women or by women who intend to become pregnant, during or for one month after, their Oratane treatment.

What is strict birth control?

Strict birth control or contraception means carefully following a procedure to make sure you do not become pregnant. The most effective form of birth control or contraception is 'the pill' (oral contraceptive) plus a barrier method (condom or diaphragm). You should carefully follow all the directions for the use of these methods of contraception.

Your local doctor or your local Family Planning Clinic can provide you with more information about contraception. You will need a prescription for 'the pill'. The phone numbers for Family Planning in your area are listed to the right.

What happens after I stop taking Oratane?

One month after you have finished your Oratane, you can resume your normal birth control practices. One month after the end of your Oratane treatment the risk of birth defects is no greater than usual. Oratane does not affect your fertility in the long term. So even after taking Oratane you should be able to become pregnant in the future. There is no known risk to males who wish to father children.

Where can I get more help & information?

For further information about contraception contact the Family Planning Association, your General Practitioner or family physician.

ACT Family Planning

Phone: 02 6248 6222

NSW Family Planning

Phone: 02 8752 4300

NT Family Planning

Phone: 08 8948 0144

SA Family Planning

Phone: 08 8638 4693

VIC Family Planning

Phone: 03 9257 0100

WA Family Planning

Phone: 08 9227 6177

TAS Family Planning

Phone: 03 6228 5244

Why are there side effects with Oratane?

All medicines have side effects. With Oratane most of the side effects are closely linked to Oratane actually working. These can range from mild to severe. Most of the side effects can be kept under control. If you are experiencing these then your Oratane is working and it won't be long before your acne starts improving.

Who will get side effects?

Almost everyone! With Oratane almost everyone taking it will get some side effects but often they can be kept under control with good skin care.

The intensity of the side effects will vary from patient to patient. Most of the common side effects are not very bad. If you get side effects while taking Oratane you may find that they wear off with time.

It is important for you to remember that you will not get all of the side effects mentioned in this section; you may only get a few side effects.

Don't forget to apply sunscreen to your lips.

While you are taking Oratane you will find that your skin is more sensitive to the sun. You will need to take extra care to avoid sunburn. You should wear a 30+ SPF sunscreen every day, even if there is no sun and try to avoid spending a long time in the sun.

What are the common side effects?

Skin dryness is the most common side effect. You may find that your lips become dry and cracked. Your face may look redder than usual, less oily and your skin may start to peel.

It is important to look after your skin, the instructions in the Skin Care section of this booklet will help you keep the side effects under control. Your dermatologist may give you an Oratane support pack to help with taking care of your skin.

A less common side effect of Oratane is drying of the inside of the nose and dry eyes. Drying of the nose can be uncomfortable and can lead to nose bleeds. There are ways to prevent and manage this using creams and ointments. Dry eyes can be a problem for people who wear contact lenses or people who work in air conditioned areas. You may find that you need to use eye drops to keep your eyes moist. You may also find that you cannot wear your contact lenses for as long as you did before starting on Oratane.



Other side effects

Most patients will not experience the side effects listed in this section, these side effects are not very common.

- fragile skin
- peeling of skin on palms of hands and soles of feet
- itchy skin rash
- sweating
- eye problems such as dry, sore, swollen or itchy eyes, discharge or trouble seeing at night
- tenderness, stiffness in bones, joints or muscles
- headache
- temporary hair loss (sometimes occurs and is usually temporary but in rare cases has persisted)
- excessive hairiness
- changes in liver enzymes, cholesterol and/or lipids
- abnormal menstrual cycles

These side effects are usually mild and dose related. After the dose of Oratane Capsules is reduced or stopped most these side effects should disappear within a few days or weeks.

Contact your doctor immediately if you experience any of the following:

- vomiting
- nausea
- persistent headache
- blurred vision or visual disturbances
- changes in your hearing or ringing in your ears
- severe upper stomach pain
- blood in stools or severe diarrhoea
- severe skin rash or severe bruising
- thinking, seeing or hearing things that are not real
- feeling depressed with or without suicidal thoughts

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

Depression

Some people with severe acne including those on Oratane have reported symptoms of depression. Although there is no established link between Oratane and depression it is important to tell your dermatologist if you notice symptoms of depression.

Symptoms of depression may include:

- start to feel sad or have crying spells
- sleep too much or have trouble sleeping
- have a change in your appetite or body weight
- have trouble concentrating
- feel like you have no energy
- start having suicidal thoughts

It is important to remember that the side effects seen with Oratane treatment are nearly always reversible. They should disappear soon after you have stopped taking Oratane.

One important side effect that is not reversible is the birth defects that can be caused if you become pregnant while taking Oratane. There is detailed information about how and why you MUST prevent pregnancy while taking Oratane in the Contraception section of this booklet.

What is important for ME to tell my Dermatologist?

It is important for you to make sure that you tell your dermatologist if any of the things listed below happen.

- If you can't tolerate the side effects you are getting while taking Oratane tell your dermatologist. Your dose of Oratane may need to be changed.
- If you get any of the serious less common side effects.
- If you feel unhappy or depressed.
- If you're finding it difficult to sleep.
- If your acne suddenly worsens soon after commencing treatment.
- If you miss a period.

Where can I get more help & information?

If you have any questions about the side effects that you have, or will get while you are on Oratane, you can talk to your dermatologist or call Ascent Pharmaceuticals (the people who distribute Oratane) on their toll free number 1800 554 414. For additional information visit www.oratane.com.au, www.dermcoll.asn.au or www.allaboutacne.com.au.



Make sure your family knows you are on Oratane.

What NOT to do while taking Oratane

It is important to follow this list of things NOT to do to help your skin remain in good condition.

- Do not squeeze any pimples. This can make the pimples worse and can damage your skin and may result in skin infections.
- Do not remove any scaly or peeling skin. Since your skin is fragile you can damage your skin by trying to remove scaly and peeling skin, this could lead to skin infections.
- Do not have facials. Your skin is fragile, the potentially harsh treatments involved in a facial can cause damage to your skin.
- Do not have waxes. Waxing while your skin is fragile can actually remove skin as well as hair! Shaving is the preferable form of hair removal while you are on treatment.
- Do not use any other acne medication. Oratane is a strong medication and you should not use any other medication (including therapeutic creams) unless your dermatologist has specifically told you to do so.
- Do not have any part of your body pierced. There can be a serious risk of infection of any new piercing while you are on Oratane.
- Do not donate blood whilst taking Oratane and for one month after stopping treatment
- Do not have electrolysis. Because your skin is fragile, electrolysis has the potential to damage your skin.
- Do not undergo physical therapy such as lasers and deep peels during treatment and for up to one year post treatment
- Do not use hair colouring containing peroxide and do not have a perm or use hair rollers. If you want to get your hair permed it is best to do so at least two weeks before you start taking your Oratane. While you are taking Oratane your scalp will be more sensitive and your hair will be more fragile, because of this it is important to avoid harsh treatments such as colours and perms.
- Do not use solariums and sunbeds. Solariums and sunbeds can burn your skin just like the sun as your skin is more sensitive to the sun while you are taking Oratane and it is also too sensitive to use a solarium and sun bed.
- Do not have overly hot showers. Very hot showers can dry and irritate your skin. with your dermatologist to see what is best for you.

What can I do to ease the side effects?

The most common side effects of Oratane is dryness. The following section contains a list of products that can be used to relieve this. If you notice anything unusual about your skin or anything that concerns you, talk to your dermatologist or local doctor about it.

It is a good idea to write down anything you notice or any questions you have for your dermatologist. The Notes section at the end of this booklet is a good place to do this.

What products can I use to ease the side effects?

Dry Skin

Dry skin is one of the most common side effects of Oratane treatment. You can expect your skin to become drier all over your body. You can however, with the advice of your dermatologist and by taking a little bit of extra care of your skin try to decrease the severity of these symptoms.

Face Cleansers

You should only use cleansers that are intended for use on sensitive skin on the face. Avoid using soap and antibacterial cleansers. Products you could try are: Avène Extremely Gentle Cleanser, Cetaphil Lotion, Neutrogena Extra Gentle Cleanser or Johnson's Sensitive Skin Face Wash.

Body Cleansers

Body cleansers should not be used on the face, unless they are also included in the Face Cleansers section. It is better for your skin if you try to avoid soaps and use one of the cleansers listed in this section. Products you could try are: Ego QV Wash, DermaVeen Soap Free Wash, Neutrogena Extra Gentle Cleanser and Hamiltons Mild Foam Wash.

To help protect your skin it is best to keep your showers shorter than two minutes if possible and use luke warm water rather than hot water.



Everybody is different, be sure to discuss elements of your normal skin care regime

Face Moisturisers

Using a water based moisturiser on your face regularly will help keep the dryness under control. The best types are water based moisturisers for sensitive skin, you should avoid greasy moisturisers. Products you could try are: Avène Skin Recovery Cream, Ego QV Face and Clinique Oil-Free Moisturiser.

Body Moisturisers

To keep your skin in good condition you should use a moisturising lotion or cream on your whole body. Moisturisers are a good idea to help reduce dry skin too. Products you could try are: DermaVeen Moisturising Lotion, Ego QV Cream, Avène Trixera Emollient and Vaseline Intensive Care Lotion, Cetaphil Moisturising Lotion.

Dry Nose

The inside of your nose can also become dry while you are taking Oratane. If this becomes severe it can result in nosebleeds. To keep the inside of your nose moist you should apply a small amount of petroleum jelly, e.g Vaseline, a few times a day using a cotton bud. If you suffer from persistent nose bleeds or your nose bleeds are difficult to stop, you will need to see your doctor or your dermatologist.

Dry Lips

Your lips are sensitive to the drying effects of Oratane. Applying a lip balm every one to two hours will help reduce lips from becoming dry and cracked. A lip balm that contains a sunscreen is best. See your doctor if your lips become very cracked or begin bleeding. Products you could try are: Avène Lip Balm, QV Lip Balm, Vaseline Lip Therapy, Lucas' Papaw Ointment and Blistex.

Dry Hair, Dry Scalp and Dandruff

If you find that your scalp and hair are drier than usual you may need to use a mild shampoo designed for dry hair. You should use a conditioner to help protect your hair and scalp. You should avoid using hair dyes, especially dyes containing peroxide, as they may make your hair and scalp drier and can cause irritation. If dandruff becomes a problem you should use a medicated anti-dandruff shampoo. You could try the following shampoo products for dry hair and dandruff: Sebizole Shampoo, DermaVeen Oatmeal Shampoo, Johnsons Baby Shampoo.

Dry Eyes

If you find that your eyes feel dry or sore then you may need to use eyedrops to keep them moist. Dry eyes can be a particular problem for people who wear contact lenses or people who work in air-conditioned areas. If you wear contact lenses you may find that you cannot wear them for as long as you did before starting on Oratane. For dry eyes, products you could try are (if you wear contact lenses check with your optometrist to make sure that these products are suitable): Allergan Refresh Liquigel, Allergan Refresh Tears Plus, Alcon Tears Naturale and Alcon Systane.

Sun Care

Oratane will make your skin more sensitive to the sun. You will need to make sure that you are well protected from the sun. You should not sunbake, even with a sunscreen, or use a solarium. The best way to do this is to cover up as much as possible, wear a wide brim hat and apply a sunscreen, preferably one with a 30+ sun protection factor. The best sunscreens are oil free and alcohol free. Products you could try are: Avène SPF 30+, Sensense Daily Face Matt 30+ and Sensitive Skin SPF 30+ sunscreens and Hamilton's everyday sunscreens for Face and Body.

Dry Vagina

You may find that your vagina is dry and this may cause pain during sexual intercourse. You can use Lubafax or KY Jelly to help relieve this problem.

Dry Anus

You may experience some dryness and irritation around the anus. You can help relieve and reduce this problem by applying petroleum jelly, e.g. Vaseline, several times a day.



Cosmetics

Makeup can sometimes aggravate your acne but if you choose your products carefully you can still wear makeup if you want to.

Foundations

You will need to use an oil free foundation, preferably one with a sunscreen. Products you could try are: Clinique Super Balanced and i.d. Bare Minerals.

Lipsticks

Most lipsticks are suitable for use while taking Oratane. The best lipsticks to use are those that contain sunscreens. It is also a good idea to wear a lip balm under your lipstick because this will provide better protection for your lips. Avoid the “all day” lipsticks that can have a drying effect on the lips.

Blushers

You should only use powder blushes while you are taking Oratane. Products you could try are: Clinique Soft-Pressed Powder Blusher or a mineral based blush.

Short term changes

While taking Oratane you can do most things you normally do – unless you have been told not to by your dermatologist or this booklet advises against it.

Some minor changes may need to be made to your lifestyle to make it easier for you to deal with the effect the medication has on you. You will have to make sure that you look after yourself by eating properly and caring for your skin.

It is important that you read and understand about all the potential side effects, but remember that you will not get all of them. Once you have finished your Oratane treatment your life should be back to normal, only without acne!

Things NOT to do when taking Oratane

- Do NOT donate blood until at least four weeks after you have stopped taking your Oratane
- Do NOT take any Vitamin A supplements (check your multivitamins)
- Do NOT take any other medication without telling your dermatologist

Note: Drink alcohol infrequently and in moderation

Other important points

While taking Oratane you should NOT take any tetracyclines. These are antibiotics, which you may have tried for your acne in the past. Tetracyclines include doxycycline, tetracycline and minocycline.

Oratane can also affect you if you do a lot of physical training or sport. You may experience muscle fatigue which can lead to poor performance. You should also try to avoid contact sports while you are taking Oratane.

If you are training for an upcoming event or playing a seasonal sport you may wish to delay your Oratane treatment until a more convenient time.

While you are using Oratane you should try to avoid using creams or gels that may irritate your skin. This includes products like sports gels and arthritis creams.



Frequently Asked Questions



Q: My face is all red. Will this go away after I stop treatment? What can I do about it?

A: In nearly all cases some redness is associated with Oratane treatment. You will note however that your face is becoming smoother as the acne clears. How red the skin of the face becomes varies between patients. Don't fret, as this will clear after treatment is complete. It will fade slowly, however, often requiring several months (sometimes longer). Avoiding hot showers, drinking hot drinks (such as tea or coffee) or soups, chilli foods and alcohol will reduce the intensity of the redness. For females going to a special event, camouflage makeup or correction makeup containing "green" pigments will help cover up the redness.

Q: Can I have a break in treatment if I go on vacation, have an operation or want to look better (not dry) for a formal occasion?

A: Yes. Your dermatologist must be informed of any change to your drug regime, however taking a "drug holiday" for a couple of weeks does not usually alter the final outcome of treatment.

Q: I read that Oratane causes liver damage? Is this true?

A: In a small percentage of patients Oratane can cause transient inflammation of the liver (usually during the first 2-8 weeks of treatment). This usually settles without any change in the dosage of Oratane. Being overweight and drinking excessive alcohol increases the risk of liver inflammation (if you have diabetes the risk is also increased). Your dermatologist will monitor your liver function throughout the treatment. If necessary the dosage may be reduced to allow the liver inflammation to settle. It is uncommon to have to cease Oratane due to severe liver inflammation. Even in this situation however the inflammation will settle usually after a month or two.

Q: Will Oratane also clear any acne scars on my face and back?

A: No. Oratane will not clear existing acne scars. On the other hand, by clearing existing acne, Oratane will prevent further scarring from occurring. Your dermatologist can advise you of what options you have depending on the severity of your scarring, but bare in mind, you will not be able to have any treatment for scarring for approximately 6-12 months after you stop your treatment.

Q: I always go out on a Friday and Saturday night. How much alcohol can I drink when I am taking Oratane?

A: Most dermatologists will advise you to keep alcohol intake to a minimum – suggesting only one to two drinks per week- and most will recommend that it is probably best to avoid it altogether. Alcohol can cause liver inflammation. If taken excessively over some time it may even scar the liver. As there is a chance that the medication (Oratane) may affect your liver (in rare cases it can increase your liver enzymes), it is best not to drink alcohol whilst on the treatment. Simply put, the combination of Oratane and alcohol increases the risk of liver problems.

Q: How long will it take for my skin to return to normal after I complete the course of Oratane?

A: The redness and dryness has usually resolved within about a month. Persistent red spots may last longer if you have a lot of sun exposure so ensure that you continue with good sun protection methods even after stopping Oratane. Acne can sometimes start again although in most instances it is of a much milder nature and is often period related in girls. This sort of minimal acne doesn't seem to start for at least 6 months after completion of Oratane.

Q: I don't have bad acne on my face – it is mainly on my back and shoulders and it is so bad I don't want to take my shirt off in front of anyone because I am embarrassed. Is Oratane a treatment option for me?

A: Oratane is a treatment option for severe cystic acne anywhere on the body including the trunk.

Q: When can I have treatments for my acne scars?

A: Any scars will keep improving for at least 12 months after stopping your Oratane. You should wait to see if the scars will improve on their own for at least this long. Certain procedures for acne scars (such as dermabrasion) are more likely to cause problems in the first one to two years after Oratane.

Q: Will my acne get worse before it gets better?

A: Most cases of acne go through good and bad weeks. Your acne may go into one of these typical bad weeks in the early weeks of treatment. If you notice significant worsening please see your dermatologist.

Thanks to Dr Artemi, Rosen and Kearney for the above Frequently Asked Questions.

Further Information On Acne



Acne is a common skin condition. Acne consists of blackheads, whiteheads, red spots and sometimes deeper boil like spots, these are called nodules or cysts. Acne affects most people during their teenage years. However, the problem sometimes continues into adulthood.

Acne develops in the oil-producing glands of the skin. These glands are called sebaceous glands. The oily substance produced by the sebaceous glands is called sebum. The sebaceous glands are present in large numbers on the face, chest, upper back and shoulders. The sebaceous glands are connected to the hairs that grow in the pores in these areas.

Normally, sebum flows on to the surface of the skin through the pores. As the sebum flows through the pore it gets rid of dead skin cells from the lining of the pore.

Acne occurs when an excess of sebum is made. The excess sebum mixes with the dead skin cells form the lining of the pore and forms a 'plug'. This plug blocks the pore. None of the sebum and dead skin cells that are still being produced can escape from the pore. This builds up and results in a pimple.

What causes acne?

The exact cause of acne is unknown. Acne is not caused by dirty skin and is not a problem suffered only by teenagers. There is some evidence that food causes acne, but following a diet will not clear acne by itself. On the other hand, some people find that their acne seems to get worse when they eat certain foods like chocolates, fried food and chillies. If you find that this is the case you should avoid the foods that appear to make your acne worse.

One idea about the cause of acne is that as the changes due to puberty occur the skin of an acne prone person reacts to these changes by making excess sebum. This extra sebum causes a plug to form, blocking the pore and resulting in the development of a pimple. When this occurs in several places at the same time, the result is acne.

Emotional stress, fatigue and cosmetics can make acne worse.

Acne most commonly first appears at the beginning of puberty when the production of hormones (called androgens) is increased. The sebaceous glands also become more active at this time. Many people outgrow acne when they reach adulthood, as the sebaceous glands settle into a normal cycle. Some people never outgrow acne and they may be bothered by it their whole lives. Sometimes women tend to break out in a pattern that follows the course of their menstrual cycle.

Family history is a factor in determining if you will get acne. If one or both of your parents had acne chances are that you may also get acne.

Outside factors can affect acne, either causing acne or making existing acne worse. Grease and oils or the use of some cosmetics and hair products can cause or irritate acne. Besides being irritants these products can act like sebum and block pores.

If you find that you break out with acne around the hairline, at the temples and in front of your ears, your hair products may be to blame. For instance, the shampoo you use, or the hair gel you use or your hairspray may be blocking your pores. Another area that can be

affected by outside factors is the jaw line. Break outs in this area can be the result of resting your head in your hand or even resting the telephone on your shoulder for long periods of time.

Although acne is not caused by dirt, it is helpful to keep the face clean. Gentle cleansing twice daily can help by cutting down on the amount of common bacteria on the skin, and by reducing the amount of other materials on the skin that can also act like sebum and contribute to the blocking of the pores. This cleansing can be accomplished by washing the face twice daily with warm (not hot) water and a gentle cleanser or soap-free cleanser.

Your fingers are actually the best washcloth you can use. If you do use a facecloth, be gentle. Scrubbing irritates pimples already present and can increase inflammation, it can also contribute to the formation of cysts.

ORATANE® Consumer Medicine Information Isotretinoin 10mg, 20mg and 40mg Capsules

What is in this leaflet?

This leaflet answers some of the common questions about ORATANE® Capsules. 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 ORATANE® Capsules against the benefits the medicine is expected to 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 is ORATANE® used for?

The active ingredient in ORATANE® Capsules is isotretinoin, a substance very similar to vitamin A.

ORATANE® belongs to a group of medicines called retinoids.

ORATANE® Capsules are used to treat acne. Of the many acne medicines, ORATANE® is used for more severe cases.

ORATANE® Capsules work by cutting down the amount of oily substances (sebum) made by glands in your skin. ORATANE® Capsules will also help to reduce bacteria, inflammation and open clogged pores.

Your doctor may have prescribed ORATANE® Capsules for another purpose.

Ask your doctor if you have any questions about why ORATANE® Capsules have been prescribed for you.

ORATANE® Capsules are not addictive.

Before you take ORATANE®

When you must not take ORATANE® Capsules

Do not take ORATANE® Capsules if:

1. you are pregnant or for at least one month before you intend to become pregnant.

If you fall pregnant while taking Oratane® Capsules there is an extremely high risk of having a baby that is severely deformed. This means that you must use effective contraception for one month before, during and one month after treatment with Oratane® Capsules.

2. you are breastfeeding.

Breastfeeding must stop before Oratane® treatment can start. Do not breastfeed while taking Oratane® Capsules.

3. you have had an allergic reaction to ORATANE® Capsules, vitamin A, other retinoids or any ingredients listed at the end of this leaflet.

4. you are taking tetracycline antibiotics. These include Tetrax®, Doryx®, Achromycin®, Rondomycin®, Minomycin®, Dioxine™, Doxy™ and Tetralysal®.

5. you have kidney or liver disease.

6. you have very high levels of fat (triglycerides, cholesterol) in your blood.

7. you have an excessive amount of vitamin A in your diet (hypervitaminosis A).

8. the packaging is torn or shows signs of tampering, or if the capsules do not look quite right.

9. the expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry has passed, it may not work as well.

If you are not sure if you should start taking ORATANE® Capsules, contact your doctor.

Do not give ORATANE® Capsules to children. There is very little information available on the effects of ORATANE® in children.

Before you start to take ORATANE® Capsules

You must tell your doctor if:

1. you have allergies to other substances, such as foods, preservatives or dyes.

2. you have any other health problems or issues including:

- diabetes, or family members with diabetes
- depression, or family members with depression
- liver disease
- kidney disease
- lipid (cholesterol or triglyceride) disorder
- hormone disorder
- stomach or bowel disease

3. you drink large amounts of alcohol.

If you have not told your doctor about any of the above, tell him or her before starting ORATANE® Capsules.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop. Some medicines interfere with ORATANE® Capsules. These include:

- tetracycline antibiotics, including Vibramycin®, Tetrax®, Doryx®, Achromycin®, Rondomycin®, Minomycin®, Dioxine™, Doxy™ and Tetralysal®.

- vitamin A or formulations containing vitamin A.

- other medicines for acne.

- the mini-pill, a progesterone-only oral contraceptive pill.

These medicines may be affected by ORATANE® Capsules, 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.

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

How to take ORATANE® Capsules

How much to take

Always take ORATANE® exactly as your doctor or pharmacist tells you to. The directions given may differ from information contained in this leaflet.

Your doctor will determine exactly how much ORATANE® you need for your condition.

This will be matched especially to your needs and your body-weight and may be adjusted by your doctor when it is known how you respond to ORATANE® Capsules.

Do not give ORATANE® Capsules to children.

Do not open ORATANE® Capsules or take damaged ORATANE® Capsules.

When to take it

ORATANE® Capsules should be swallowed whole with a glass of water or milk.

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If it is almost time for your next dose, skip the dose that you have missed and take the next dose when you are meant to. If you have missed several doses please inform your doctor and follow the advice given to you.

In case of an overdose

Immediately telephone your doctor, or Poisons Information Centre (Ph: 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too many ORATANE® Capsules. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs of overdose include transient headache, vomiting, facial flushing, reddened, cracked lips, stomach pain, headache, dizziness and unsteady walking.

Keep telephone numbers for these places handy.

While you are taking ORATANE®

Things you must do

If you become pregnant while taking ORATANE® Capsules, stop taking it and inform your doctor immediately. ORATANE® Capsules can cause birth defects (damage to unborn babies). This means that you must use strict birth control for at least 1 month before you start ORATANE® and for the whole time you are taking ORATANE® Capsules and for at least 1 month after you finish taking ORATANE® Capsules.

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symptoms seem similar to yours.

Do not donate blood while taking ORATANE® Capsules or for at least four weeks after stopping treatment.

Do not take any other medicines without first telling your doctor or pharmacist.

Things to be careful of

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

Wearing contact lenses during treatment with ORATANE® Capsules may cause discomfort. ORATANE® Capsules cause dry eyes so an artificial lubricant might be necessary. Otherwise you may need to compensate by wearing your glasses.

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- change in colour of the skin
- peeling of skin on palms of hands and soles of feet
- itchy skin rash
- an increased susceptibility to sunburn
- sweating
- changes to nails
- eye problems such as dry, sore, swollen or itchy eyes, discharge or trouble seeing at night
- nosebleeds
- tenderness, stiffness in bones, joints or muscles
- headache
- tiredness
- temporary hair loss (sometimes occurs and is usually temporary but in rare cases has persisted)
- excessive hairiness
- hoarseness

These side effects are usually mild and dose related. After the dose of ORATANE® Capsules is reduced or stopped most of these side effects should disappear within a few days or weeks.

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- start having thoughts about hurting yourself or taking your own life (suicidal thoughts).

These may be serious side effects and may require urgent medical attention. Serious side effects are rare.

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

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. In some cases your doctor may want to reduce your dose or stop treatment.

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

If you are concerned about these or any other unexpected effects, please talk to your doctor.

After taking ORATANE® Capsules

Storage

Keep your capsules in the blister pack and closed carton until it is time to take them. If you take the capsules out of the packaging they will not keep as well.

Keep ORATANE® 10 mg Capsules in a cool dry place where the temperature stays below 25°C. Protect from light and moisture.

Keep ORATANE® 20 mg Capsules in a cool dry place where the temperature stays below 30°C. Protect from light and moisture.

Keep ORATANE® 40 mg Capsules in a cool dry place where the temperature stays below 25°C. Protect from light and moisture.

Do not store ORATANE® Capsules or any other medicine in the bathroom or near a sink.

Do not leave ORATANE® Capsules in the car or on windowsills. Heat and dampness can destroy some medicines.

Keep ORATANE® Capsules where children can not reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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Product description

What ORATANE® Capsules look like

ORATANE® 10 mg capsules are soft, oval, opaque light violet in colour containing a yellow/orange liquid.

ORATANE® 20 mg capsules are soft, oval, opaque maroon-red in colour containing a yellow/orange liquid.

ORATANE® 40 mg capsules are soft, oval, opaque orange in colour containing a yellow/orange liquid.

ORATANE® 10 mg and 20 mg capsules are available in blister packs of 60 capsules.

ORATANE® 40 mg capsules are available in blister packs of 30 capsules.

Ingredients

Active ingredient:

Isotretinoin

Inactive ingredients:

Soya oil, DL-alpha-tocopherol, disodium edetate, butylated hydroxyanisole, partly hydrogenated soya oil and yellow beeswax. The 10mg and 20mg capsules also contain hydrogenated vegetable oil. The 40mg capsules also contain hydrogenated soya oil.

The capsule shells contain:

Gelatin, glycerol, sorbitol solution 70% (non-crystallising), titanium dioxide and purified water. The ORATANE® 10mg capsule also contains iron oxide black C177499 and Brilliant Scarlet 4R C116255. The ORATANE® 20mg capsule also contains Brilliant Scarlet 4R C116255 and indigo carmine C173015. ORATANE® 40mg capsule also contains Sunset Yellow FCF C115985.

ORATANE® 10 mg AUST R 75034

ORATANE® 20 mg AUST R 69868

ORATANE® 40 mg AUST R 117206

Further information

If you have any questions about ORATANE® capsules, please ask your doctor or pharmacist. Further information may also be obtained from Genepharm (Ph: 1800 554 414). ORATANE® capsules are only available on your dermatologist's prescription.

Supplier

Ascent Pharma Pty Ltd

151-153 Clarendon Street

South Melbourne VIC 3205

www.ascentpharma.com.au

This leaflet was prepared in April 2010