

PHARMACOR ISOTRETINOIN

(isotretinoin) capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PHARMACOR ISOTRETINOIN. 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 PHARMACOR ISOTRETINOIN 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 PHARMACOR ISOTRETINOIN is used for

PHARMACOR ISOTRETINOIN contains the active ingredient isotretinoin.

PHARMACOR ISOTRETINOIN is used to treat acne.

PHARMACOR ISOTRETINOIN belongs to a group of medicines called retinoids, which are similar to vitamin A.

The retinoids work by reducing the amount of the oily substance (ie. sebum) made by glands in your skin, reducing bacteria, reducing inflammation and opening clogged pores.

There are many different types of medicines used to treat acne. PHARMACOR ISOTRETINOIN is used for more severe cases.

Your doctor, however, may have prescribed PHARMACOR ISOTRETINOIN for another purpose.

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

This medicine is available only with a doctor's prescription.

PHARMACOR ISOTRETINOIN is not addictive.

Before you take PHARMACOR ISOTRETINOIN

When you must not take it

Do not take PHARMACOR ISOTRETINOIN if:

1. you are pregnant, or for at least one month before you plan to fall pregnant.

If you fall pregnant while taking PHARMACOR ISOTRETINOIN there is an extremely high risk of having a baby that is severely deformed. You must use effective contraception for one month before, during and one month after treatment.

2. you are breastfeeding. Breastfeeding must stop before treatment begins. Do not breastfeed while taking PHARMACOR ISOTRETINOIN.

3. you have had an allergic reaction to PHARMACOR

ISOTRETINOIN, vitamin A, other retinoids or any other ingredients of PHARMACOR ISOTRETINOIN (listed at the end of this leaflet).

- 4. you are taking tetracycline antibiotics (such as Akamin, Vibramycin, doxycycline hydrochloride (Doryx), Frakas, Minomycin).**
- 5. you have severe liver disease.**
- 6. you have very high fat levels (cholesterol, triglycerides) in your blood.**
- 7. you have hypervitaminosis A. This is a condition caused by an excessive amount of vitamin A in the diet.**
- 8. the packaging is torn or shows signs of tampering.**
- 9. the expiry date (EXP) printed on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should start taking PHARMACOR ISOTRETINOIN, contact your doctor.

Do not give PHARMACOR ISOTRETINOIN to children.

There is limited information on the use of PHARMACOR ISOTRETINOIN in children before puberty.

Before you start to take it

Tell your doctor if:

- 1. you have any allergies to any other medicines, foods, preservatives or dyes.**
PHARMACOR ISOTRETINOIN capsules contain soya oil, which may

contain traces of arachidic acid (a component of peanut oil).

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

- diabetes, or a history of diabetes in your family;
- 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 them before you start taking PHARMACOR ISOTRETINOIN.

Taking other medicines

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

Some medicines may interfere with PHARMACOR ISOTRETINOIN. These include:

- tetracycline antibiotics (such as Akamin, doxycycline hydrochloride (Doryx), Frakas, Vibramycin, Minomycin);
- vitamin A, or preparations containing vitamin A (including vitamin supplements);
- other medicines you are using to treat your acne;
- the "mini-pill", a progestogen-only oral contraceptive pill.

These medicines may be affected by PHARMACOR ISOTRETINOIN, 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 and pharmacist have more information on medicines to

be careful with or avoid while taking PHARMACOR ISOTRETINOIN.

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

How to take PHARMACOR ISOTRETINOIN

How much to take

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

They may differ from the information contained in this leaflet.

Take PHARMACOR ISOTRETINOIN exactly as your doctor has prescribed.

Your doctor will tell you how many PHARMACOR ISOTRETINOIN capsules to take each day.

This dose will be calculated to suit your individual needs and your body weight. This dose may be adjusted during treatment when the doctor knows how you respond to PHARMACOR ISOTRETINOIN.

How to take it

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

Do not open the capsules and do not take any capsules that are damaged.

When to take it

PHARMACOR ISOTRETINOIN may be taken once or twice a day and must always be taken with meals.

Female patients should wait until the 2nd or 3rd day of their next normal menstrual period before starting PHARMACOR ISOTRETINOIN treatment.

This helps ensure that you aren't pregnant before you start taking PHARMACOR ISOTRETINOIN.

How long to take it

Continue taking PHARMACOR ISOTRETINOIN for as long as your doctor prescribes.

Acne treatment with PHARMACOR ISOTRETINOIN will usually last 4 to 8 months. In the first few weeks of treatment your acne will probably get a little worse before it gets better.

Do not worry about this, it is a sign that PHARMACOR ISOTRETINOIN is working.

At the end of this time your acne should have cleared up significantly. Most patients notice their skin condition continues to improve even after PHARMACOR ISOTRETINOIN treatment is finished.

Please note that PHARMACOR ISOTRETINOIN 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 try to make up for missed doses by taking an extra dose.

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

If it is almost time for your next dose, skip the dose you 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.

If you take too much (overdose)

Immediately telephone your doctor, or Poisons Information Centre (telephone 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 much PHARMACOR ISOTRETINOIN.

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 PHARMACOR ISOTRETINOIN

Things you must do

If you become pregnant while taking PHARMACOR ISOTRETINOIN, stop taking it and tell your doctor immediately.

PHARMACOR ISOTRETINOIN can cause birth defects (damage to unborn babies). You must use strict birth control, starting at least 1 month before you begin taking PHARMACOR ISOTRETINOIN, for the whole time you are taking PHARMACOR ISOTRETINOIN and for 1 month after you finish taking PHARMACOR ISOTRETINOIN.

There is no known risk to males who wish to father children.

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

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 PHARMACOR ISOTRETINOIN capsules are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor may ask you to have regular blood tests to monitor your liver function, blood sugar levels and blood cholesterol levels.

If you are intending to do a lot of heavy lifting or exercise, tell your doctor.

Your muscles and joints may be more prone to tenderness or stiffness if you do a lot of heavy exercise while taking PHARMACOR ISOTRETINOIN.

Things you must not do

Do not stop taking PHARMACOR ISOTRETINOIN 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 give PHARMACOR ISOTRETINOIN to anyone else even if their symptoms seem similar to yours.

Do not use PHARMACOR ISOTRETINOIN to treat other complaints unless your doctor says to.

Do not donate blood during treatment with PHARMACOR ISOTRETINOIN or for at least 1 month after stopping treatment.

Things to be careful of

Be careful driving or operating machinery until you know how PHARMACOR ISOTRETINOIN affects you.

Normally PHARMACOR ISOTRETINOIN would not affect your ability to drive a car or operate machinery. However altered night vision and other visual disturbances may occur when taking PHARMACOR ISOTRETINOIN. Make sure you know how you react to PHARMACOR ISOTRETINOIN 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 PHARMACOR ISOTRETINOIN may cause discomfort.

PHARMACOR ISOTRETINOIN may cause dry eyes. An eye lubricant or artificial tears, available from your pharmacist, should relieve this problem. Otherwise, you may temporarily need to wear your lenses for shorter periods or wear glasses instead.

Avoid excessive sun exposure and solariums and apply a sunscreen while taking PHARMACOR ISOTRETINOIN.

Your skin may be more prone to sunburn while on PHARMACOR ISOTRETINOIN.

Avoid waxing and dermabrasion while taking PHARMACOR ISOTRETINOIN and for 5 to 6 months after stopping PHARMACOR ISOTRETINOIN treatment.

Your skin may be more sensitive while on PHARMACOR ISOTRETINOIN. Waxing may cause dermatitis and dermabrasion may cause scarring during and for several months after PHARMACOR ISOTRETINOIN treatment.

Avoid using facial peels, electrolysis and some hair treatments.

Your skin and hair may be more delicate during treatment and for a while after PHARMACOR ISOTRETINOIN treatment.

Side effects

PHARMACOR ISOTRETINOIN helps most people with 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 treatment if you get some of the side effects.

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

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

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

- dryness of the lips, mouth, nose and skin. A moisturiser or petroleum jelly can be used to soften the lining of the nose, lips and the skin areas not affected by the acne;
- fragile skin;
- change in colour of the skin;
- peeling palms of the hands and soles of the feet;
- itchy skin rash;
- an increased susceptibility to sunburn;
- sweating;
- changes to the nails;
- eye problems such as dry, sore, swollen or itchy eyes, discharge or trouble seeing at night;
- nosebleeds;
- tenderness or stiffness in your bones, joints or muscles;
- tiredness;
- headache;
- inflammation of the urethra
- hair loss (sometimes occurs and is usually temporary but in rare cases, has persisted);
- excessive hairiness;
- hoarseness
- sexual changes or changes in breast tissue.

Talk to your doctor if you experience persistent pain in your lower back or buttocks during treatment with Isotretinoin Pharmacor. These symptoms may be signs of sacroiliitis, a type of inflammatory back pain. Your doctor may discontinue treatment with Isotretinoin Pharmacor and refer you to a specialist for treatment of inflammatory back pain. Further evaluation may be

needed including imaging modalities such as MRI.

These side effects are usually mild and dose related. Most of them disappear completely in a few days to a few weeks after the dose of PHARMACOR ISOTRETINOIN is lowered or stopped.

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

- nausea;
- vomiting;
- 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 bruising;
- sudden red, often itchy spots, similar to the rash of measles starting on the face, hands or feet. The spots may blister or change to flat round raised, red, pale-centred marks. Also, you may have fever, sore throat, headache and/or diarrhoea;
- painful red areas, that change to large blisters and end with peeling of layers of skin, that may occur on lips, mouth, eyes, nose and genitals. Those affected may have fever and chills, aching muscles and generally feel unwell;
- thinking, seeing or hearing things that are not real;
- feeling depressed, with or without suicidal thoughts.

Symptoms of depression may include:

- feeling sad or having crying spells;
- losing interest in activities you once enjoyed;
- sleeping too much or having trouble sleeping;
- changes in your appetite or body weight;

- having trouble concentrating;
- withdrawing from your friends or family;
- feeling like you have no energy;
- feelings of worthlessness or inappropriate guilt.

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

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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

After taking PHARMACOR ISOTRETINOIN

Storage

Keep your capsules in the blister pack until it is time to take them.

If you take the capsules out of the packaging they will not keep well.

Keep the blister pack in a cool dry place where the temperature stays below 25°C.

Do not store PHARMACOR ISOTRETINOIN, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep PHARMACOR ISOTRETINOIN where young children cannot reach it.

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

Protect PHARMACOR ISOTRETINOIN from light.

Disposal

If your doctor tells you to stop taking PHARMACOR ISOTRETINOIN, or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.

Distributor

Pharmacor Pty Ltd
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821 Pacific Highway,
Chatswood NSW 2067
Australia
Web: www.pharmacor.com.au
Phone: 1300 138 805

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Product description

Availability

PHARMACOR ISOTRETINOIN capsules come in one strength, 20 mg.

PHARMACOR ISOTRETINOIN 20 mg are available in packs of 60 capsules.

What it looks like

PHARMACOR ISOTRETINOIN 20 mg – red-orange, size 6, oval, soft gelatin capsules marked P20.

Ingredients

Active ingredient

- Each 20 mg capsule contains 20 mg isotretinoin.

Inactive ingredients

The capsules also contain:

- soya oil;
- yellow beeswax;
- hydrogenated soya oil; and
- partially hydrogenated soya oil.

The capsule shell contains:

- gelatin;
- glycerol;
- titanium dioxide;
- ferrous oxide red and yellow.

The printing uses Videojet Inksource 16-9000 ink, which contains Brilliant Blue FCF and shellac.

Australian Registration Numbers

PHARMACOR ISOTRETINOIN 20 mg:
AUST R 165123