

Package leaflet: Information for the user

Alipalmtin 10 mg zachte capsules
Alipalmtin 30 mg zachte capsules
Alitretinoïne

WARNING

CAN SERIOUSLY HARM AN UNBORN BABY

Women must use effective contraception

Do not use if you are pregnant or you think you may be pregnant

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alipalmtin is and what it is used for
2. What you need to know before you take Alipalmtin
3. How to take Alipalmtin
4. Possible side effects
5. How to store Alipalmtin
6. Contents of the pack and other information

1. What Alipalmtin is and what it is used for

The active substance in Alipalmtin is alitretinoin. It belongs to a group of medicines known as *retinoids*, which are related to Vitamin A. Alipalmtin capsules come in two strengths, containing 10 mg or 30 mg of alitretinoin.

Alipalmtin is used to treat adults with severe chronic hand eczema that has not got better after any other topical treatments, including steroids. Treatment with Alipalmtin must be supervised by a specialist skin doctor (a dermatologist).

2. What you need to know before you take Alipalmtin

Do not take Alipalmtin:

- If you are **pregnant** or **breast-feeding**.
- If there is any chance you could become pregnant, you must follow the precautions under “Pregnancy and prevention programme, see section on “Warnings and precautions”.
- If you have **liver disease**.

- If you have **severe kidney disease**.
- If you have **high blood fats** (such as high cholesterol or raised triglycerides).
- If you have **thyroid disease**, which is not sufficiently treated.
- If you have **very high levels of vitamin A** in your body (*hypervitaminosis A*).
- If you are **allergic** to alitretinoin, to other retinoids (such as isotretinoin), to peanut or soya or any of the other ingredients of this medicine (listed in section 6).
- If you are **taking tetracycline** (a type of *antibiotic*).

➤ If any of these apply to you, **go back to your doctor. You must not take Alipalmtin.**

Warnings and precautions

Pregnancy and prevention programme

Women who are pregnant must not take Alipalmtin

This medicine can seriously harm an unborn baby (the medicine is said to be ‘teratogenic’) – it can cause serious abnormalities of the unborn baby’s brain, face, ear, eye, heart and certain glands (thymus gland and parathyroid gland). It also makes a miscarriage more likely. This may happen even if Alipalmtin is taken only for a short time during pregnancy.

- You must not take Alipalmtin if you are pregnant or if you think you might be pregnant.
- You must not take Alipalmtin if you are breastfeeding. The medicine is likely to pass into your milk and may harm your baby.
- You must not take Alipalmtin if you could get pregnant during treatment.
- You must not get pregnant for one month after stopping this treatment because some medicine may still be left in your body.

Women who could get pregnant are prescribed Alipalmtin under strict rules. This is because of the risk of serious harm to the unborn baby

These are the rules:

- Your doctor must explain the risk of harm to the unborn baby - you must understand why you must not get pregnant and what you need to do to prevent getting pregnant.
- You must have talked about contraception (birth control) with your doctor. The doctor will give you information on how not to get pregnant. The doctor may send you to a specialist for contraception advice.
- Before you start treatment, your doctor will ask you to take a pregnancy test. The test must show that you are not pregnant when starting treatment with Alipalmtin

Women must use effective contraception before, during and after taking Alipalmtin

- You must agree to use at least one very reliable method of contraception (for example an intra uterine device or contraceptive implant) or, two effective methods that work in different ways (for example a hormonal contraceptive pill and a condom). Discuss with your doctor which methods would be suitable for you.
- You must use contraception for a month before taking Alipalmtin, during treatment and for a month afterwards
- You must use contraception even if you do not have periods or you are not sexually active (unless your doctor decides this is not necessary).

Women must agree to pregnancy testing before, during and after taking Alipalmtin

- You must agree to regular follow-up visits, ideally every month.
- You must agree to have regular pregnancy tests, ideally every month during treatment and, because some medicine may still be left in your body, 1 month after stopping Alipalmtin (unless your doctor decides this is not necessary in your case).
- You must agree to extra pregnancy tests if your doctor asks you.

- You must not get pregnant during treatment or for a month afterwards because some medicine may still be left in your body.
- Your doctor will discuss all these points with you, using a checklist and will ask you (or a parent/guardian) to sign it. This form confirms that you have been told about the risks and that you will follow the rules above.

If you get pregnant while taking Alipalmtin, **stop taking the medicine straight away**, and contact your doctor. Your doctor may send you to a specialist for advice.

Also, if you become pregnant within one month after you stop taking Alipalmtin, you should contact your doctor. Your doctor may send you to a specialist for advice.

Advice for men

The levels of oral retinoid in the semen of men taking Alipalmtin are too low to harm their partners' unborn baby. However, you must never share your medication with anyone.

Additional precautions

You should never give this medicinal product to another person. Please take any unused capsules to your pharmacist at the end of treatment.

You should not donate blood during treatment with this medicine and for 1 month after stopping Alipalmtin because an unborn baby could be harmed if a pregnant patient receives your blood.

Talk to your doctor or pharmacist before taking Alipalmtin:

- **If you have ever had any kind of mental health problems.** This includes depression, aggressive tendencies or mood changes. It also includes thoughts about hurting yourself or ending your life. This is because your mood may be affected while taking Alipalmtin.
- **If you have kidney disease.** Alipalmtin is not recommended for people with moderate kidney disease. If you have kidney disease – check with your doctor that Alipalmtin is suitable for you.
- **If you have high blood fats,** you may need blood tests more often. Alipalmtin commonly increases blood fats, such as cholesterol or triglycerides. If your blood fats stay high, your doctor may lower your dose, or take you off Alipalmtin.
- **If you have high blood sugar (diabetes),** your blood sugar levels may need to be checked more often and your doctor may start you on a lower dose of Alipalmtin.
- **If you have been suffering from thyroid disease.** Alipalmtin may lower your thyroid hormone levels. If your thyroid hormone level is low, your doctor may prescribe supplements.

You need to take care during treatment:

- **If you experience any problems with your sight, tell your doctor immediately.** Alipalmtin may need to be stopped and your sight monitored.
- **If you get a persistent headache, nausea or vomiting (feeling or being sick) and blurred vision,** these may be signs of a condition called benign intracranial hypertension. **Stop the capsules immediately** and contact your doctor as soon as possible.
- **If you have bloody diarrhoea stop the capsules immediately** and contact your doctor as soon as possible.
- **Minimise your exposure to sunlight** and avoid sun lamps. Your skin may become more sensitive to sunlight. Before you go out in the sun, use a sun protection product with a high protection factor (SPF 15 or higher). **If you get dry skin and lips** during treatment, use a moisturising ointment or cream and a lip balm.
- **Cut down on intensive physical exercise:** alitretinoin can cause muscle and joint pain.

- **If you develop dry eyes**, lubricating eye ointment or tear replacement drops can help. If you wear contact lenses, you may need to wear glasses during alitretinoin treatment. Dry eyes and sight problems normally return to normal once treatment is stopped.
- **Alipalmtin may increase liver enzyme levels.** Your doctor will do blood tests during treatment to check these levels. If they stay high, your doctor may lower your dose or take you off of Alipalmtin.

Mental health problems

- You may not notice some changes in your mood and behaviour and so it is very important that you tell your friends and family that you are taking this medicine. They may notice these changes and help you quickly identify any problems that you need to talk to your doctor about.
- **If you develop any mental health problems** including depression, aggressive tendencies, mood changes, thoughts about hurting yourself or ending your life, **you must stop taking Alipalmtin immediately** and contact your doctor as soon as possible.

Children and adolescents

Alipalmtin is not recommended for people aged under 18 years old. It is not known how well it works in this age group.

Other medicines and Alipalmtin

Do not take other retinoid medicines (e.g. isotretinoin), **vitamin A supplements or tetracyclines** (a type of antibiotic) while taking Alipalmtin. This increases the risk of side effects.

Tell your doctor or pharmacist if:

- you are taking **amiodarone** (a medicine that helps to regulate heart rate). Amiodarone is not recommended to be taken together with Alipalmtin.
- you are taking **ketokonazole, fluconazole, miconazole** (medicines used to treat infections). Your doctor may decide to reduce your dose of Alipalmtin.
- you are taking **simvastatin** (a medicine used to lower cholesterol). Alipalmtin may decrease the amount of this medicine in your body.
- you are taking **gemfibrozil** (another medicine used to lower cholesterol) or **oxandrolone** (an anabolic steroid). Your doctor may decide to reduce your dose of Alipalmtin.
- you are taking **paclitaxel** (used to treat cancer), **rosiglitazone** or **repaglinide** (used to treat diabetes). Alipalmtin may increase the amount of these medicines in your body.

Tell your doctor or a pharmacist if you are taking, or have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines.

Pregnancy, breast-feeding and fertility

For more information on pregnancy and contraception, see section 2 "Pregnancy and prevention programme".

Driving and using machines

You may not see as well at night during your treatment. If this happens to you, you should not drive or operate machinery.

Alipalmtin contains soya oil

If you are allergic to peanut or soya, do not use this medicinal product.

Alipalmtin contains sorbitol

Each Alipalmtin 10 mg capsule contains 13.28 mg sorbitol

Each Alipalmtin 30 mg capsule contains 25.55 mg sorbitol

3. How to take Alipalmtin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When to take the capsules

The capsule should be taken with a main meal, preferably at the same time each day. The capsules should be swallowed whole and not chewed.

How much to take

The dose is either 10 or 30 mg once daily. If your body can't tolerate the recommended 30 mg dose, you may be prescribed the lower 10 mg dose.

How long should you take the capsules

A course of treatment usually lasts for 12 to 24 weeks depending how your disease gets better. If your first treatment was successful, your doctor may prescribe another course of treatment if symptoms return.

If you take more Alipalmtin than you should

If you take too many capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital immediately.

If you forget to take Alipalmtin

If you miss a dose take it as soon as you can. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not take a double dose to make up for a forgotten capsule.

- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common effects (may affect more than 1 in 10 people)

- **Headache**
- **Raised blood fats:** higher levels of fats (triglycerides) and cholesterol in the blood.

Common effects (may affect up to 1 in 10 people)

- **Blood cell disorders:** increase in the number of blood platelets (cells that help blood to clot), decrease in the number of red and white blood cells seen in blood tests.
 - **Thyroid problems:** decreased levels of thyroid hormones.
 - **Eye problems:** inflammation of the eye (conjunctivitis) and eyelid area; eyes feel dry and irritated.
- Ask a pharmacist for suitable eye drops. If you wear contact lenses and get dry eyes, you may need to wear glasses instead.

- **Ear problems:** persistent noise in the ears (tinnitus)
- **Dizziness**
- **Blood and circulation:** flushing, high blood pressure (hypertension)
- **Gut and stomach problems:** feeling sick (nausea), being sick (vomiting), dry mouth
- **Muscle and joint pain:** muscle pain, joint pain, lack of energy (fatigue). High levels of muscle breakdown products in your blood if you exercise vigorously.
- **Skin and hair problems:** dryness of the skin, especially of the face, dry and inflamed lips, redness of the skin, itchy skin rash, inflamed skin, hair loss.
- **Liver problems:** raised liver enzymes seen in blood tests.

Uncommon effects (may affect up to 1 in 100 people)

- **Sight problems** including blurred vision, distorted vision, cloudy surface on the eye (corneal opacity, cataracts).
- If your sight is affected, **stop taking Alipalmtin immediately** and contact your doctor.
- **Skin problems:** itchy skin, skin peeling, rash, dry skin eczema.
- **Ear, nose and throat problems:** nose bleeding.
- **Gut and stomach problems:** indigestion (dyspepsia)
- **Bone disorders:** extra growth of bone, including the spine disorder ankylosing spondylitis.

Rare effects (may affect up to 1 in 1,000 people)

- **Lasting headache**, along with feeling sick (nausea), being sick (vomiting) and changes in your eyesight including blurred vision. These may be signs of benign intracranial hypertension.
- If you experience these symptoms, **stop taking Alipalmtin immediately** and contact your doctor.
- **Blood and circulation:** inflammation of blood vessels.
- **Skin and hair problems:** nail disorders, increased sensitivity of the skin to sunlight, hair texture changes.

Mental problems

Rare effects (may affect up to 1 in 1,000 people)

- **Depression or related disorders.** Signs of this include sad or altered mood, anxiety, feelings of emotional discomfort.
- **Existing depression** getting worse.
- Becoming violent or aggressive.

Very rare effects (may affect up to 1 in 10,000 people)

- Some people have had thoughts or feelings about hurting themselves or ending their own lives (**suicidal thoughts**), have tried to end their own lives (**attempted suicide**), or have ended their lives (**suicide**). These people may not appear to be depressed.
- **Unusual behaviour.**
- **Signs of psychosis:** a loss of contact with reality, such as hearing voices or seeing things that are not there.

Contact your doctor straight away if you get signs of any of these mental problems. Your doctor may tell you to stop taking Alipalmtin. That may not be enough to stop the effects. You may need more help, and your doctor can arrange this.

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown:

Severe allergic reactions

Signs include:

- raised and itchy rash (hives)
 - swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
 - collapse.
- **Contact a doctor immediately if you get these symptoms. Stop taking Alipalmtin.**

Gut and stomach disorders

Severe stomach (abdominal) pain, with or without bloody diarrhoea, feeling sick (nausea) and being sick (vomiting).

- **Stop taking Alipalmtin immediately** and contact your doctor. These can be signs of serious gut conditions.

Problems seeing at night

Sight problems normally return to normal once treatment is stopped.

Blood and circulation

Swelling of the hands, lower legs and feet (peripheral oedema).

Side effects of other medicines in the same family as Alipalmtin

These effects haven't been seen in Alipalmtin so far, but they can't be ruled out. They are very rare and may affect less than 1 user in 10,000.

Diabetes

Excessive thirst; frequent need to urinate; blood tests show an increase in your blood sugar. These can all be signs of diabetes.

Bone disorders

Arthritis; bone disorders (delayed growth, changes to bone density); growing bones may stop growing.

Eye and visual disorders

Colour blindness and colour vision gets worse; intolerance to contact lenses.

In rare cases soya oil can lead to severe allergic reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system Nederlands Bijwerkingen Centrum Lareb

Website: www.lareb.nl

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alipalmtin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Alipalmtin contains

- The active substance is Alitretinoin.
Each capsule, soft contains 10 mg of alitretinoin.
Each capsule, soft contains 30 mg of alitretinoin.
- The other ingredients are:
Capsule content: soya-bean oil (refined), partially hydrogenated soya-bean oil, hydrogenated vegetable oil, glycerol monostearate, triglycerides (medium chain), all-rac- α -tocopherol.
Capsule shell: gelatin, glycerol, sorbitol liquid (non-crystallising) (E420), titanium dioxide (E171), water purified, iron oxide red (E172), iron oxide yellow (E172) and iron oxide black (E172).
Capsule content: soya-bean oil (refined), partially hydrogenated soya-bean oil, hydrogenated vegetable oil, glycerol monostearate, triglycerides (medium chain), all-rac- α -tocopherol.
Capsule shell: gelatin, glycerol, sorbitol liquid (non-crystallising) (E420), titanium dioxide (E171), water purified, iron oxide yellow (E172).

What Alipalmtin looks like and contents of the pack

Alipalmtin comes in capsules, soft.

Alipalmtin 10 mg capsules are light brown, oval soft gelatin capsules, 10 mm x 6 mm, and contain a yellow to orange, opaque, viscous suspension.

Alipalmtin 30 mg capsules are yellow, oval soft gelatin capsules, 13 mm x 8 mm, containing a yellow to orange, opaque, viscous suspension.

Capsules are packaged in PVC/PVDC/Aluminium blisters

Packs size: 30 capsules.

Houder van de vergunning voor het in de handel brengen

Orifarm Healthcare A/S
Energivej 15
5260 Odense S
Denemarken

Fabrikant

Orifarm Generics A/S
Energivej 15
5260 Odense S
Denemarken

In het register ingeschreven onder:

Alipalmtin 10 mg zachte capsules: RVG 121503

Alipalmtin 30 mg zachte capsules: RVG 121504

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Alipalmtin 10 mg zachte capsules
Verenigd Koninkrijk	Alitretinoin 10 mg capsules, soft
Nederland	Alipalmtin 30 mg zachte capsules
Verenigd Koninkrijk	Alitretinoin 30 mg capsules, soft

Deze bijsluiter is voor het laatst goedgekeurd in maart 2024.

Detailed and updated information on this product is available by scanning the QR code included in the PL with a smartphone. The same information is also available on the following URL: *[URL to be included]* and the <NCA> website.
'QR code to be included' + <URL