

产品说明

Neotigason 10毫克及25毫克胶囊

请在使用本药物之前，详细阅读此使用说明。如果您有任何疑问或不了解的事项，请向您的皮肤专科医生或您的医生/药剂师咨询。

什么是Neotigason?

Neotigason内含有效成份**acitretin**。市面上有两种药量出售：

- ✓ **10毫克acitretin**: 棕色胶囊盖与白色胶囊身
- ✓ **25毫克acitretin**: 棕色胶囊盖与黄色胶囊身

Acitretin属于一种称为维甲酸类(**retinoid**)的药物，通常用来治疗皮肤问题。

Neotigason有什么用处?

本药物是用来治疗皮肤出现增厚以及脱落症状的皮肤问题。

如: 银屑病(**psoriasis**)和严重角质化(**keratinization**)的病症，其中包括: 鱼鳞病(**ichthyosis**)，毛发红糠疹(**pityriasis rubrapilaris**)和达理埃氏病(**Darier's disease**)。

为了让您从本药物中获得最多的好处，请您详细阅读此使用说明，并且请医生为您解说任何您不明白的事项。

用药前的检查

为了确保您适合使用Neotigason，您的皮肤医生会事先为您做一次彻底的身体检查以及血液测试。

在什么情况下不能使用Neotigason?

- ✓ 如果您怀孕或者认为您可能怀孕
- ✓ 如果您正在哺乳
- ✓ 如果您在接下来的三年内计划生育
- ✓ 如果您血脂过高(脂肪疾病)
- ✓ 如果您对Neotigason或其中任何成份过敏

倘若您在服用任何其他的药品或药物，请通知您的医生。

在挺振期间不可服用Neotigason

重要注意事项

属生育年龄的女性患者必须严格遵守以下指示

- ✓ 您必须再治疗前的一个月内，治疗期间以及治疗结束后的三年内，采取有效的避孕措施。您的医生会在您的治疗开始前确保您没有怀孕。
- ✓ 您应该在月经后的第二或第三天开始服用Neotigason
- ✓ 您不可再治疗期间以及治疗结束后的三年内怀孕。
- ✓ 如果您在治疗期间或在治疗结束后的三年内怀孕，或者认为您可能怀孕，请立即通知您的皮肤专科医生。

如果您有以下情况，请通知您的医生:

- ✓ 血液三甘油脂**triglyceride**指数过高的家族病历
- ✓ 糖尿病的家族病历
- ✓ 现在患有或曾经患过肝脏疾病。请将您全部重要的病况都告知您的医生。以上所提供的资料将有助医生决定您是否适合服用Neotigason，或者在您服用Neotigason前需不需要接受特别的指示。
- ✓ 捐血者请注意：您不可以在接受Neotigason的治疗期间或在治疗结束后的三年内捐血。

请在服用Neotigason前向您的医生咨询:

这是因为如果您曾经历过任何的心理健康问题，包括抑郁症，攻击行为倾向或情绪不稳定。服用Neotigason可能会对您的情绪造成影响。

心理健康问题

您可能不会注意到自己的情绪和行为所出现的一些变化，因此，告诉您的家人和朋友这种药可能会影响您的情绪和行为是非常重要的事。因为他们可能会注意到这些变化，并帮助您进一步确定任何您必须与医生讨论的问题。

Neotigason应该怎样服用?

- ✓ 按照医生的指示服用胶囊。治疗的时间和剂量将根据您的体重，皮肤病的严重性，以及对治疗的反应而定。
- ✓ 一般的剂量为每天**25毫克至50毫克**，初始平均疗程为**2到4周**。然后进一步**6到8周**维持剂量。
- ✓ 胶囊应在用餐时以水吞服。请勿吮吸或咀嚼胶囊。
- ✓ 如果您忘记服用胶囊，请在记起时尽快服用。但如果已经接近下一次服药的时间，您可以不必补服漏掉的这一剂，并如常服用药物。请勿服用双倍的剂量。
- ✓ 医生可能会在您皮肤有所改善的时候，降低剂量或停止给予Neotigason。如果您的病况在改善后再度复发，医生可能会让您接受第二次疗程。

Neotigason可能造成什么副作用?

您可能会在治疗期间经历一些副作用。有时这些副作用甚至会在您的皮肤状况好转之前出现。一般上，这些副作用在持续治疗一段时间后都能得到控制。医生将协助您控制这些副作用。Neotigason的不良副作用会在您停止治疗后消失。如果您受到副作用的困扰，请与您的医生讨论解决的方法。

- ✦ **通常初期经历的副作用是嘴唇干燥。**您可以经常使用保湿唇膏以防止不适。
 - ✦ **皮肤干燥、瘙痒和皮疹。**避免使用肥皂和热水洗澡。您应该使用油性的沐浴露和润肤剂。
 - ✦ **鼻腔内部干燥。**您可以在内部轻抹一层凡士林油(**petroleum jelly**)以缓解不适。
 - ✦ **皮肤易裂。**您的皮肤在治疗期间可能比较容易破裂。您可以使用润肤剂以减少这样的情况发生。
 - ✦ **眼睛干燥。**您的眼睛可能会感到干燥和轻微不适。这可能会让您无法使用隐形眼镜。您应该请教医生，让他建议适当的眼药水以舒缓不适。
 - ✦ **服用Neotigason时对阳光敏感。**您应当避免受到阳光的照射；您可以在晒太阳之前涂抹防晒油，并使用适当保护(如：帽子，雨伞)。
 - ✦ **头发脱落。**有些患者可能会在服用药物一段时间后感到发质改变或脱发。这只是暂时性的；头发在治疗结束后应该会恢复正常生长。
 - ✦ **肌肉酸痛。**有些患者在服用本药物的时候会感到肌肉酸痛。避免激烈的运动可以减少这样的情况发生。但如果肌肉酸痛或关节疼痛对您造成困扰，您应该将这样的情况告知您的医生。
 - ✦ **在服用Neotigason时，其它比较常见的副作用包括：**头痛、疲劳、恶心、冒汗、手臂和腿部脱皮、夜晚视力减退、视线模糊、牙床疾病、指甲易裂、指甲周围发炎、阴道发炎、黄瘟病和肝脏疾病。
- 如果您对于这些副作用有任何疑问，请向您的医生咨询。

Neotigason应该如何保存?

本胶囊应该存放于原有的包装内。贮存温度应低于**25°C**。请将药物存放在儿童无法触及，并且安全的地方。

请谨记：此药物只供您个人使用。只有医生才能开此药方给您。此药可能会对别人造成伤害；即时别人症状与您相同，此药亦不可转交他人使用。

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WHAT YOU SHOULD KNOW BEFORE TAKING

Neotigason®

Acitretin

使用须知

PATIENT PRODUCT INFORMATION

Neotigason 10mg & 25mg Capsules

Please read this leaflet carefully before you start to take your medicine. If you have any questions or are not sure about anything, ask your dermatologist or alternatively your doctor or pharmacist.

What is Neotigason?

Neotigason contains the active ingredient acitretin. Two strengths are available:

- ✓ the capsules with a brown cap and white body contain 10mg acitretin
- ✓ the capsules with a brown cap and yellow body contain 25mg acitretin

Acitretin is one of a group of medicines known as retinoids which are usually used to treat skin problems.

What is Neotigason used for?

This medicine is used to treat skin problems characterized by the thickening and shedding of skin, such as psoriasis and severe disorders of keratinization which includes ichthyosis, pityriasis rubra pilaris and Darier's disease.

To help you get the full benefits from this medicine you should read this leaflet carefully and ask your doctor to explain anything you do not understand.

PRE-MEDICATION ASSESSMENT

Your dermatologist will usually perform a full physical examination and request blood tests to ensure you are suitable to benefit from taking Neotigason.

When must Neotigason NOT be used?

- ✓ If you are pregnant or think you may be pregnant
- ✓ If you are breast-feeding
- ✓ If you are planning to get pregnant in the next 3 years
- ✓ If you have very high fat levels in your bloods (lipid disorder)
- ✓ If you are allergic to Neotigason or any of the ingredients it contains

Inform your doctor if you are taking any other drugs or medication.

Neotigason must NOT be taken during pregnancy

IMPORTANT

Female patients in the reproductive age group must strictly follow these instructions

- ✓ You must use an effective method of birth control for one month before treatment, during treatment and for three years after treatment ends. Before you start treatment, your doctor will determine that you are not pregnant. You should start taking Neotigason on the second or third day of your menstrual cycle.

- ✓ You must not become pregnant at any time during treatment and for three years after treatment ends.
- ✓ Contact your dermatologist immediately if you do become pregnant or think you may be pregnant during treatment or in the three years after treatment ends.

Inform your doctor if:

- ✓ there is a family history of high triglyceride levels in the blood.
- ✓ there is a family history of diabetes mellitus.
- ✓ you have or have had a liver disease. Inform your doctor of all your major medical events. The above information will enable your doctor to determine if you are suitable to receive Neotigason or if special advice is needed before taking Neotigason.
- ✓ Special note for blood donors. You should not donate blood either during or for at least three years after Neotigason treatment.

Talk to your doctor before taking Neotigason:

If you have ever had any mental health problems including depression, aggressive tendencies or mood changes. This is because taking Neotigason may affect your mood.

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 this medicine could affect your mood and behaviour. They may notice these changes and help you identify any problems that you need to talk to your doctor about.

How should Neotigason be taken?

- ✓ Always take the capsules as your doctor tells you to. The duration and dose of the treatment will depend on your body weight, severity of your skin condition and response to the treatment.
- ✓ You will usually be on a dose of between 25mg and 50mg a day. The average treatment duration is 2-4 weeks for initial daily dosage followed by further 6-8 weeks for maintenance dose.
- ✓ The capsules should be taken at mealtimes with a drink. Swallow the capsules whole, do not suck or chew them.
- ✓ If you miss a dose, take it as soon as possible. However, if it is nearly time for your next dose, skip the missed dose and carry on as before. Do not double a dose.
- ✓ When your skin has improved, your doctor will probably lower the dose and stop giving you Neotigason. If your condition relapses after clearing, your doctor may prescribe a second course.

What are the possible unwanted effects of Neotigason?

You will probably have some unwanted reactions to your treatment, even before you see your skin getting better. These effects will stabilize as your treatment continues and your doctor can help you deal with them. The unwanted effects of Neotigason will disappear when you stop your treatment. If the side effects are troublesome, discuss with your doctor.

- ❖ **Dryness of the lips** will be experienced earliest. Can be prevented by using lip balm frequently.

- ❖ **Dryness of the skin** associated with itching and rash. Avoid soaps and hot showers. Use shower gel/ oil and emollient.
- ❖ **Drying of the inside** of the nose. Smearing a thin layer of petroleum jelly on the inside of the nose will help.
- ❖ **Skin fragility.** Your skin may also break more easily during therapy. Use emollients.
- ❖ **Dry eyes.** Your eyes may feel dry and slightly irritated. This may be a problem if you wear contact lenses. Ask your doctor to suggest some suitable eye drops to help.
- ❖ **Sensitivity to sunlight while taking Neotigason.** Avoid too much sun. Before going into strong sunlight, apply a sun block and use adequate protection (like hats, umbrellas).
- ❖ **Hair loss.** Some patients may notice changes in hair texture or hair loss after taking the medicine for a while. This is only temporary. Hair should return to normal after the treatment ends.
- ❖ **Muscle aches and pains.** Some people have muscle aches and pains when they are taking this medicine. These will normally be relieved by avoiding vigorous exercise. However, if the muscle aches or joint pains are troublesome inform your doctor.
- ❖ Other less common unwanted effects reported include headaches, tiredness, nausea, sweating, peeling of skin of arms and legs, poor night vision, blurred vision, gum disease, nail fragility, infections round the base of the nail, thrush, jaundice and liver disease in patients while taking Neotigason.
- ❖ If you have any questions about these or any other unwanted effects, talk to your doctor.

How should Neotigason be stored?

The capsules should be stored in the original package. Do not store above 25°C.

Keep this medicine out of reach of children, in a safe place.

REMEMBER this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours