

Package leaflet: Information for the patient

CAPCIDERM 0.075% cream

For external use.

- **Active substance(s):** Each one gram cream contains 0.75 mg capsaicin.
- **Excipient(s):** Benzyl alcohol, cetyl alcohol, sorbitol (70%) solution (E420), white paraffin, isopropyl myristate, glyceryl stearate, PEG 100 stearate and deionized water.

Read all of this leaflet carefully before you start using 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.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher or lower** dose other than the recommended to you.*

What is in this leaflet?

1. *What CAPCIDERM is and what it is used for?*
2. *What you need to know before you use CAPCIDERM?*
3. *How to use CAPCIDERM?*
4. *Possible side effects*
5. *How to store CAPCIDERM?*

1. What CAPCIDERM is and what it is used for?

- CAPCIDERM is marketed in aluminum tubes covered with high density polyethylene (HDPE) massage cap closures containing 45 g cream. It contains capsaicin and is for external use.
- CAPCIDERM is used,
 - to relieve pain arising from nerves near to the surface of the skin after having Shingles (Herpes Zoster)
 - to relieve pain in patients who have nerve damage to their hands or feet caused by diabetes.
 - to relieve joint inflammation, joint calcification, muscle and joint pain.

2. What you need to know before you use CAPCIDERM?

DO NOT use CAPCIDERM

- If you are allergic (hypersensitive) to capsaicin or any of the other ingredients of CAPCIDERM
- On broken or irritated skin
- In children under 12 years old

Warnings and precautions

- Keep away from the eyes, nose and mouth. If it does accidentally get into your eyes, nose and mouth or onto broken or irritated skin, wash off with plenty of water.
- Wash your hands immediately after applying CAPCIDERM, unless the hands are treated areas, in which case, they should be washed 30 minutes after applying.
- Avoid hot baths or showers immediately before or just after applying CAPCIDERM.
- Do not apply tight bandages on top of CAPCIDERM.
- Avoid breathing in any vapors from CAPCIDERM, as this can cause irritation of the eyes and breathing difficulties (including making asthma worse).

If these warnings apply to you, even if at any time in the past, please consult your doctor.

CAPCIDERM with food and drink

It has no interaction with food and drink.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

Use it under the supervision of your doctor when necessary during pregnancy.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

Do not use CAPCIDERM during breastfeeding without consulting your doctor.

Driving and using machines

It has no known adverse effects on the ability to drive and use machines.

Important information about some of the excipients of CAPCIDERM

CAPCIDERM may cause local skin reactions (e.g. contact dermatitis) due to the product containing cetyl alcohol.

Other medicines and CAPCIDERM

CAPCIDERM has no known or expected interaction with other medicinal products through external (topical) application.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use CAPCIDERM?

• Instructions for use and dosage/frequency of administration:

Apply CAPCIDERM 3-4 times a day unless otherwise recommended by the doctor. There should be a gap of at least 4 hours between each application. Treatment normally takes 8 weeks when CAPCIDERM is used to relieve pain from nerve damage due to diabetes.

• Route of administration and method:

CAPCIDERM is for external use only.

- A small amount of cream (about the size of a pea) should be rubbed with your fingers onto the area to be treated. Continue rubbing until the cream becomes invisible.

- **Wash your hands immediately** after application of CAPCIDERM, but if you are treating nerve damage in your hands, then you should wait 30 minutes before washing your hands.

- After CAPCIDERM is applied, it may cause a short-term burning sensation on the hands. Therefore, when needed, it is recommended to be used with a massage head.

- **Different age groups:**

- **Use in children:**

- It should not be used in children under 12 years of age.

- **Use in elderly:**

- The use of CAPCIDERM in elderly patients is the same as in adults.

- **Special cases of use:**

- **Kidney/liver failure:**

- There is no special use in case of severe kidney and liver failure.

If you have impression that the effect of CAPCIDERM is very strong or weak, tell a doctor or pharmacist.

If you use more CAPCIDERM than you should:

If you use more CAPCIDERM than you should, tell your doctor or pharmacist.

Since CAPCIDERM is used in a limited and superficial area, overdose has no side effects.

If you forget to use CAPCIDERM:

Do not take a double dose to make up for a forgotten dose.

If you stop using CAPCIDERM:

None. If there is no improvement after the treatment period, the diagnosis and treatment should be reviewed.

4. Possible side effects?

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

If you notice any of the followings stop using CAPCIDERM and immediately inform your doctor or go to the nearest emergency department:

- Swelling in the face, tongue, throat
- Shortness of breath, wheezing

These are all very serious side effects. If you have one of these, you have a serious allergy to CAPCIDERM. You may need an emergency medical intervention or hospitalization.

All of these very serious side effects are very rare.

If you experience any one of the followings tell your doctor:

- Runny nose
- Coughing

- Sneezing
- Brief irritation of the eyes, nose and throat in the form of breathlessness or worsening of asthma

CAPCIDERM can cause skin irritation or a brief burning feeling when applied. This burning is more common when:

- The cream is used more than 4 times a day
- Too much cream is applied
- The cream is applied just before or after a hot bath or shower.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store CAPCIDERM?

Keep this medicine out of the sight and reach of children and in its original packaging.

Store at room temperature below 25°C.

Use in accordance with expiry date.

Use CAPCIDERM before the expiry date which is stated on the tube or packaging.

Do not use this medicine if you notice any defects in the product and / or packaging.

Marketing Authorization Holder:

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